# Other Transaction Authority Training

# Participant Guide

# Table of Contents

A. Agenda ..... 1

B. Slides—*Federal Acquisition Regulation*-Based Research and Development Contracting ..... 3

C. Slides—Why Other Transactions? ..... 15

D. Slides—Intellectual Property in Other Transactions ..... 19

E. Slides—Other Transactions ..... 33

F. Reserved ..... -

G. Slides—Acquisition of Property in Other Transactions ..... 133

H. Slides—Foreign Access to Technology Created Under Other Transactions ..... 139

I. Slides—Other Transactions: A Summary ..... 147

J. Policy Documents

10 U.S.C. 2371 ..... 157

OTA in Various Federal Agencies and NIH Authorities ..... 163

K. NIH *Other Transactions Policy Guide* ..... 171

L. OTAO Desktop Guide ..... 203

M. Model OT for Prototype Projects ..... 295

N. Sample Broad Agency Announcement ..... 321

O. Model OTFR Agreement ..... 335

P. Sample Program Solicitation ..... 371

Q. BARDA OT Sample ..... 405

R. Sample Articles of Collaboration ..... 463

S. Case Studies ..... 479

T. Justification for Use of OTA ..... 503

# A. AGENDA

A

# AGENDA

## Other Transaction Authority (OTA) Training


| Day 1 | Page Number |
|---|---|
| **Introduction and Administrative Details** | |
| **B. *Federal Acquisition Regulation* (FAR)-Based Research and Development** | **3** |
| ▪ Case (Tab N) | 321 |
| **C. Why Other Transactions (OTs)?** | **15** |
| **Lunch** | |
| **D. Intellectual Property in OTs** | **19** |
| **E. Other Transactions in NIH, Part 1** | **33** |
| ▪ Statutory History | |
| ▪ Products | |
| ▪ Limitations | |

| Day 2 | Page Number |
|---|---|
| **E. Other Transactions in NIH, Part 1 (continued)** | |
| ▪ Teaming | 56 |
| ▪ Planning and Strategy | 66 |
| ▪ Case (Tab S) | 479 |
| **Lunch** | |
| ▪ Solicitation | 78 |
| **E. Other Transactions in NIH, Part 2** | |
| ▪ Cost Sharing | 79 |
| ▪ Case | 491 |
| ▪ Pricing and Payments | 87 |
| ▪ Case | 94 |
| ▪ Intellectual Property | 103 |

| Day 3 | Page Number |
|---|---|
| **L. OTAO Desktop Guide** | **203** |
| ▪ Award | |
| ▪ Agreements | 107 |
| ▪ Post-Award Administration | 111 |
| ▪ Closeout | 124 |
| ▪ Benefits | 125 |
| **Lunch** | |
| **G. Acquisition of Property in OTs** | **133** |
| **H. Foreign Access to Technology Created Under OTs** | **139** |
| **I. Summary** | **147** |

B

# *Federal Acquisition Regulation* (FAR)-Based Research and Development Contracting

Other Transaction Authority (OTA) Training

Part B

## Tool Box

| Acquisition | | | Non-Acquisition | | | |
|---|---|---|---|---|---|---|
| Procurement Contracts | | Non-FAR Contracts/ Other Transactions (OTs) | Grants | Cooperative Agreements | Other Transactions (OTs) | |
| 31 U.S.C. 6303 → *Federal Acquisition Regulation* | | •NIH Statutes<br>•NASA Space Act<br>• 2016 National Defense Authorization Act (NDAA), 10 USC 2371(b)<br>• BARDA 2006<br>• Homeland Security Act, Section 831<br>• Transportation Equity Act for the Twenty-First Century (TEA-21), Section 502<br>• FAA authority<br>•DOE ARPA-E | 31 U.S.C. 6304 | 31 U.S.C. 6305 | NIH Statutes 10 U.S.C. 2371 | NIH Statutes 10 U.S.C. 2371 |
| Part 15 | Part 12 Commercial Items | | | Traditional/ Flexible | Consortium/ Multi-Party Nontraditional Firm | Bailments Lease Arrange-ment Loan-to-Own |
| Cost/ Price Based | Price Based | | | | | |

2

# What is R&D Contracting?

*The FAR says:*

* Primary purposes of R&D contracting:
  - Advance scientific and technical knowledge
  - Apply that knowledge to the extent necessary to achieve agency and national goals
* Unlike contracts for supplies and services, most R&D contracts are directed toward objectives for which the work or methods cannot precisely be described in advance.
* For some R&D contracts, it may be difficult to judge the probabilities of success or required effort for technical approaches.

3

# What is R&D Contracting? (continued)

Per FAR part 35, the R&D contracting process shall:

* Encourage the best sources from the scientific and industrial communities to become involved in the program
* Provide an environment in which the work can be pursued with reasonable flexibility and minimum administrative burden

4

# What is R&D Contracting? (continued)

- The FAR is built around buying products and services
  - R&D contracting has its own rules under FAR part 35.
  - Other FAR parts may apply, such as parts 5, 6, 15, 16, 31, and 37.
- R&D contracting differs from other contracting:
  - Industry focus is developing technology, not making a profit.
  - Government contracting officers (COs) must understand the reduced "risks" inherent in R&D contracting.
- R&D contracting is that part of the product development process before "products" are developed for "market."

5

# The R&D Contracting Process

- The contracting process is built around fairness and openness.
- Competition in Contracting Act of 1984 (CICA)
  - Sealed-bid process/negotiated proposal process versus competition
  - Sole source:
    - Justification and approval (J&A)
    - Competitive advocates
  - Broad Agency Announcements (BAAs): Announcing government State of Art needs (more later)

6

# Contract Types Suitable for R&D

Three main contract types suitable for R&D under FAR part 16—

* Firm-fixed-price (FFP)
* Cost-reimbursement (CR)
* Hybrid—time-and-material/labor-hour

7

# Contract Types Suitable for R&D (continued)

FFP contracts

* Used for minor R&D projects when—
  - Objectives of the research are well defined.
  - There is sufficient confidence in the cost estimate for price negotiations.
* Include—
  - Fixed price incentive
  - Fixed-price with level-of-effort
* Short-duration fixed-price contract may be useful for developing system design concepts, resolving potential problems, and reducing government risks.

8

# Contract Types Suitable for R&D (continued)

CR contracts

* Generally most appropriate for R&D projects
* Provide for reimbursable payments of allowable costs incurred during the period
* A cost is allowable only when it:
  - Is reasonable
  - Is allocable
  - Meets standards promulgated by the Cost Accounting Standards (CAS) Board, if applicable
  - Meets terms of the contract

9

# Contract Types Suitable for R&D (continued)

CR contracts (continued)

* Under a CR contract, a cost is reasonable if, in its nature and amount, it does not exceed the cost that would be incurred by a prudent person in the conduct of competitive business.
* Reasonableness depends on—
  - Whether it is the type of cost generally recognized as ordinary and necessary for the conduct of the contractor's business or the contract performance
  - Generally accepted sound business practices, arm's-length bargaining, and federal and state laws and regulations
  - The contractor's responsibilities to the government, other customers, the owners of the business, employees, and the public at large
  - Any significant deviations from the contractor's established practices

10

## Contract Types Suitable for R&D (continued)

CR contracts (continued)

* Under a CR contract, a cost is allocable if it is assignable or chargeable to one or more cost objectives on the basis of relative benefits received or other equitable relationship.
* Subject to the above, a cost is allocable to a government contract if it—
  - Is incurred specifically for the contract,
  - Benefits both the contract and other work and can be distributed to them in reasonable proportion to the benefits received, or
  - Is necessary to the overall operation of the business, although a direct relationship to any particular cost objective cannot be shown

11

## Contract Types Suitable for R&D (continued)

CR contracts include—

* Cost
* Cost plus fixed-fee (CPFF)
  - Fee
    - Completion
    - Level of effort
    - Statutory limits
* Cost plus award/incentive fee (CPA/IF)
* Time-and-material/labor-hour

12

# Solicitation Methods for R&D Contracts

- Requests for proposals (RFPs)
- Letter RFPs
- Oral solicitations
- Unsolicited proposals per the requirements of FAR subpart 15.6
- BAAs per FAR parts 6 and 35

13

B

# Solicitation Methods for R&D Contracts (continued)

RFPs

- A tradeoff process is appropriate when it is best to consider award to other than the lowest-priced offeror or other than the highest technically rated offeror.
- The solicitation must state—
  - All evaluation factors and significant subfactors that will affect contract award and their relative importance
  - Whether all evaluation factors other than cost or price, when combined, are significantly more important than, approximately equal to, or significantly less important than cost or price

14

# Solicitation Methods for R&D Contracts (continued)

RFPs (continued)

* The tradeoff process permits tradeoffs among cost or price and non-cost factors and allows the government to accept other than the lowest priced proposal.
* The perceived benefits of the higher-priced proposal shall merit the additional cost, and the rationale for tradeoffs must be documented in the file in accordance with FAR 15.406.

15

# Solicitation Methods for R&D Contracts (continued)

BAAs

* Other competitive procedures (under FAR 6.102)
  - Selection of sources for architect-engineer contracts in accordance with the provisions of Pub. L. 92-582 (40 U.S.C. 541, *et seq*.) is a competitive procedure (see FAR subpart 36.6 for procedures).
  - Competitive selection of basic and applied research and that part of development not related to the development of a specific system or hardware procurement is a competitive procedure if award results from:
    - A BAA that is general in nature, identifying areas of research interest, including criteria for selecting proposals, and soliciting the participation of all offerors capable of satisfying the government's needs; and
    - A peer or scientific review

16

# Solicitation Methods for R&D Contracts (continued)

BAAs (continued)

* Value of the BAA process
  - Allows competition and proprietary information to coexist
  - Offerors do not propose against common work statement
  - Allows awards based on technical superiority or technical promise (revolutionary ideas) (**tradeoff process of FAR part 15 does not apply)**
  - Facilitates very rapid acquisition when needed
  - Customer-friendly to both program managers and offerors

17



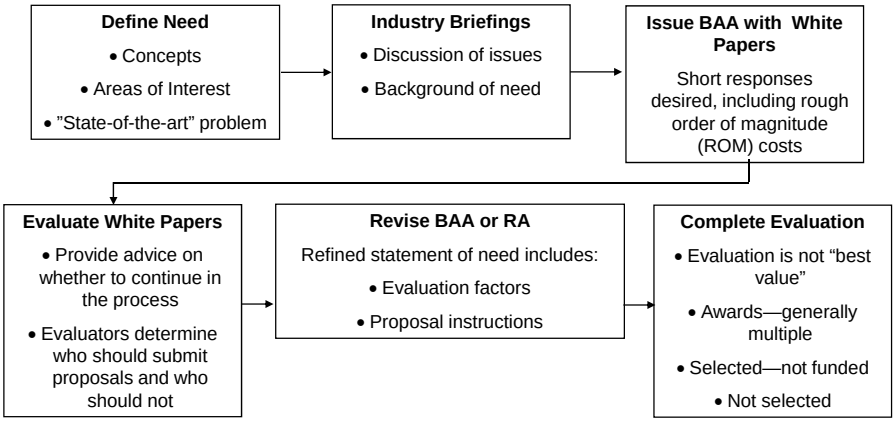
# Solicitation Methods for R&D Contracts (continued)

BAAs (continued)

* Evaluation
  - Conducted by a panel of scientists and other technical experts
  - Involves scientific review against published evaluation criteria
* Selection
  - Made by technical personnel
  - An innovative, but risky, proposal may be chosen
  - The best business deal is not always the winner

18

# Evaluation Process




19

# Solicitation Methods for R&D Contracts (continued)

## BAAs (continued)

* Post-selection
  - Government holds debriefings if requested
  - Protests are rare
    - Technical judgment on varying approaches
    - Very little case law on BAAs exists
  - Alternative dispute resolution (ADR) is encouraged
  - Effective monitoring requires Program Manager (PM) involvement

20

# R&D Contracting for Services

- Service contracts
  - Directly engage the time and effort of a contractor whose primary purpose is to perform an identifiable task rather than furnish an end item of supply
  - May be for either nonpersonal or personal services
- Some of the services for which service contracts are used include:
  - Maintenance, overhaul, repair, servicing, rehabilitation, salvage, modernization, and modification of supplies, systems, and equipment
  - Research and development (see FAR part 35)

21



# R&D Contracting for Services (continued)

- A nonpersonal services contract is one under which the personnel rendering the services are not subject, either by the contract's terms or by the manner of its administration, to the supervision and control usually prevailing in relationships between the government and its employees.
- People are the key to R&D contracting.

22

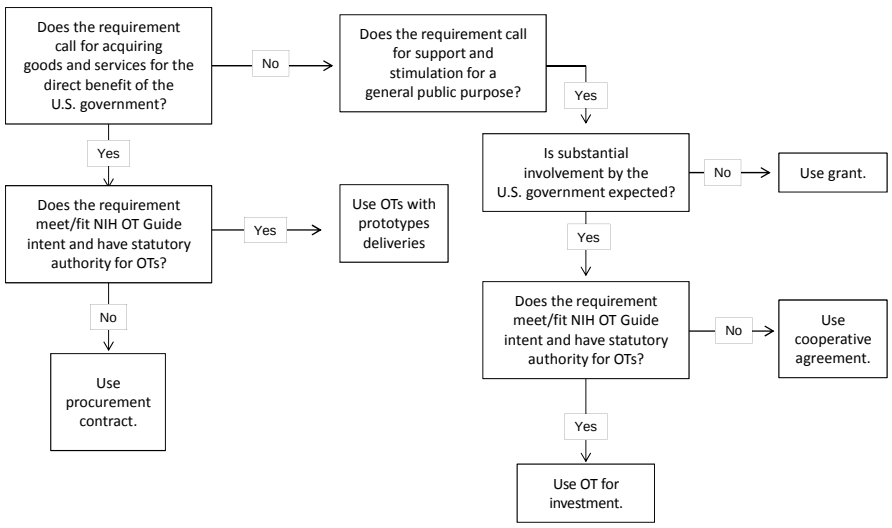
# R&D Contracting for Services (continued)

When determining whether a service is personal or nonpersonal, the CO should consider the following:

* Will the service be performed on site?
* Will the government furnish the principal tools and equipment?
* Will the service be applied directly to the integral effort of agencies or an organizational element in furtherance of an assigned function or mission?
* Are comparable services, meeting comparable needs, being performed in the same or similar agencies using civil service personnel?
* Is there a reasonable expectation that the service will need to last beyond one year?
* Does the inherent nature of the service, or the manner in which it is provided, reasonably require—directly or indirectly—government direction or supervision of contractor employees?

23

## Notional Guide to Selection of R&D Instruments




24

# Why Other Transactions ?

Other Transaction Authority (OTA) Training
Part C

C

# Why OTs?

21st Century

* Unfriendly world with diverse threats
* Movement toward more oversight and control
* Information technology as cornerstone of government activities
* Defense/government industrial base is shrinking
* Civilian technology is more advanced than military technology (*Rand Study of Commercial Buying: Aviation and Wireless Communications Industries)*
* Innovative civilian products are introduced rapidly

2

# Why OTs? (continued)

Partnering within industry and between government and industry has become increasingly common

* World Wide Web Consortium (W3C) develops interoperable technologies (specifications, guidelines, software, and tools) to lead Web to its full potential.
* U.S. Display Consortium (USDC) has mission to develop flat-panel-display supply chain and support world-class competitive display industry.
* California Fuel Cell Partnership is unique collaboration of auto manufacturers, energy companies, fuel cell technology companies, and government agencies.

3

# Why OTs? (continued)

* When he signed the Armed Services Procurement Act (ASPA), President Harry Truman pointed out—
  - It gives unprecedented freedom from specific procurement restrictions.
  - It permits flexibility and latitude.
  - It may lead to excessive placement of contracts by negotiation.
  - It may lead to undue reliance upon large concerns.
* Truman enjoined all procurement personnel to follow strictly the standards and requirements set forth in ASPA.

4

## Why OTs? (continued)

* Result was a "follow-the-rules" culture
  - Through training and mentoring
  - At least until acquisition reform of the mid-1990s
  - Culture limited flexibility and disincentivized participation by Nontraditional Research Performers (NRPs)

5

C

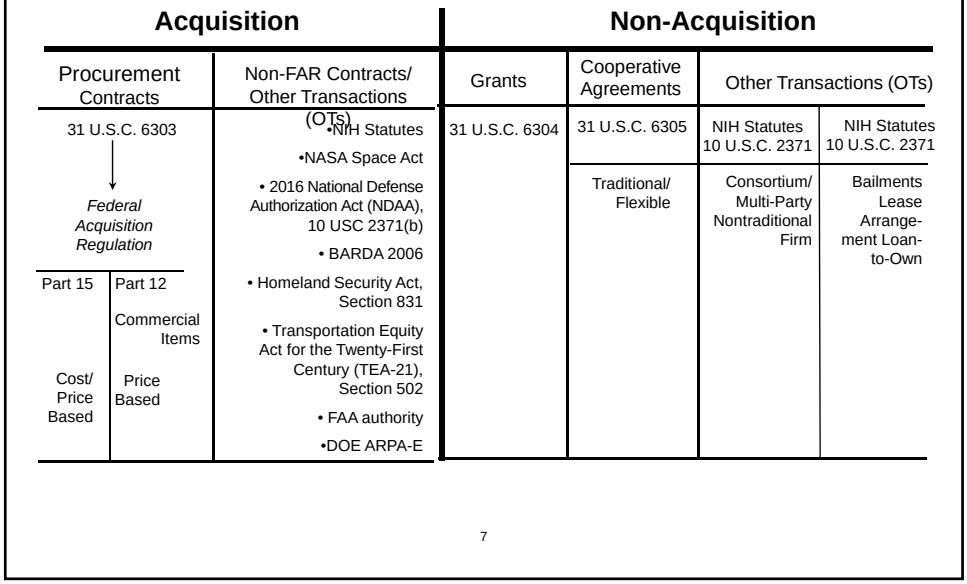
## Why OTs? (Continued)

OTs provide flexibility to attract Nontraditional Research Performers(NRPs)

* Main impediments to new players:
  - Cost and pricing data submittals and certifications
  - Cost Accounting Standards (CAS)
  - Perceived excessive oversight
  - Socioeconomic provisions
  - Subcontract flow-down of Federal Acquisition Regulation (FAR)-based clauses
  - Preconceived inflexible government position on licensing of intellectual property (IP) rights

6

# Tool Box


Acquisition
Non-Acquisition
Procurement Contracts
Non-FAR Contracts/ Other Transactions (OTs)
Grants
Cooperative Agreements
Other Transactions (OTs)
31 U.S.C. 6303
Federal Acquisition Regulation
Part 15
Cost/ Price Based
Part 12
Commercial Items
Price Based
•NIH Statutes
•NASA Space Act
• 2016 National Defense Authorization Act (NDAA), 10 USC 2371(b)
• BARDA 2006
• Homeland Security Act, Section 831
• Transportation Equity Act for the Twenty-First Century (TEA-21), Section 502
• FAA authority
•DOE ARPA-E
31 U.S.C. 6304
31 U.S.C. 6305
Traditional/ Flexible
NIH Statutes 10 U.S.C. 2371
Consortium/ Multi-Party Nontraditional Firm
NIH Statutes 10 U.S.C. 2371
Bailments Lease Arrange-ment Loan-to-Own
7

# Intellectual Property in OTs

Other Transaction Authority (OTA) Training
Part D

## Objectives

In this section, we introduce—

- Intellectual property (IP)
  - Creations of the human mind
  - Physical manifestations of original thought
  - Products of the intellect that have commercial value
  - Intangible personal property interests
- Standard IP licensing rights in the *Federal Acquisition Regulation* (FAR)
- The flexibility offered by OT authority

2

D

# Road Map

1. Introduction to Intellectual Property (IP)
2. Policy
3. Regulatory IP Coverage for Procurement Contracts
4. Trade Secrets
5. IP Overview

3

# Why Do IP Rights Matter?

IP rights are—

* Very important to commercial industry
* The lifeblood of any high-technology company
  - Help the company differentiate itself from its competitors
  - Help the company keep its leading edge
* The primary means to recoup the investment of nonrecurring costs and seek profit by:
  - Inserting the IP into unique products or processes, or
  - Licensing the IP rights to others for royalties

4

## Why Do IP Rights Matter? (continued)

* IP is an intangible asset; therefore, it is difficult to estimate its value.
* IP rights restrict others from using the IP.

5

## IP Provisions

* In commercial contracting, IP consists of:
  - Patents
  - Copyrights
  - Trade secrets
  - Trademarks
  - Service marks
* In government funding instruments, IP consists of everything above except trade secrets.

6

# IP in Procurement Contracts

* Statutory coverage: Patents—Bayh-Dole Act
* Regulatory coverage
  - Patents
    - Commerce Department regulations in the *Code of Federal Regulations* (CFR)
    - FAR
  - Technical Data
    - FAR for civilian agencies
    - *Defense Federal Acquisition Regulation Supplement* (DFARS) for Department of Defense (DoD) agencies
  - Computer Software
    - FAR for civilian agencies
    - DFARS for DoD agencies

7

# Bayh-Dole Act

* Codified at Title 35 of the *United States Code* (U.S.C.), Section 200 et seq.
* Applies to procurement contracts, grants, and cooperative agreements; does not apply to OTs.
* Congress passed in 1980 in an effort to encourage entities doing work under government contracts to commercialize their inventions.
* Prior to 1980, the government would take ownership of inventions and make them public.
  - Few U.S. contractors were commercializing these inventions.
  - Foreign countries were reaping the benefit of many of these inventions.

8

# Bayh-Dole Act (continued)

* Universities and nonprofits lobbied to retain more rights in the inventions, so they could have commercial exclusivity to exploit the inventions in the marketplace.
* Statutory language applies only to nonprofits, including universities, and small businesses.
* President Reagan issued an Executive Order in 1983 stating that the same allowances should be extended to large businesses.

9

# Bayh-Dole Act (continued)

* 35 U.S.C. 201, Definitions
  - Funding agreement: a contract, grant, or cooperative agreement
  - Invention: any invention or discovery that is or may be patentable
  - Subject invention: any invention conceived or first actually reduced to practice in the performance of work under a funding agreement
  - Practical application: to manufacture, practice, or operate under conditions establishing that the invention is being utilized and the benefits are available to the public

10

# Bayh-Dole Act (continued)

* 35 U.S.C. 202, Disposition of Rights
  - Allows the contractor to retain title to the subject invention, except in unusual circumstances.
  - Before the government takes title, it must make a determination and file with the Department of Commerce for approval.
  - The contractor must disclose the subject invention, elect to retain title, and file a patent within a certain period of time.
  - The patent application must state that the invention was made with government support.

11

# Bayh-Dole Act (continued)

* 35 U.S.C. 202, Disposition of Rights (continued)
  - The federal agency receives a license in the invention that is—
    - Nonexclusive
    - Nontransferable
    - Irrevocable
    - Paid up
  - The license allows the government to—
    - Practice the invention itself or
    - Have the invention practiced for or on behalf of the government throughout the world

12

# Bayh-Dole Act (continued)

* 35 U.S.C. 203, March-In Rights
  - Allows the agency that funded the instrument to require the inventor to grant a license to someone else under certain circumstances
  - If the contractor refuses, the government can grant the license itself if it determines that such action is necessary—
    - Because the contractor has not taken effective steps to achieve practical application within a reasonable time
    - To alleviate health or safety needs
    - To meet requirements for public use specified by regulations or
    - Because the agreement required in 35 U.S.C. 204, Preference for U.S. Industry, was not obtained

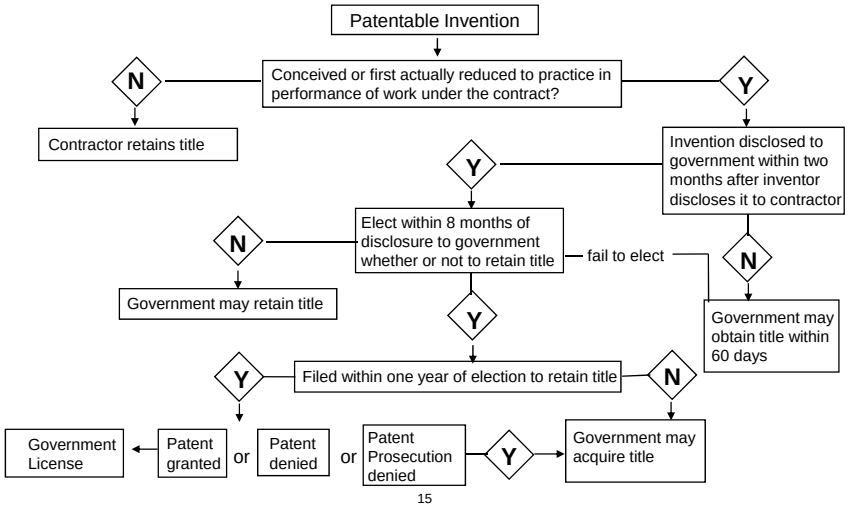
13

# Bayh-Dole Act (continued)

* 35 U.S.C. 204, Preference for U.S. Industry
  - Prohibits the granting of an exclusive right to sell or use the invention in the U.S. unless the potential licensee agrees to manufacture substantially in the U.S.
  - Can be waived if the contractor shows that it has made reasonable but unsuccessful efforts to find an appropriate licensee, or domestic manufacture is not commercially feasible

14

# Government Patent Rights in Funding Agreements




15

# FAR Part 27

FAR part 27 – Patents, Data, and Copyrights: Definitions

* Data
  - Recorded information regardless of form or media
  - Includes technical data and computer software
  - Does not include financial, administrative, cost or pricing, or management information
* Technical Data
  - Scientific or technical data
  - Does not include computer software
* Computer Software: Computer programs, computer databases, and documentation

16

# FAR Part 27 (continued)

* Form, fit, and function data
  - Data relating to items, components, or processes sufficient to enable physical and functional interchangeability
  - Data identifying source, size, and configuration characteristics
  - Functional characteristics and performance requirements
  - For software—
    - Includes source, functional characteristics. and performance requirements
    - Excludes source code, algorithms, process, formulae, and flow charts of the software
* Unlimited rights: Right of the government to use, disclose, reproduce, prepare derivative works, distribute copies, and perform and display publicly
  - In any manner, for any purpose, and
  - Permit others to do so

17

# FAR Part 27 (continued)

* Limited-Rights Data
  - Excludes computer software
  - Commercial, financial, confidential, or privileged data
  - Data pertaining to items developed at private expense
* Restricted-Rights Computer Software
  - Software that is developed at private expense and is a trade secret
  - Software that is commercial, financial, confidential, or privileged
  - Software that is published and copyrighted

18

# FAR Clause 52.227-14

FAR 52.227-14, Rights in Data—General

* Government receives unlimited rights in—
  - Data first produced in the performance of the contract
  - Form, fit, and function data delivered under the contract
  - Data delivered in the form of manuals, instructional materials, and training materials
* Contractor has the right to use the data, subject to rights given to the government.

19

# FAR Clause 52.227-14 (continued)

* Copyright
  - Contractor is free to establish copyright on data first produced in performance of the contract and used in articles, symposia, or similar works.
  - Copyright notice shall acknowledge government sponsorship.
  - Government receives a paid-up, nonexclusive, irrevocable, worldwide license.
  - Government shall not remove copyright notices.
* Limited-Rights Data
  - If the contracting officer (CO) determines a need for limited-rights data, he/she should include Alternate II.
  - Data will not be used for manufacture or disclosed outside the government.
  - Data cannot be used for a future competitive procurement.

20

# FAR Clause 52.227-14 (continued)

* Restricted-Rights Computer Software
  - If the CO determines a need for restricted-rights software, he or she should include Alternate III.
  - The software may be—
    - Used or copied for use only in the computer with which it was acquired
    - Used or copied for use only in a backup computer
    - Reproduced for only archival or backup purposes
    - Used by support contractors
  - Alternate IV copyright clause should be used in contracts for basic or applied research performed solely by universities.

21

# FAR Clause 52.227-15

FAR 52.227-15, Representation of Limited Rights Data and Restricted Computer Software

* Should be used if the CO wishes to have offerors state whether limited-rights data or restricted-rights software will be used
* Include in solicitations

22

D

# FAR Clause 52.227-16

FAR 52.227-16, Additional Data Requirements

* Should be included in solicitations and contracts
* Applies to experimental, developmental, research, or demonstration work (not including basic or applied research by a university)
* Is used in contracts where additional data may be required but such requirement is unknown at the outset of the contract

23

# Comparison of Rights Categories for Noncommercial Computer Software and Technical Data

| Rights Category | Applicability: Technical Data or Computer Software? | Permitted Uses Within Government | Permitted Uses Outside Government |
|---|---|---|---|
| Unlimited Rights | Both | Unlimited—no restrictions | |
| Limited Rights | Technical data only | Unlimited, except cannot be used for manufacture | Emergency repair or overhaul; evaluation by foreign government |
| Restricted Rights | Computer software only | Only one computer at a time; minimum backup copies; modification | Emergency repair or overhaul; certain service or maintenance contracts |
| Prior Government Rights | Both | Same as under previous contract | |
| Specifically Negotiated License Rights | Both | As negotiated by the parties but must not be less than either limited rights in technical data or restricted rights in computer software | |

24

# What is a Trade Secret?

* Means of protecting secret business information against unauthorized use or disclosure
* Applicable to information that—
  - Derives independent economic value from not being generally known or generally ascertainable by others who could use the information and
  - Is the subject of efforts that are reasonable under the circumstances to maintain secrecy
* Recognition of this type of protection began in the early 1800s
* Popular way to protect information

25

# How Do You Obtain Trade Secret Protection?

* Information must—
  - Be eligible for protection
    - Any concrete information (i.e., information that is more than an idea, theory, or possibility) qualifies
    - Can be no technical information, customer lists, or a combination of otherwise unprotectable information
  - Be secret, as judged in light of the circumstances
  - Have commercial value
* Methods of obtaining trade-secret protection are based on individual state laws.

26

## How Long Does A Trade Secret Last?

* Can last as long as the owner successfully prevents it from becoming widely known
* If secrecy is destroyed, the protection is lost.
  - Insufficient precautions
  - Marketing of a product the discloses the secret
  - Compliance with patent laws
  - Disclosure in judicial proceedings or to government agencies
* Generally, confidential disclosure on a "need-to-know" basis to employees, teammates, and suppliers will be deemed sufficient for secrecy.

27

## Common Misperceptions—FAR-based IP

* Government owns IP developed under contract.
  - Wrong
  - Government gets a license for use, but rarely does it take title.
* When rights are given to the government, they are given to the agency signing the contract.
  - Wrong
  - The term "government" means the entire federal government.

28

# Other Transactions (OTs)

Other Transaction Authority (OTA) Training
Part E

# Tool Box

| Acquisition | | | Non-Acquisition | | | |
|---|---|---|---|---|---|---|
| Procurement Contracts | | Non-FAR Contracts/ Other Transactions (OTs) | Grants | Cooperative Agreements | Other Transactions (OTs) | |
| 31 U.S.C. 6303 ↓ *Federal Acquisition Regulation* | | •NIH Statutes<br>•NASA Space Act<br>• 2016 National Defense Authorization Act (NDAA), 10 USC 2371(b)<br>• BARDA 2006<br>• Homeland Security Act, Section 831<br>• Transportation Equity Act for the Twenty-First Century (TEA-21), Section 502<br>• FAA authority<br>•DOE ARPA-E | 31 U.S.C. 6304 | 31 U.S.C. 6305 | NIH Statutes 10 U.S.C. 2371 | NIH Statutes 10 U.S.C. 2371 |
| Part 15 | Part 12 | | | Traditional/ Flexible | Consortium/ Multi-Party Nontraditional Firm | Bailments Lease Arrange-ment Loan-to-Own |
| Cost/ Price Based | Commercial Items<br>Price Based | | | | | |

2

E

# Other Transactions (OT) Defined

* An OT is a legally binding instrument other than a procurement contract, grant, or cooperative agreement.
* Generally their nature is either focuses as investments (OT) or to acquire something that the government needs (OT).

3

# NIH OT Guide Definitions

* **Government team** means the subject matter experts from several disciplines and other employees and officials that are essential to successfully planning and managing an OT throughout its life-cycle.
* **Other Transaction Agreement Officer (OTAO)** means a senior-level warranted contracting officer with research and development contracting experience in good standing and possessing a Level III acquisition certification. These individuals possess a level of experience, responsibility, business acumen, and judgment that enables them to operate in the relatively unstructured business environment of the OT.

4

# Assistance Definitions

Assistance

* Transferring a thing of value from the government to a recipient to carry out a public purpose of support or stimulation
* Examples: highway construction funding, support to the National Guard, research on common diseases, low-cost housing support

5

# Assistance Definitions (continued)

Grant

* A legal instrument used to transfer a thing of value from the government to a recipient to carry out the public purpose of support or stimulation instead of acquiring property or services for the government's direct benefit or use
* Substantial involvement is not expected between the government and the recipient when carrying out the activity contemplated by a grant.

6

# Assistance Definitions (continued)

Cooperative Agreement

* A legal instrument used to enter into the same kind of relationship as that under a grant, except substantial involvement is expected between the government and recipient when carrying out the activity contemplated by a cooperative agreement
* This term is not related to cooperative research and development agreement (CRADA), which is a legal agreement between a federal laboratory and industry used for the transfer of commercially useful technologies from federal laboratories to the private sector and to make unique technical capabilities and facilities accessible.

7

# Assistance Definitions (continued)

Substantial involvement

* May include collaboration, participation, or intervention in program or activity to be performed under award
* For example—
  - Agency review and approval required at the completion of one stage prior to moving on to subsequent phases
  - Agency review and approval of subcontracts or subgrants that exceed standard regulatory approvals
  - Agency involvement in the selection of key personnel

8

# Assistance Definitions (continued)

* Examples of type of involvement not considered substantial involvement—
  - Approval of recipient plans prior to award
  - Normal exercise of federal oversight responsibilities, including performance reviews, financial reviews, site visits, audits, etc.
  - Unanticipated involvement to correct deficiencies identified during performance

9

# Acquisition Defined

* Contracts: A **contract** refers to a legally binding agreement between parties in which they are obligated to do something. **Commercial contracts** can be written, verbal, or implied in a formal or an informal manner.
* Federal Contracts: Written contracts that acquires goods and services for the direct benefit of the government.
* FAR: Federal contracts executed in accordance of procurement statutes.

10

# The First DOD OT Authority: OTs for Research

* In 1989, the first OT authority for Basic, Applied and Advance Research appeared in 10 U.S.C. 2371
  - Granted authority to Defense Advanced Research Projects Agency (DARPA) to "enter into ***transactions other*** *than* contracts, grants, and cooperative agreements to carry out basic, applied, and advanced research and development projects that are otherwise authorized and necessary to the responsibilities of the agency"

11

# The First DOD OT Authority (continued)

* The additional language of the first OT authority, now generally considered a non-acquisition authority, is summarized as follows:
  a) In exercising OT authority, the SECDEF shall act through Director, DARPA
  b) Advance payments are authorized.

12

# The First DOD OT Authority (continued)

d) Recovery of funds is permitted.

e) The SECDEF shall ensure that:

(1)(A) To the maximum extent practicable, no transaction for research duplicates research conducted under existing programs

(1)(B) To the extent the SECDEF determines practicable, funds provided by the government do not exceed the total provided by other parties to the OT

(2) The OT authority is used only when a standard contract, grant, or cooperative agreement is not appropriate

f) Support accounts.

h) Report to Congress.

i) Protect certain information from disclosure.

13

# The First DOD OT Authority (continued)

* The first OT was with Gazelle Microcircuits.
  - Sole-source based on an unsolicited proposal
  - Offered no cost share

14

E

# The Second DOD OT Authority: OTs for Prototype Projects Authority (OTFP)

* Fiscal Year (FY) 1994 National Defense Authorization Act (NDAA) Section 845 created a ***temporary*** new, second authority to acquire prototypes.
* Now the OT for Prototypes are governed by 10 U.S.C. § 2371b.
  - This authority allows DARPA to use OTs for prototype projects directly relevant to enhancing the mission effectiveness or improvements of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed, by DOD or any of its elements.
  - This OTA authority requires there be at least one nontraditional defense contractor involved to an significant extent.
  - A non-traditional defense contractor is defined as an entity that is not currently performing or has not performed in the last one-year period any contract for the Department of Defense that is subject to full Cost Accounting Standards (CAS) coverage or a small business.

15

# OT's Extended Authority

* FY 1997 NDAA, Section 803, granted the authority to services and Defense agencies and extended the authority to FY 2001.
* FY 2001 NDAA, Section 803, extended the prototype projects authority to FY 2004 and applied new requirements to be met before entering into OTs for Prototype Projects.
  - Also added General Accountability Office (GAO) access to records for OTs for prototype projects valued greater than $5 million.

16

# OT's Extended Authority (continued)

* 2004 NDAA, Section 1441 , gave OT authority to civilian agencies "to facilitate defense against, or recovery from, terrorism or nuclear, biological, chemical, or radiological attack."
* Many departments now have OTA authorities.
  - See attachment Tab J

17

# Break

E

# NIH's FIRST OT Authorities

* Beginning in 1972, NIH's National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program had other transaction authority (OTA).
  - In Section 402(n) of the Public Health Service (PHS) Act, 42 U.S.C. 282(n)
  - For projects that carry out the Precision Medicine Initiative or the NIH Common Fund (subject to a limit of not more than 50 percent of Common Fund funding). Such projects must represent "high impact cutting-edge research."

19

## OT Authority For Common Fund, Precision Medicine Initiative

* Pursuant to the requirements of section 402(n) of the PHS Act, 42 U.S.C. 282(n), a plan must be submitted to the Director of NIH for the use of the OT authority for a proposed Common Fund or Precision Medicine Initiative (a.k.a. All of Us) OT program before conducting or supporting the research.
  - why the use of OT authority is essential to promoting the success of the project
* Upon receiving approval, OT authority may be exercised, and an annual report must be submitted to the Director on the activities relating to research performed under the OT agreement.

# NIH's Second OT Authority

* Section 480(e)(3)(C) of the PHS Act, 42 U.S.C. 287a(e)(3)(C), which authorizes the National Center for Advancing Translational Sciences (NCATS) to use up to 20% of the fiscal year funding authorized to be appropriated under section 480 of the PHS Act to enter into OT agreements for its Cures Acceleration Network (CAN) program.

21

# NIH's Additional OT Authorities

* 42 U.S.C. 284 n (b), which grants OT authority to NIH to conduct "high-risk, high-reward research" funded by appropriations authorized under section 402A(b) of the PHS Act, 42 U.S.C. 282 a (b)
* Section 421(b)(3) of the PHS Act, 42 U.S.C. 285b-3(b)(3), which authorizes the National Heart, Lung, and Blood Institute (NHLBI) to enter into OT agreements
* Other authority: *provide citation and scope of authority*

22

# NIH's Reasons to Use OT Authority

* Need for flexibility to negotiate terms and conditions appropriate for the specific program/agreement, such as—
  - Requiring fluid implementation of a program:
    - Awards may need to begin quickly on a small scale, with additional funds added later if particular milestones are met, or
    - Awards may need to be downsized or discontinued
* Nontraditional review and award management practices are needed because the science is expected to be highly evolving, with requirements for additional aims or expertise added to, or removed from, the project throughout the award period.

19

# Reasons to Use OT Authority

* The requirement for collaborative involvement by the government in the technical direction and oversight of the research, which can be akin to partnering
  - Examples of involvement can include—
    - Participation in progress reviews and decisions on future efforts or direction
    - Government may also be a voting or non-voting member of the consortium

24

# Reasons to Use OT Authority
(continued)

* Seeking participation by nontraditional research performers (NRPs), such as—
  - Small businesses, patient advocacy organizations, educational institutions, pharmaceutical companies, foreign entities, or other organizations that are typically not inclined to work with the federal government
  - Consortia comprised of the entities above who collaborate as peers with the government to manage the project and share its costs
  - Nonprofit entities that have an interest in the goals of the OT program
  - Individuals

25

# NIH OT Guide, Actions Required Before Award

* Per NIH OT Guide, prior to issuing an agreement, an NIH Institute, Center or Office (ICO) must—
  - Document its rationale for using an OT
  - Document internal controls for assessing the risks associated with meeting the project objectives, including—
    - Estimating the risk's significance
    - Assessing the likelihood for the risk to occur
    - Deciding how to manage the risks and what specific actions to undertake
  - Document that the proposed awardee is a responsible party and is not on the Exclusions list in the System for Award Management (SAM), or otherwise prohibited from receiving federal appropriations
  - Document the reasonableness of the anticipated cost and applicable terms and conditions

26

# NIH OT Guide

* During the planning process coordinate with—
  - Legal advisors for appropriate use of OT statutory
  - Higher headquarter as required by appropriate statute
* See Tab T, Justification and Approval of Use of the OT Authority

27

# NIH OT Guide

* OTs are not subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (Uniform Regulations) (45 CFR part 75), which are limited in applicability to grants, cooperative agreements, or other forms of federal financial assistance, nor are OTs subject to the NIH Grants Policy Statement.

28

# NIH OT Guide

* Generally speaking, procurement statutes and regulations do not apply.
* NIH OT Policy Guide lists federal statutes that do not apply to OTs.
* This list is not intended to be definitive; laws may be determined to apply to a specific NIH OT.
* Let's look at Tab K, NIH's Other Transactions Guide.

29

# What Does Apply?

* There is no regulatory system of mandates, but the following do apply:
  - Criminal laws (false claims/statements)
  - Federal fiscal laws
  - General laws (e.g., Title VI, Civil Rights Act)
* There is no supporting regime of commercial law.
  - No Uniform Commercial Code to fill in gaps.
  - Therefore, there is freedom to create new contract form and provisions.

30

# NIH OT Guide

* Although some assistance and acquisition laws and regulations do not apply to OTs, NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds.

31

# Actions Required Before Award

* OTAO's and Program Managers should establish and track any metrics that measure the value or benefits directly attributed to the use of the OT authority.

32

# Actions Required After Award

* The NIH Institute, Center or Office (ICO) must track performance throughout the life of the agreement to ensure the use of OT authority continues to be appropriate.

33

# How are OTs Used?

* For now there are no limits to the use for OTs at NIH, except as defined in the NIH OT Guide
* In some OTs, the impact of government funding is often more like **investment** than purchase of goods and services.
  - Government funds are not expected to have an immediate impact or result.
  - Industry benefits because the government funds part of the risk.
  - The government will benefit when the resulting goods or services are available in the commercial marketplace and meet government needs.
  - The government business manager's (OTAO) focus should be not on the instant costs of the research, but on its long-term economic / social benefits.

34

# How are OTs Used?

* Some OTs take can be used to acquire prototypes
* Some OTs, have cost sharing. Cost sharing is an option as an administrative requirement, unless the authorizing legislation for the particular OT program specifies otherwise.
  - Programs in which industry and government share expenses and results are more successful (my opinion).

35

# How are OTs Used?
(continued)

* To NRPs, *all* OTs say—
  - The government will negotiate.
  - The government wants win/win situation.
* Remember, the goal of OT is the development of the best research and development/technologies to further the agency mission needs.

36

# Past OT Programs with Investments

* Telesurgery systems
  Enable surgeons in mobile army surgical hospital (MASH) units or base hospitals to carry out emergency surgical procedures on soldiers in armored mobile surgical vehicles in the combat zone.
* Diagnostics systems
  The Personnel Status Monitor, worn by each soldier, monitors and reports vital signs and location and enables medics to quickly locate wounded soldiers and assess the severity of their injuries.

37

# Past OT Programs with Investments(continued)

* Other examples:  Hybrid electric vehicles
* USAF Evolvable Expendable Launch Vehicle (EELV)
* DHS S & T Innovation, Resilient Electric Grid

38

E

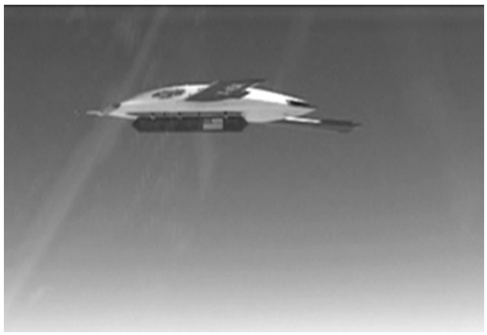
# Past OT Programs with Prototype Deliverables

* DARPA & USAF High Altitude Long Endurance Unmanned Air Vehicles (DARKSTAR and Global Hawk)
  - 1994
* DARPA & USN Arsenal Ship - 1995
* DOD Commercial Operations and Support Savings Initiative (COSSI)
* DHS Counter-MANPADS 2001
* DHS S & T Infrastructure Protection & Disaster Mgmt, Recovery Transformer 2012

39

# Past OT Programs with Prototype Deliverables

Unmanned Combat Air Vehicle (UCAV) Program (transitioned to J-UCAS) 1995



***Place cursor below image to play***

# Big Picture
# Doing Business Under OTs

* Project size is not a factor: OTs can and should be used when executing (small) prototype projects that result from—
  - Small Business Innovation Research (SBIR) Program
  - Unsolicited proposals
* Agreement Flexibility
  - Changes
    - No government-directed unilateral changes
    - No claims for equitable adjustment caused by changes

41

# Doing Business Under OTs (continued)

* Termination clauses should—
  - Identify conditions that would permit terminations
  - Include procedures for deciding termination settlements
* Costs
  - No mandatory cost principles or accounting standards
  - No certified cost or pricing data
* Subcontracting
  - Government system not required
  - No mandatory clause flow-downs

42

E

## Doing Business Under OTs (continued)

* Profit or fee
  - OT that are like investments: Past experience has not permitted
  - OT with prototype deliveries
    - No limitations
    - Performance bonuses based on achievable performance standards (not on costs)
    - Recognition of investments made by industry (independent research and development)
    - Balanced with sharing in "preventable overruns"
    - Profit based on commercial technology content (more "buy" than "make")

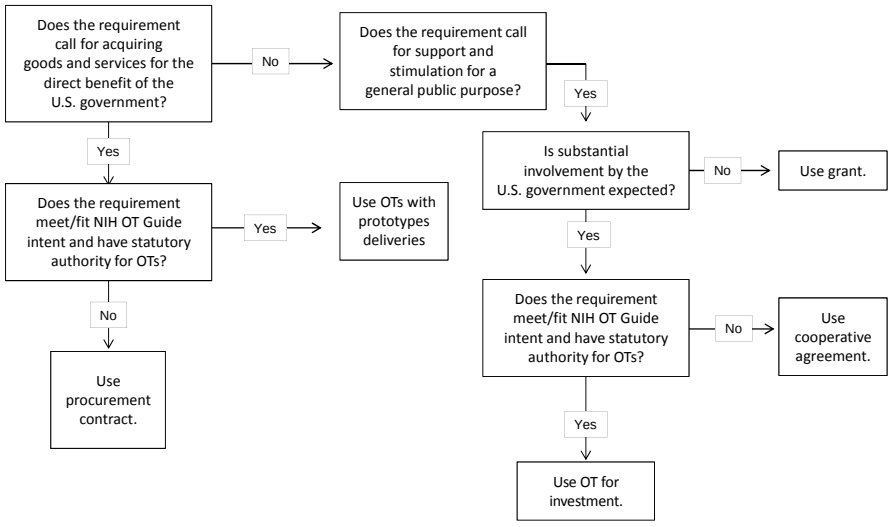
43

## Doing Business Under OTs (continued)

* Management structure—true teaming possible
* Summary Thoughts
  - Sound business judgment absolutely necessary.
  - Contracts/Legal/Program/Financial team
  - Recovery of funds is allowed and may be warranted.
  - Safety net is not there.

44

## Notional Guide to Selection of R&D Instruments



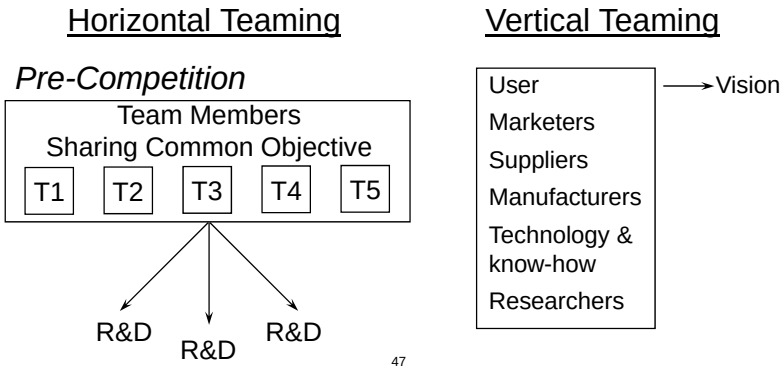

45

BREAK

E

# Types of Teams

Type of team formed depends on strategic direction




47

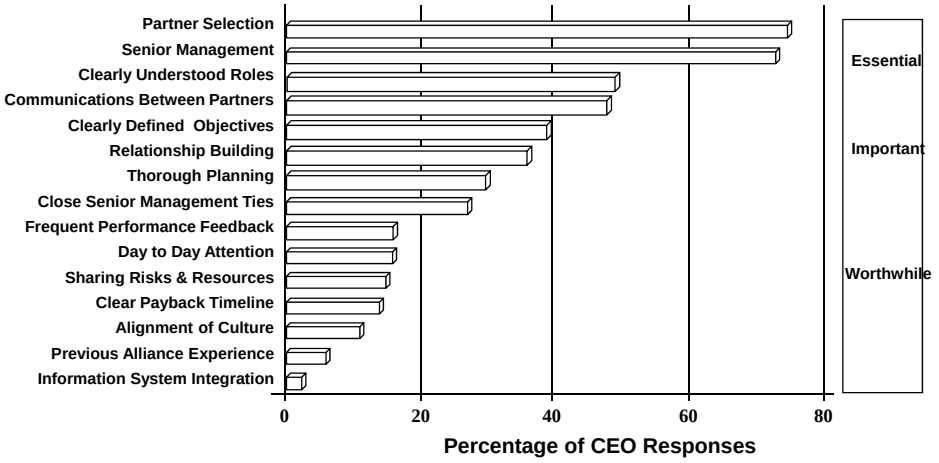
# Multi-Party Agreements

* Unique set of team members
* Unique set of relationships
  - Market forces
  - Competition
  - Business strategies
  - Resources

48

# Elements of Successful Consortia

Results of Dataquest survey of 455 electronics company CEOs




49

# Unique Advantages for Government

* Technical insight: visibility at all levels
* Leverage of resources: risk reduction (cost sharing)
* Decreased oversight requirements: self-policing

50

E

# Relationship Building

Best practices for **building** the relationship:

* Be proactive; use a "jump-start" approach.
* Identify "show-stoppers" early.

51

# Relationship Building (continued)

Best practices for **managing** the relationship:

* Use agreement flexibility.
* Allocate risks, responsibilities, and rewards.
* Maintain win/win posture.
* Find common ground.
* Transition relationship during movement through phases.

52

# Articles of Collaboration/ Teaming Agreements

* Provide a set of rules and procedures that govern activities and relationships of industry participants in the agreement.
* Must answer the following:
  - What are the names of the consortium members, and what cost share will each contribute?
  - What will be each member's responsibilities for the program?
    - Detailed list of each member's tasks and rewards should appear here rather than in OT agreement.
  - Who will manage and govern the consortium?
  - Who will conduct billing, and how will members be paid?

53

# Articles of Collaboration/ Teaming Agreements (continued)

- Who will be responsible for disputes?
- How will changes to the articles of collaboration/teaming agreement be accomplished?
- How will new members be added or old members terminate or be terminated?
- How will IP be handled?
- Where will the research take place?
- Who will sign the agreement between the government and the consortium?

54

# Articles of Collaboration/ Teaming Agreements (continued)

* OTAO must review the articles of collaboration/ teaming agreement for consistency with the OT.
* See Tab R, Sample Articles of Collaboration.

55

# Lessons Learned

* A loosely formed team tends to be very unfocused.
* The industry team should designate one member (person with best vision) to be firmly in charge.
  - Represents the team to the government
  - Maintains the program vision
* The entire team must be committed to the agreement goals.
* The selection of partners or team members is critical to the success of an OT.

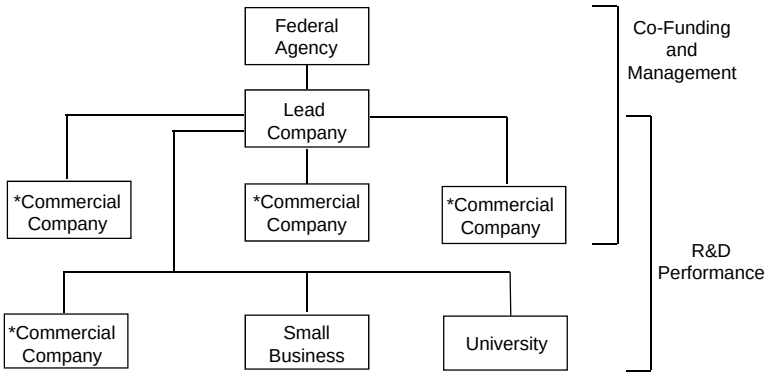
56

# Lessons Learned (continued)

* Having too many contractors on the industry team can be problematic.
* Because OTs offer significant flexibility, it is critical for the government to assign qualified personnel and to train the administrators.
* Careful construction of the OT agreement can help ensure a successful partnership between government and industry.

57

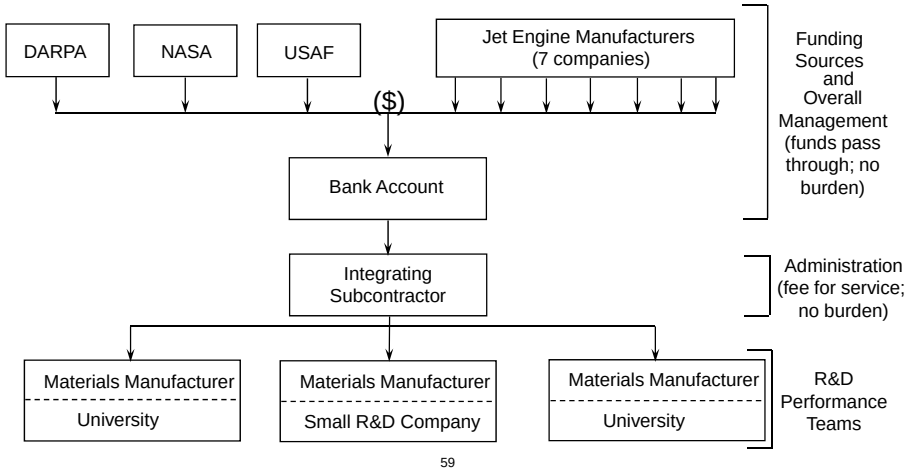
# OT for Investment (OTFI) Agreement Example




58

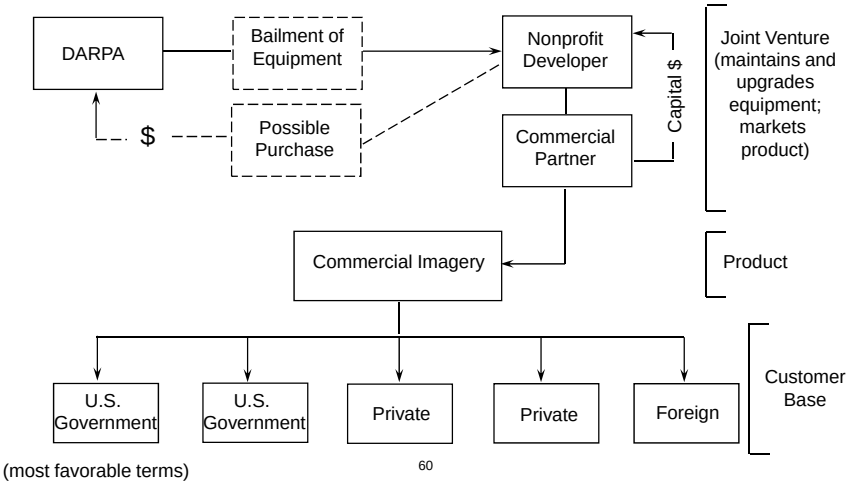
E

# OTFI Joint Funding Agreement Example




59

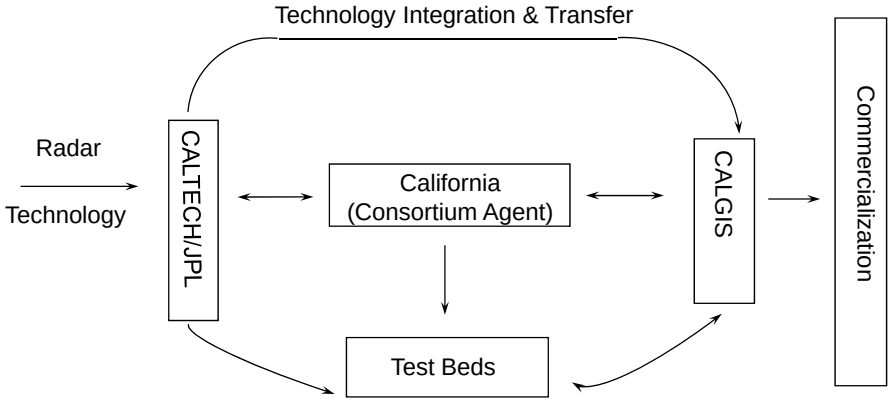
# OT Commercialization Example




60

## OTFI Dual-Frequency, Foliage Penetrating Interferometric GeoSAR System Example

- GeoSAR: Geographic Synthetic Aperture Radar
- CALTECH/JPL, California Department of Conservation, CALGIS, Inc.
- $33 Million, 42 Months

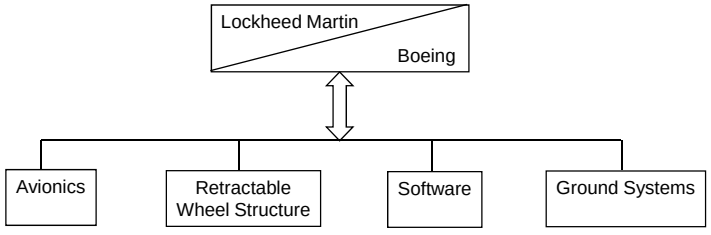



61

## OT Team Partnership Example

Teams share 50/50—

* Revenue
* Fees
* Cost and technical risks




62

E

# Key Points

* True teams are encouraged.
  - Not prime contractors and subcontractors
  - Saves money
* Team leadership may change during program.
* Teams must be legally responsible to execute agreements, but joint ventures are neither desired nor required.
* Let's look at a sample OT agreement.
* Case material
  - Two groups

63

# Breakout Questions Group 1

1. Why are we using the OT authority?
2. What are the limitations for using OTs?
3. What happens when proposals are evaluated against each authority's limitations and do not meet the criteria?
4. When does government approve use of the OT authority?

64

# Breakout Questions
# Group 2

1. Name four advantages for teaming under OT agreements.
2. How can the OTAO ensure the parties are committed to each another?
3. Name four important elements to a successful team.

65

# BREAK

E

## Introduction to Planning and Strategy

* Plan how to leverage NRP activities with government R&D investments.
* Plan how to transition OT relationships.
* Plan how to get everyone involved early—OTAOs, users, technical personnel, legal counsel, and industry.

67

## Legal Authority for the Use of NIH's OTs

* Over the years, there have been several examples of specific OT authorities that exist, or have existed, for NIH or for s specific institute, center, or office (ICOs) in U.S. public law.
* It is important to note that authorities may expire, be revised, or be repealed, and must be accompanied by a Congressional appropriation of funding for that purpose.

68

# Government Use Products

Government products are not important to industry.

* Attracting NRPs to participate in OT programs requires innovative approaches.
* Government must seek opportunities and partners
  - Advertise in trade journals, because nontraditional government contractors might not read Federal Business Opportunities (FedBizOpps) or Grants.gov.
  - Host "Industry Days" to brief potential offerors on program goals and provide opportunities to discuss programs.
  - When speaking at symposium or like meetings mention your upcoming "solicitation" and introduce your needs

69

# Government's Role in Industry Partnering

* Help promote successful OT NRP-led consortium/team.
  - Suggest or refer contractors to one another, with view toward optimizing consortium.
  - Especially important when a team consists of entities that have not previously considered working together.
  - Create Internet-based collaboration tools with which a contractor can find partnership opportunities without exposing its proprietary information beforehand.
* At the onset of the planning stage, encourage potential consortium members to create Articles of Collaboration/Teaming Agreement.

70

# Government's Role in Planning and Strategy

* Conduct market research; consider nature of competition for related industry.
* Assess risks of project.
* Develop program structure and schedule.
* Consider strategy for follow-on activity.
* Allow time for proposal preparations.
* Consider the appropriate OT terms.
  - See Tab M, Model OT.

71

# Industry's Role in Planning and Strategy

After draft solicitation has been issued and/or Industry Day has been held, industry should—

* Be involved early in team organization: identify teaming barriers.
* Identify requirements barriers: what the government needs versus what the government wants.
* Point out any preconceived notions of government plans or strategies that preclude dual-use solutions.

72

# Broad Agency Announcement

* Since there is no detailed common work description, proposals can vary widely in scope, structure, and cost; competition is on which idea offers the best solution.
* BAAs are particularly suited to NRPs who wish to submit proposals but do not want to agree to all of the perceived impediments prescribed in the FAR and its supplements.
* If OTs are to be encouraged, the BAA should discuss their OTs' Limitations of Use.

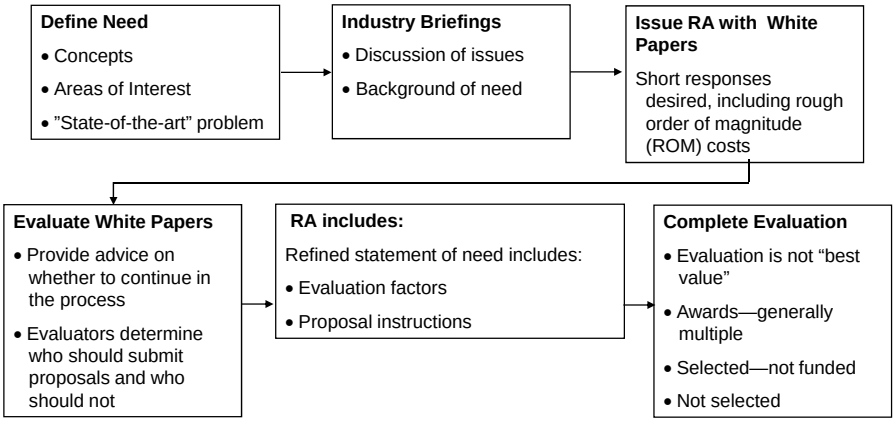
73

# Research Announcements

* Research Announcements (RAs) are the most popular solicitation method for OTs focusing on research.
* They are the same as BAAs in form, structure, and content, but unlike BAAs they are specific to nonprocurement instruments.
* They broadly describe R&D problems to which the government is seeking solutions.

74

# RA Process




75

# Peer Review

* Current peer review regulations (42 CFR Part 52h) and the Public Health Service Act [as enacted in section 492 (42 U.S.C. 289a)] apply specifically to grants (and by definition, cooperative agreements), as well as contracts.
* While these authorities do not apply directly to OT awards, historically some NIH OT authorities have required some level of peer review to occur.
* Consultation with the NIH Legal Advisor's Office is recommended to determine whether and to what extent peer review requirements apply to a particular proposed OT program.

76

# OT Phased Program (OTPP)'s Written Solicitation Process

* Industry briefing
* Plain-worded Program Solicitation
  - Program, including all phases, money, schedule, and management processes (government's acquisition strategy)
  - Draft agreement, including draft Task Description Document (TDD), Statement of Work (SOW), and payable milestones
* Ask industry to design "its program."
* See Tab P, Sample Program Solicitation (Counter MANPADS Phase II).

77

# OTPP's Approach for Multiphase Programs

* Prototype delivery at end of each phase (but agreements are for duration of program).
* Solicitation, evaluation, and selection during Phase I are focused on entire program [but negotiated terms and conditions (Ts & Cs) are based on only the phase the program is entering].
* Phase 1 of an OT for a complex project should be long enough to ensure effective innovation.

78

# OTPP's Approach for Multiphase Programs (continued)

* Each industry team proposes—
  - SOW
  - Milestone payments
  - Exit criteria
  - Ts & Cs
  - Resources industry needs to achieve "its program"

79

# OTPP's Approach for Multiphase Programs (continued)

* Innovations in business practices are seen in:
  - Team structure
  - Risk management
  - Focus on affordability
  - Sharing of programmatic information
  - Documentation

80

# OTPP's Approach for Multiphase Programs (continued)

* Programmatic approach
  - Programs are designed to have no break in performance between phases.
  - Team ability to "quit" is restricted when competition is no longer effective.
  - Insight versus oversight, performed by small government Program/Scientist Staff during all phases

81

# Comparison of OTPPs Program Phases

| **Phase I: Design Concepts** | **Phase II: Design Concepts** | **Phase III: Fabrication and Testing of Prototypes** |
|---|---|---|
| • Performance based (i.e., very few requirements)<br>• Government needs<br>• "Blank sheet of paper" approach<br>• Trade studies under control of industry<br>• Simple Ts & Cs; limited or no IP; commitment for other phases<br>• SOW written by industry | • Performance based (i.e., very few requirements)<br>• Government needs<br>• Detailed design and risk reduction<br>• Simple Ts & Cs; added complexity; limited IP/focused on maintenance and support<br>• SOW written by industry as follow-up to previous work | • Agreed-to performance specifications, with detailed specifications incorporated as appropriate<br>• Complex Ts & Cs; possibly many FAR clauses |

E

# Comparison of OTPPs Program Phases (continued)

| Phase I: Design Concepts | Phase II: Design Concepts | Phase III: Fabrication and Testing of Prototypes |
|---|---|---|
| • Type of agreement: Fixed-price; exit criteria and payable milestones by industry<br>• No Changes clause<br>• Competition unlimited<br>• Awards to four or five teams | • Type of agreement: Fixed price; exit criteria and payable milestones by industry<br>• No Changes clause<br>• Competition limited to Phase I agreement-holders<br>• Awards to two or more teams | • Type of agreement: Fixed-price-incentive (FPI)/CPIF or fixed-price<br>• Changes clause inserted<br>• Competition involves selection of remaining agreement holders<br>• Award normally to one contractor |

# Comparison of OTPPs Program Phases (continued)

| Phase I: Design Concepts | Phase II: Design Concepts | Phase III: Fabrication and Testing of Prototypes |
|---|---|---|
| • Cost sharing possible<br>• Solicitation covers entire program, but selection and awards are for Phase I only | • Cost sharing possible but not likely<br>• Solicitation covers remaining program; selection and awards are for Phase II only | • Cost sharing not expected nor reasonable<br>• Solicitation covers remaining program |

# OTPPs Program Source Selection Process (continued)

* Evaluation: Various methods include color, number, and adjective.
* Big change from traditional contracting is documentation.
  - Selection Evaluation Board (SEB) briefing to Selection Authority becomes sole documentation of technical, cost, and management deliberations.
  - Use documentation to brief winners and unsuccessful offerors.
* Lessons Learned
  - Online review of proposals has facilitated source selection review process.
  - Encourage winners to concentrate on entire program rather than only on weaknesses in phase that was evaluated.

85

# OT Phased Program Practical Matters

* In early phases—
  - Ts & Cs are simpler
  - Total amount of government total funds generally is known
* Ts & Cs in later phases are subject to discussion by parties
* Rules of engagement: how government acts during competitive phases
* Disputes
  - While Contract Disputes statute does not apply to OTs, resolution of disputes at lowest possible level is encouraged.
  - Several existing OT agreements have dispute language that captures this approach.

86

# Lessons Learned for OTPPs

* Beginning the negotiation of terms and conditions in advance of the source selection decision can save time.
  - May be possible when there are limited offerors
    - E.g., when moving from Phase 1 to Phase 2 in a competitive program
* When seeking proposals for an OT, it is important to allow as much response time as practicable.

87

# Lessons Learned for OTPPs (continued)

* Generally applicable terms and conditions should be developed in advance for use as a starting point when drafting OT agreements.
* A library of negotiated provisions also can save time.
* See OTAO's Desktop Guide for Construction of OT's.

88

# Lessons Learned for OTPPs (continued)

Debriefing—OT awardees should be encouraged to focus on both positive and negative information provided during their debriefing to prepare them for competition for later phases.

89

# Comparison of R&D Solicitation Types

| Solicitation | Award | Type | Recipient | Requirement |
|---|---|---|---|---|
| Request for Proposals (RFP)/ Request for Quotations (RFQ) | Procurement contract | Cost-based pricing | Any organization | Government-defined, common SOW if RFP |
| BAA/RA | Procurement contract, grant, CA, or OT | Cost-type or milestone payments | Traditional government contractor, consortium, or nontraditional firm | Broad, scientific problem for which solution is expected to be generated |
| Program Solicitation | OTFPP | Cost plus fixed fee (CPFF), cost plus incentive fee (CPIF), milestone payments | Typically consortium or government contractor (including nontraditional government contractors) | Few or no requirements; broad government goals; contractor solutions through technical, schedule, and cost tradeoffs |

90

# Questions

*Break

91

# Expenditure/Cost-Sharing Concept

There should be evidence in industry's management plan of its commitment to and self-interest in the project's technical success.

* Reduces the need for government oversight
* Reflected in resource-share proposals

92

# Statutory Requirement

* Cost sharing is an option as an administrative requirement, unless the authorizing legislation for the particular OT program specifies otherwise.
* When the potential awardee willingly offers cost sharing, or when the government requires it for a specific project, the NIH OTAO must include it in the negotiated agreement.
* Pre-agreement cost sharing may not be included for costs incurred before the date on which the OT agreement becomes effective unless the OTAO approves in writing.

93

# Cost-Sharing Guidance

Recipient's commitment and cost sharing

* Strong evidence of commitment
  - Proven self-interest
  - One form—meaningful cost share
* Cost share
  - Should equal the government's contribution
  - As practicable

94

# Types of Cost Sharing

* Cash—Outlays of funds to support the total project
* In-Kind—Reasonable value of equipment, materials, or other property used in performance of the work

95

# Components and Sources of Cash

* Components of cash
  - Labor
    - Benefits
    - Direct overhead
  - Materials expenses
* Sources of cash
  - Independent research and development (IR&D) pool
  - Profit or fee from another government contract
  - Overhead or capital equipment expense pool

96

# Sharing Within the Team

* Cost sharing does not need to be uniformly imposed on industry team members.
* The team or consortium, as a single entity, meets the set cost share.

97

# Tips for Success

* Cost sharing should be straightforward and clear.
* The proposer's specific SOW should dictate the costs.
* The goal is cost-sharing, not cost-matching.

98

# Constraints

Cannot use:

* Foregone profit/fee and Cost of money
* Federal from other programs
* Cost of prior research
  - Exception: Value of prior research to the current project is relevant and brings value to the effort.

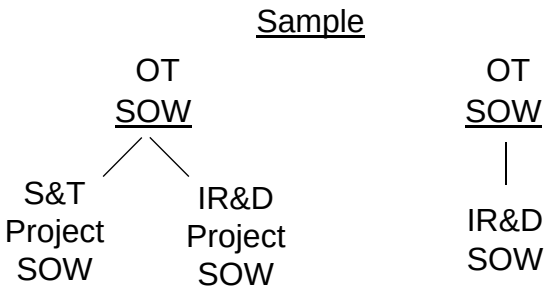
99

# IR&D Implications

* Traditional government contractors: FAR 31.205-18(e) authorizes commingling of IR&D money in OTs
* Commercial industry's internal R&D: a portion of sales is reinvested in new technology
* In both cases, these investments are:
  - Under the sole discretion of industry
  - Considered the lifeblood of corporate future
  - A source of intellectual assets

100

# IR&D Examples, Cost Treatment




101

# IR&D Examples, IR&D Split Example—OT SOW

**IR&D Project**

| | |
|---|---|
| Direct Labor | $100 |
| Direct Material | $100 |
| Other Direct Costs | $100 |
| Subtotal | $300 |
| Overhead (100%) | $300 |
| Total Costs | $600 |

**S&T Project—Contracted Research**

| | |
|---|---|
| Direct Labor | $100 |
| Direct Material | $100 |
| Other Direct Costs | $100 |
| Subtotal | $300 |
| Overhead (100%) | $300 |
| Direct Costs | $600 |
| Gen. & Admin. (25%) | $150 |
| Subtotal | $750 |

*Profit/fee/cost of money also could be added*

102

E

# IR&D Responsibilities

* The OTAO has a responsibility to request the awardee disclose how it intends to treat the government cost share of the agreement.
* If the awardee is using IR&D as cost share and government-provided funds as direct effort, the OTOTAO should notify the cognizant administrative contracting officer (ACO).
* The ACO would determine the next required steps to address noncompliance with CAS 402.

103

# Lessons Learned—Leverage from IR&D

Significant leverage can be gained by allowing competing contractors to treat the program as an externally funded IR&D activity.

* Under this accounting technique, direct labor need not be burdened with general and administrative (G&A), cost of money, or fee, thus reducing hourly rates and increasing hours applied across the team.
* Under OT authority, companies also may contribute discretionary funds directly to program.

104

# Components of In-Kind

* Equipment/space/land
  - Central to the project
  - Fair market value: burden of proof is with industry
* Intellectual Property (IP)
  - Central to the project
  - Fair market value: burden of proof is with industry

105

# Evaluation of In-Kind

* Is it necessary to the overall statement of work?
* Is it under the control of project management?
* Is it the only source?
* How is it valued? (Is it reasonable?)

106

# Lessons Learned

## In-kind Contributions

* Knowledgeable about—
  - Availability
  - Timeliness
  - Control of resources
* Document the file
  - What has been accepted
  - The method of determining the value of in-kind contributions

107

# Lessons Learned (continued)

* Cost-sharing is possible for any OT: the contributions must be closely evaluated to ensure their acceptability.

108

# Cost Sharing Case

* Tab S , page 493

109

# Introduction to Pricing and Payments

* Commercial industry is concerned about traditional government forms of contract pricing and payments.
  - Fixed-price or level-of-effort arrangements are normal commercial practice.
  - Government's firm-fixed-price (FFP) research contract approach generates significant risks for industry.
* Need to establish new relationship with industry.
* Three primary payable milestone options:
  - Fixed
  - Adjustable (cost reimbursable)
  - Hybrid approach (combines other two options)

110

E

## Introduction to Payable Milestones

* Payable milestones mark **observable technical achievements or events** that assist in program management and focus on the agreement's end goal.
  - Recognition of completion by the government Technical Program Manager includes value of effort.
  - Substantial compliance is accepted.
* Payable milestones are **a method of paying the government's commitment to the agreement,** and any **cost share**.
* Each milestone should be evaluated using "just enough" analysis.

111

## Types of Payable Milestones

* Adjustable (cost-type) milestones
  - Change retrospectively and prospectively based on experience
  - Expenditure data must be known
* Fixed-payable milestones
  - Change prospectively only
  - Expenditure details are unknown

112

## Types of Payable Milestones (continued)

* Characteristics of adjustable (cost-type) payable milestones
  - Duration, schedule, and tasks are adjusted on the basis of mutual agreement.
  - Adjustments **can** be made at any time.
  - Milestone technical accomplishments are based on "best efforts."
  - At the end of the agreement, either continue technical performance until both parties' funds are exhausted or return remaining government funds.
  - Most OT guide discussion is about this type of payments.

113

## Adjustable Payable Milestones

* "Amounts generated from the awardee's financial or cost records as the basis for payment." Examples:
  - Progress payments
  - Cost reimbursement
* Must have adequate records to account for federal funds received and cost-sharing, if any
* Must have an accounting and management system that identifies and accumulates the amounts/costs to individual agreements
  - Any system that segregates direct costs from indirect costs, identifies and accumulates direct costs by project, and provides for an equitable and consistent allocation of indirect costs to intermediate and final cost objectives is acceptable. [114]

# Audits

* Flowdown: The awardee must insert an appropriate audit access clause in awards to key participants.
* Frequency of Audits: Normally performed only when necessary to verify awardee compliance with the terms of the agreement.
* Indirect Cost Rate Agreements: NIH Division of Financial Advisory Services (DFAS) within OAMP, or the cognizant audit group, should establish negotiated indirect cost rates.
* The provisions of the Single Audit Amendments Act of 1996 (31 U.S.C. 7501 *et seq.*) should be followed when the awardee is a state government, local government, or nonprofit organization, as applicable.

115

# Types of Payable Milestones (continued)

* Characteristics of fixed-payable milestones:
  - Represent a series of fixed payments that are initially negotiated; may be changed prospectively if the situation warrants.
  - Each milestone has an established value to the buyer.
  - Each milestone represents progress toward program completion.
  - Once a milestone has been accepted and paid, it is no longer subject to any termination provisions.
  - Milestones are not subject to retroactive adjustment.

116

# How Do We Establish Payable Milestones?

* NIH OTAOs must determine the agreement amount as "price is fair."
  - Use independent government cost estimates spread over life of the agreement.
    - Is it reasonable? Current? Considering NRPs?
  - Competition
  - Consider each acceptable offeror's expenditure profile or other than cost data.
* Establish milestones that are key activities/events.
  - Assign dollar values that approximates effort to get to events.
  - Adjust if cost sharing is present.

117

# Relationship Between Payment Types and Audits

| Type of Payment | Characteristics of Payment | Accounting Principles | Audit Requirements | Auditors |
|---|---|---|---|---|
| Fixed-Price Payable Milestones | Prenegotiated, fixed-price milestone payments are not adjusted based on actual amounts generated from industry team's financial or cost records. | None | None | None |

E

# Relationship Between Payment Types and Audits (continued)

| Type of Payment | Characteristics of Payment | Accounting Principles | Audit Requirements | Auditors |
|---|---|---|---|---|
| Cost-Type Payable Milestones | Prenegotiated cost-type milestone payments may be adjusted based on actual amounts generated from industry team's cost records. | For traditional government contractors, FAR parts 30 and 31 apply.<br>For nontraditional contractors, principles are defined in agreement. | Required<br>• Requirements based on type of recipient<br>• Single audit for not-for-profits/ education<br>• Traditional audit for government contractors<br>• For nontraditional government contractors, to be negotiated | Independent public accountant (IPA) or DCAA, whichever meets needs of both parties |

119

# Relationship Between Payment Types and Audits (continued)

| Type of Payment | Characteristics of Payment | Accounting Principles | Audit Requirements | Auditors |
|---|---|---|---|---|
| Cost Reimbursement/ Fixed Fee/ Incentive Fee/ Award Fee | Payments of allowable costs incurred in performance of agreement | For traditional government contractors, FAR parts 30 and 31 apply.<br>For nontraditional contractors, principles are defined in agreement. | Annual review of indirect rates and close-out audit after completion of agreement efforts | IPA or DCAA, whichever meets needs of both parties |
| Level of Effort | Prenegotiated payments based on loaded hourly rates | None | Review of actual time consumed | IPA or DCAA, whichever meets needs of both parties |

120

# Lessons Learned

* Watch use of the term "best efforts" (cost type).
* Fixed-payable milestones encourage post-award administration without cost and pricing data; labor hours can be projected and expended.
* The agreed-upon payment arrangement must be specified clearly and accurately in the agreement.

121

# Lessons Learned (continued)

* Consider the following in drafting the agreement payment clauses:
  - Are payments based on amounts generated from the awardee's financial or cost records?
  - Are the payment amounts subject to adjustment during the period of performance?
  - If the payments can be adjusted, what is the basis and process for the adjustment?
  - What are the conditions and procedures for final payment and agreement close-out?
  - Is an interim or final audit of costs needed?

122

# Lessons Learned (continued)

* Agreement must identify type of payment structure selected.
  - Agreement Ts & Cs must be consistent with identified payment structure.
  - Milestones and exit criteria
    - All milestones must have associated dollars and dates.
    - Exit criteria should be reasonable to preclude unnecessary technical and business risks.
  - Audits and oversight have their role in OTs but should not be allowed to undermine the collaborative nature of these agreements.

123

# Case 1 of 5 –OT Payable Milestones

* How do you…
  - Establish fixed-payable milestones?
  - Treat the milestones during performance of the agreement?

124

# Case 1 Payable Milestones—OT Example (continued)

* Sample fixed-price payable milestones
  - Selected offeror's proposal value: $500,000
  - First phase of multiple-phase program

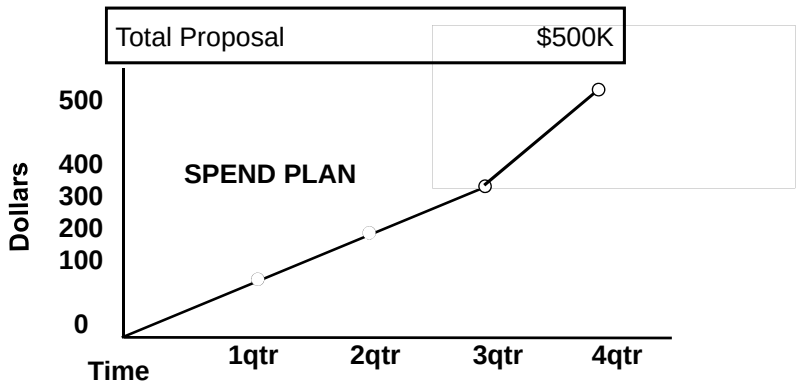
125

# Case 1 Payable Milestones—OT Example (continued)

* Fixed-payable milestone descriptions below are to be delivered quarterly except for the first milestone, which will be accomplished in month 1:
  1. Kick-off meeting, First Interim Program Review (IPR)
  2. Second IPR and laboratory testing
  3. Interoperability demonstration
  4. Present testing and demonstration report
* Are these good enough for fixed-payable milestones?
  - What is missing?
* Next chart was provided by offeror: does it help determine the fixed-payable milestone amount?

126

# Case 1 Payable Milestones— OT Example (continued)




127

# Case 2 Payable Milestones— OT Example

* How do I...
  - Establish payable milestones under an OTFR?
    - Relationship to projections
    - Relationship to program completion
  - Treat the milestones during performance of the agreement?

128

# Case 2 Payable Milestones—OTFR Example (continued)

* Sample fixed-payable milestones
  - Selected offeror's proposal value: $500,000
  - Requesting $250,000 from government
  - First phase of multiple-phase program

129

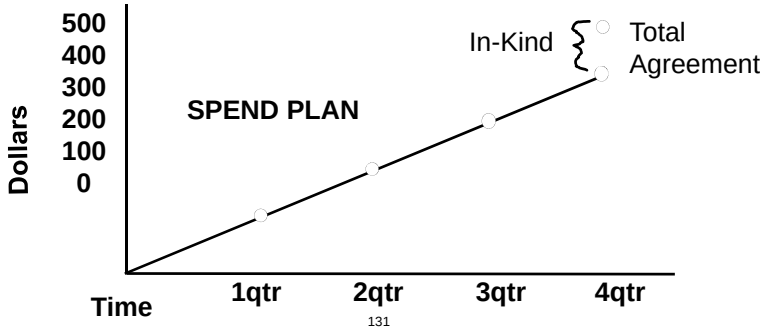
# Case 2 Payable Milestones—OT Example (continued)

* Fixed-payable milestone descriptions below will be accomplished quarterly except for the first milestone, which will be accomplished in month 1:
  1. Kick-off meeting, Interim Program Review (IPR) 1
  2. IPR 2
  3. Draft final report
  4. Delivery of technical designs
* Are these good enough for cost-type payable milestones?
  - What is missing?
* Next chart was provided by offeror: What should be the fixed-price payable milestone amounts?

130

# Case 2 Payable Milestones—OT Example (continued)

| | |
|---|---|
| Total Proposal | $500K |
| Total Estimated Cash Expenditure | $400K |
| In-Kind [IPR] | $100K |
| Government Cash Share | $250K |
| Consortium Cash Share | $150K |




131

# Case 3 Payable Milestones Example

* What is the impact on (1) adjustable payable milestones and (2) fixed-payable milestones, during performance of the agreement, for the situations described below?
  - First milestone value = $62,500
    - The business report says the total expenditure is $90,000.
  - First milestone value = $62,500
    - The business report says the total expenditure is $130,000.

132

# Case 4 Breakout Questions

* When are OTs used?
* How does the type of recipient matter?
* Why would for-profit firms want to get an OT ? Profit or fee?
* Read Case 4 and identify the circumstances under which an OT would be appropriate, developing your answer as a group.

133

# Case 4

**Statement of Work**

The U.S. Army wishes to increase its technical strength through the infusion of external technology solutions (i.e., "spin-in" of outside technologies into the U.S. Army).

This can be done through effective and efficient partnerships with the commercial/industrial/academic/federal sectors. Partnerships are desired in countermeasures to biological agent attacks from five agents to be determined at a later date.

The recipient shall perform studies and analyses as necessary to improve the U.S. Army's countermeasure knowledge base.

134

# Case 5 Breakout Questions

* Using Case 2's information, answer the following questions
  - A small nontraditional contractor has requested a milestone for 25% of the total agreement at the beginning of performance: is that reasonable?
  - If reasonable, what should the payable milestone amount be for a fixed-payable OT?
* How much pricing information does the government need to determine price reasonableness?

135

# *BREAK

136

# Case 1 - Fixed-Payable Milestones Answer

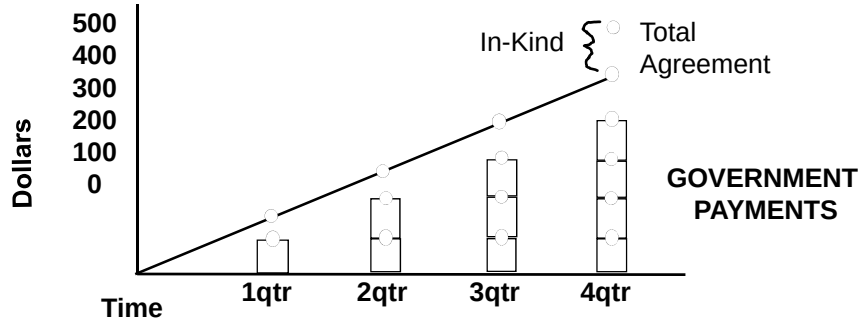
* With the technical support from your PM, the OTAO should determine the value to achieve each milestone and its impact on the completion of the overall SOW.
* If possible, independent government cost estimates by milestone can be used as a price comparison tool.

137

# Case 2 Solution

| Milestone | Government |
|---|---|
| 1. | 62.5 |
| 2. | 62.5 |
| 3. | 62.5 |
| 4. | 62.5 |
| | 250.0 |

| | |
|---|---|
| Total Proposal | $500K |
| Total Estimated Cash Expenditure | $400K |
| In-Kind [IPR] | $100K |
| Government Cash Share | $250K |
| Consortium Cash Share | $150K |




138

E

# Relationship Between Payment Types and Audits

| Type of Payment | Characteristics of Payment | Accounting Principles | Audit Requirements | Auditors |
|---|---|---|---|---|
| Fixed-Support Payable Milestones | Prenegotiated fixed-support milestone payments are not adjusted based on actual amounts generated from industry team's financial or cost records. | None | None | None |

139

# Relationship Between Payment Types and Audits (continued)

| Type of Payment | Characteristics of Payment | Accounting Principles | Audit Requirements | Auditors |
|---|---|---|---|---|
| Cost-Based Payable Milestones | Pre-negotiated, expenditure-based milestone payments<br>May be adjusted based on actual amounts generated from industry team's cost records | For traditional government contractors, FAR parts 30 and 31 apply.<br>For nontraditional contractors, principles are defined in agreement. | • Requirements based on type of recipient<br>• Single audit for nonprofits/ education<br>• Traditional audit for government contractors<br>• For nontraditional government contractors, to be negotiated | Independent public accountant (IPA) or DCAA, whichever meets needs of both parties |

140

# IP in OTs

* Bayh-Dole Act does not apply: flexibility in allocation of rights
* Contractor/government will negotiate appropriate IP rights
  - May waive government license for a period of years
  - Allow protection of materials as trade secrets
  - The "contract" file should document the rationale behind changes to the standard going-in position
* Identify the data you want delivered and ask for only that; then define the license rights you need and negotiate a reasonable deal.

141

# IP in OTs (continued)

* Cost savings are possible by limiting the government's need for data license rights in OTs.
* The government's need for data and license rights changes based on program phases: when many competitors exist, the need for data rights is reduced.

142

# IP in OTs (continued)

* OTA staff should assess the impact of IP rights on the government's total life cycle cost of the research.
* Obtaining insufficient IP rights hinders the government's ability to adapt the developed research for use outside the initial scope of the project.
* While the obtaining excessive IP rights might come at great cost, with little benefit
* The negotiated IP clauses should facilitate the agreement's strategy and balance the relative investments and risks borne by the parties.

143

# IP in OTs (continued)

* OTA staff should ensure that the Termination and Disputes clauses included in the agreement can accommodate specialized termination and disputes arising under the IP clauses, such as—
  - Continued validity of the exercise of IP "march-in rights"
  - Restrictions on technical data, computer software, or other rights provided to the government
* OTA staff should consider how the IP clauses applicable to the awardee flow down to others, including whether to allow others to submit any applicable IP licenses directly to the government.

144

# IP in OTs (continued)

* OTA staff should consider impact of restricting awardees from licensing research developed under the agreement; i.e., whether restriction—
  - Would hinder potential domestic manufacture or use of the research
  - Facilitates the commercial development or research use of products or services that will benefit public health
* The Agreements Officer must also be aware that export restrictions prohibit awardees from disclosing or licensing certain research to foreign firms.

145

# IP Lessons Learned

* FAR-based solicitations lack flexibility to attract nontraditional contractors and to encourage innovative terms and conditions.
  - Make flexibility known in solicitations for OT agreements.
  - Write your own provisions, or leave it to industry.
* Know what you want and ask for only that.
* Flexible treatment of IP under an OT represents a cultural challenge for traditional government contractors and government.

146

# Lessons Learned (continued)

* If mixed funding is involved (or the IP was developed during prior work), the government must be clear in what its license rights are for each deliverable.
* Ensure the agreement describes marking instructions for deliverables.
* The OT must be clear on how to handle sensitive/ proprietary commercial or business information.

147

# Negotiation Factors

* Allocation of rights may depend on the science or technology.
* Know the standard rights in industry.
* Take into account contractor investment through both cost-sharing and previous investments.
* Always keep in mind the goals of both the awardee and the government set out in the vision statement and commercialization plan.
* Remember that there are no standard approaches.
* As early as possible in the negotiation process, obtain the assistance of the NIH Legal Advisor's office, the appropriate technology transfer office representative, or the OPERA Division of Extramural Inventions and Technology Resources, as appropriate.

148

# Agreement Clauses

* Let's review the Patents and Data Clauses in the OTAO Desktop Guide, Part L

149

# Conclusion

* IP is very important to industry and will be the most hotly negotiated issue when developing an OT agreement.
* Both the government and contractors must take time to consider and plan their IP positions.
* One great advantage of OTs is flexibility in the negotiation of "win/win" IP provisions.

150

# Agreement Analysis (AA)

The AA must "tell the complete story" of why an OT is needed and the results of its use, including—

* A clear statement regarding reason(s) for use of OT authority
* A discussion of the selection process
* A description of the project background
* A discussion of the type of pricing arrangement (fixed-payments versus adjustable payments)
* The government price analysis of elements of the price proposal and fees/profits, Including written technical input, which should answer the following questions:
  - Why is this "fair", and to what is it comparable?
  - How did you arrive at the negotiated cost/price?

151

# Agreement Analysis (continued)

The AA must include (continued)—

* A discussion of each agreement article, what was negotiated, and why, including:
  - Security issues and controls, if any
  - Data ascension lists, if any

152

# Agreement Analysis (continued)

The discussion should address:

* Pre-agreement costs if applicable
* Cost sharing: contributions by each member of consortium
* Suspended and debarred

153

# Agreement File

* Filing should be in a logical order, with a cover sheet in front of each section stating the location of documents, and tabbed for ease of locating documents.
* File organization should be consistent with office standard operating procedures.

154

# Agreement File (continued)

* The file should contain:
  - The PM's review and approval of the data ascension lists; all appropriate documents must be signed
  - Significant documentation (e.g., technical evaluations of cost elements)
  - Copies of the invoices and reports

155

# Agreement File (continued)

* Original signatures should be on the following documents, at a minimum:
  - AA
  - Technical Program Manager responsibilities letter
  - Technical Evaluations
  - Source Selection Memorandum
  - Memorandum for the Record (MFR)

156

# Post Award Administration

* This part is a possible standalone training module focused at Post Award Administration.
* The two key government representatives in OT administration is the OTAO and the Other Transaction Technical Representative (OTR).

157

# Administrative OTAO Responsibilities

* OT agreements should be administered directly by the OTAO or by a well-trained administration group that understands OTs.
* If a new OTAO is assigned, the new OTAO must—
  - Receive all pertinent documentation to ensure effective administration of the agreement.
  - Ensure all Ts & Cs of the agreement are being satisfied.
  - If the OT awardee has failed to comply with any term of the agreement, take timely, appropriate action to remedy the situation.

158

# Administrative OTAO Responsibilities (Continued)

* Programs with OT authority are not required to use most financial assistance provisions or *Federal Acquisition Regulation* (FAR) clauses but are free to negotiate provisions that are mutually acceptable to all affected parties.
* OTR must know the agreement, because each one *could* be different.
  - Many federal agencies incorporate the proposal into the agreement that includes the unique technical scope, duration, and funding.

# Preaward Business Evaluation

* In the preaward business evaluation, the OTAO has determined:
  - Recipient qualification
  - Management capability and financial and technical resources
  - Satisfactory record of performance
  - Integrity and ethics
  - Eligibility under applicable laws
* The evaluation should address the financial aspects of the proposal, including:
  - Determining that the total amount of funding for the proposed effort is reasonable
  - Justifying the use of a fixed support instrument, if applicable
  - Determining amounts for milestone payments, if used

# Pre-Award Business Evaluation

(Continued)

* In the preaward business process, the OTAO—
  - Has assessed the value and reasonableness of the recipient's proposed cost share, if any
  - Has assessed the team (partnership, consortium) construction and plans
  - Understands the scope of the agreement, as well as all key terms and conditions, and is prepared to discuss any questions you may have

# Resource Sharing

* There should be evidence in industry's "letter of commitment" in the proposal and management plan of its commitment to and self-interest in the success of the project.
  - Strong commitment and self-interest in the project's technical success—
    - Reduces need for government oversight
    - Is reflected in resource share proposals
* Resource sharing does not need to be uniformly imposed on team members.
  - The consortium meets the set resource share.

# Articles of Collaboration/ Teaming Agreement

The articles of collaboration or teaming agreement is the document that sets out the rights and responsibilities of each consortium member.

* Binds the individual consortium members together, whereas the OT agreement binds the government and the consortium as a group (or the government and a consortium member on behalf of the consortium
* OTR should look for:
  - Management structure/plan
  - Method of making payments to consortium members
  - Means of ensuring and overseeing members' efforts on the project
  - Provisions for members' cost sharing contributions
  - Provisions for ownership and rights in IP developed previously or under the agreement

# Teaming: Unique Post-Award Advantages for the Government

* The government (through the OTR) is a member of the team.
  - If a teaming agreement is not available, determine team characteristics at the kick-off meeting.
  - Help guide the team to joint government /industry goals.
    - Timing is not specific
    - As you deem necessary
* Technical insight: visibility at all levels
* Decreased oversight requirements by self-policing

# IP in OTs

* The Bayh-Dole Act does not apply.
  - Flexibility in allocation of rights
* Traditional data rights terms do not apply.
* The consortium/government have negotiated appropriate IP rights; e.g.,—
  - May waive government license for a period of years
  - Allow protection of materials as trade secrets
* The OTR should be aware of what data deliverables are required and what license rights the government has.

# OTR Letter of Appointment

* OTAO should issue an appointment letter to those technical individuals responsible for providing insight into the actions of the agreement holder.
* These letters should be filed and available upon request.

# Monitoring Performance

* Monitoring performance is the process of checking by direct observation.
  - This is done through insight gathered as a teammate through team meetings and monthly status updates and quarterly reports
  - Conduct site visits and/or attend team meetings. The kick-off meeting is mandatory for discussing key aspects of the team and its plans.
* The OTR assists the consortium to ensure delivery is—
  - On time
  - At the quality level specified
  - In adherence to the terms and conditions of the agreement

# Monitoring Performance (Continued)

* Provide technical insight or guidance to the consortium or its members, as needed.
  - Remind the recipient that your suggestion was given for guidance only.
  - Remember, you are part of a team.
* The OTR shall discuss any decrease in or lack of performance with the consortium to resolve issues.
  - If problems continue, bring them to the attention of the OTAO or agreement administrator/specialist.

## Monitoring Performance (Continued)

* The OTR's actions as a teammate of the consortium include:
  - Helping to identify potential delinquencies
  - Helping to isolate specific quality problems
  - Supporting recipient requests
  - Pointing out a need for government assistance

## Monitoring Effort

* Adjustable (Cost) Type Payments
  - Adjustable (Cost) Type Payments sometime creates variances in quarterly accounting
  - OTRs instructed to follow activities that have variances from one quarter to another and to treat these in the context of total project costs and remaining un-invoiced and with communication with consortium about concluding within current project totals
* Using Fixed Price Type OTs
  - Removes difficulties of tracking cost variance
    - Cost variance to be reviewed as a submitted cost modification
    - OTRs to recommend, PMs to seek leadership approval
  - Removes the OTR's review of quarterly finances

# Monitoring Effort and Payments

* Additional major OTR responsibility is reviewing and evaluation of the consortium's expended effort in relation to meeting the payable milestones schedule and approving payment requests. These two topics are separated for clarity.
* Monitoring Effort Actions:
  - Review the Quarterly Business Status Reports for consistency with the Technical and Deliverable Milestone Schedule (Attachment # 3) to the agreement
  - Determine whether the consortium is expending effort in accordance with the project

# Monitoring Effort (Continued)

* Bring to the OTAO's attention any inefficient or wasteful methods being used by the recipient. Make recommendations for corrective action or preventive measures as appropriate

## Monitoring Payments

* OTR's will approve payable milestone payments per the schedule after completion of the observable technical events as described in the agreement
  - *Payable milestones* mark observable technical achievements or events that assist in program management and focus on the end goal of the agreement
    - Recognition of completion by the government OTR
    - Substantial compliance is accepted
    - Payable milestones are a method of paying the

## Fixed Price Or Adjustable Payable Milestones?

- The performer must consider how cash flow is to be executed through all quarters in a project. This is especially important on Items that continue through multiple quarters.
- Each quarter is an opportunity to be paid for completed Items.
- If the performers' project is on schedule, then the Items in that quarter will equal the amount shown for the Quarterly Payable Milestone Schedule.
- If the performer is behind schedule and did not complete an Item in that quarter, then the Quarterly Payable Milestone invoice must be lower by the exact amount of the Item(s) not completed.

## Monitoring Payments (Continued)

* Acceptance of any priced tasks (milestones) should match requests for payment (invoices)
* Approve or disapprove the consortium's invoices/vouchers for payment and send to the OTAO
  - The review must be completed within five days after receipt of the invoice or voucher
    - If you cannot meet the required review time, advise the OTAO or the agreement administrator/specialist.
* The consortium's cost sharing should also be monitored to ensure contributions to the project have been received as projected
    - Ensure the consortium is not spending all the federal dollars before chipping in its share

# Invoice Example

| Item # | Task # | Activity Title | Projected Amount | | Actual Amount | |
|---|---|---|---|---|---|---|
| | | | Federal Share | | Non-Federal Resource Share | |
| 1 | 1 | Literary Search | $1,000 | $1,000 | $0 | $1,000 |
| 2 | 2 | Test Protocols | $10,000 | $0 | $10,000 | $10,000 |
| 3* | 4 | Technical Analysis | $5,000 | $2500 | $2,500 | $$0 |
| 4 | 6 | Quarterly Reporting | $1,000 | $1,000 | $1,000 | $1,000 |
| 9** | 2 | Field Demonstration | $4,000 | $1,000 | $4,000 | $1,000 |
| **Projected & Actual Totals:** | | | **$21,000** | **$5,500** | **$17,500** | **$13,000** |
| **Federal Invoice Amount:** | | | ? | | | |

# Changes to the Agreement

* OTR's, when monitoring the agreement, shall avoid any action that may be inconsistent with the agreement requirements
- The OTR cannot authorize the recipient to stop work, to delete, change, waive, or negotiate any of the requirements of the agreement's overall scope or other terms and conditions of the agreement
  - Changes to the agreement are necessary only if the scope of the agreement or terms of the agreement are going to be affected

# Changes to the Agreement (continued)

* Any change to the agreement, requested by the recipient, must be submitted in writing by the recipient and forwarded to the OTAO for action; however, you should advise the OTAO of the proposed change if it may affect the agreement price, cost, or delivery/performance schedule
  - You must report to the OTAO any government-required changes to the agreement (e.g., item or work no longer required, radical changes in approach, etc.).
* When the proposed change is received by the OTAO, you will be required to provide the OTAO with a written analysis, the rationale for the change, and an evaluation of any costs associated with the change
  - Changes are not expected nor happen often

# Changes to the Agreement (continued)

* **Things to Know…**
  - **No-Cost Extensions:**
    - OTAO will send the proposed mod to OTR and R&D Program
    - OTR to recommend or not back to OTAO and RD Program
  - **Fixed Price Increase + Time:**
    - OTAO will send the proposed mod to OTR and RD&T Program with attachments
    - OTR to technically recommend or not to RD&T Program
      * RD&T Program to then review costs and clear funds with PHP leadership if OTR recommends
      * RD&T Program prepares PR and agreement documents and transmits action to modify to OTAO with cc to OTR

# Changes to the Agreement (continued)

**OTR should discuss the merits of any proposed modification with the researcher and resource sharing partner(s)**

- When ready the researcher/award recipient should officially submit a request for modification to OTAO via email
- Researcher/award recipient must supply revisions to agreement files with proposed mods where applicable
  - Team Activities, Deliverables List & Accounting/Milestone Chart
- Since there is no Unilateral Changes Clause, no action by the OTR can result in claims to the agreement

# Types of Site Visits

* Proactive site visits, where the OTR visits recipients to gain technical insight, are very common
  - For example, kick-off meetings
* Reactive site visits, where a specific teammate is visited to investigate a problem found through other monitoring, are rare
* Reverse site visits, where the consortium visits you, almost never happen

# Enforcement Measures

* The OTR should try to resolve all issues with the consortium at the local level.
* Unresolved issues should be discussed with the OTAO and program officials, who should hold additional detailed discussions with the consortium to resolve any problems.
* Enforcement measures should match the seriousness of the problem.
  - If a contractor fails to materially comply with award Ts and Cs, the OTAO may suspend the OT pending corrective action, or terminate the OT.
  - Termination provisions vary in OTs.
* Remedies for noncompliance may include:
  - Temporarily withholding cash payments pending correction of the deficiency by the recipient (if cost type)
  - Disallowing all or part of the cost of the activity or action not in compliance (if cost type)
  - Wholly terminating the current agreement

# Closeout

* Fixed-price payable milestones versus cost-type payable milestones
* IP rights (do not kick in for several years after period of performance)
* Recoupment (does not kick in for several years after period of performance)
* Disposition of property
* Necessity of audit
* Review of special clauses designed for that agreement

183

# Break

184

# Summary Thoughts

* Summary thoughts concerning benefits others have seen or received

185

# Two Types of Benefits

1. Instant savings (what PMs want)
    * Broader assess to technology
    * Management flexibility
        - Better use of available funds
        - Better communications
        - Better ability to change directions
2. Results from OT projects (what management/ oversight wants)
    * Broader industrial base
    * Future savings; reduced acquisition costs
    * Performance increases

186

E

# Instant Savings: Management Flexibility

* Better use of available funds
  - Improved management of risks and uncertainties
  - Improved project structure through new and innovative business relationships
  - More value to the government per dollar spent

187

# Instant Savings: Management Flexibility (continued)

* Better use of available funds (continued)
  - Increased technical effort
    - Use of IR&D pool: one program reported 12% increase in hours/materials available
    - Teaming arrangements reduce overhead expenses: one program reported 5% increase in hours/materials available
    - Cost-sharing increased technical efforts

188

# Instant Savings: Management Flexibility (continued)

* Better communications
  - Innovative business arrangements
  - Open lines of communications among "team"
  - Industry's internal management increased programmatic control
    - Commercial cost/schedule control and reporting
    - Payable milestones focus corporate achievements on near term

189

# Instant Savings: Management Flexibility (continued)

* Better communications (continued)
  - Terms and conditions
    - Contractor strives for goals rather than fixed specifications.
    - Allow for changes with minimum disruption when problems or opportunities occur.
  - IP
    - Minimal government rights may be appropriate.
    - Contractor would not have participated in Mobile Tracking System (MTS) Program under traditional IP arrangements.

190

# Instant Savings: Management Flexibility (continued)

* Better ability to change directions
  - Contractor strives for goals rather than fixed specifications
  - Allows for changes with minimum disruption when problems or opportunities occur

191

# Results from OT Projects: Broader Industrial Base

* OTs not only bring broader access to technology, but also encourage NRPs to sell products to satisfy the government's needs.
* Two examples
  - Frontier Systems: Unmanned helicopters for special forces
  - Comtech Mobile Datacom: Mobile tracking system for DoD logistics assets

192

# Benefits Conclusion

* PMs want instant savings.
* Management/oversight wants results from OT projects.
* The studied OTs provided both.

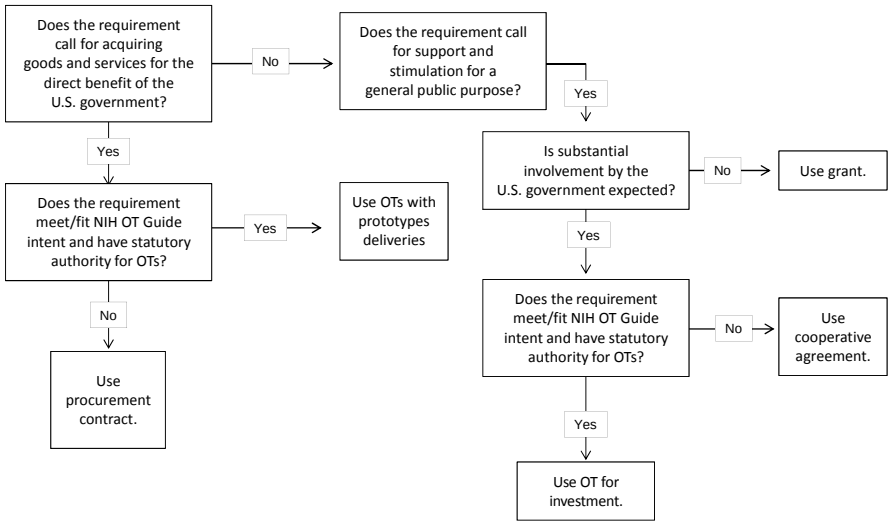
193

# Summary:
# OTFIs and OTPPs

194

E

## Notional Guide to Selection of R&D Instruments




195

# Characteristics and Comparison of Types of OTs

| | **OTFIs** | **OTPPs** |
|---|---|---|
| Use | Investment decisions; research | Buying goods and services; purely government needs |
| Products | Prototypes (products) consumed in testing | Prototypes ***potentially*** to remain in inventory |
| Teaming | Co-managed; articles of collaboration; changeable | Generally prime/sub relationship because of focus on prototypes, but team is bound together for affordability goals (Strategic Alliances) |
| Cost Share | Higher based on commercial market potential | None or low, depending on potential spinoff |

196

# Characteristics and Comparison of Types of OTs (continued)

| | **OTFIs** | **OTPPs** |
|---|---|---|
| IP | More rights to private parties; based on strength of resource/cost sharing; imperative to commercialization | Focus on what is necessary in operation and support (O&S) of prototypes<br>Prototypes are not likely the final product |
| Property | Greater rights conveyed if resource (cost) share is higher | Focus on what is necessary in O&S of prototypes |
| Solicitation | Broad research goals, asking for ***high risk***, unique, and innovative solutions | Program Solicitations, directed at solving specific agency needs |
| Pricing | More like financing or investing | Obtaining value for specific accomplishments |

197

E

This page is intentionally left almost blank.

# F. RESERVED

# Acquisition of Property in Other Transactions

Other Transaction Authority (OTA) Training
Part G

G

## Property Acquired under an OTFR: Definition

Definition

* Property: Any tangible personal property other than—
  - Property actually consumed during the execution of work under OT or
  - Delivered under the agreement

2

# Considerations

* Where the government owns or takes title, the property is subject to the Procurement statute (formerly known as the Federal Property and Administrative Services Act).
  - A property clause must be included in the agreement.
  - At a minimum, the property clause should address the following:
    - All property to which the government has or will obtain title
    - Who is responsible for maintenance, repair, or replacement
    - Who is liable for loss, theft, destruction of, or damage to the property
    - Who is liable for loss or damage resulting from use of the property
* The threshold above which contractors are required to mark, maintain, and control property should not be higher for OTs than for FAR-based contracts.

3

# Considerations (continued)

* If possible, acquire property outside of the OT; put these costs in their indirect rates.
* If the government is completely funding the OT effort and property is acquired, the government takes title in a cost-type arrangement unless the property is determined insignificant.
* If the government and nontraditional research performer (NRP) are cost sharing the effort and property is acquired:
  - The government may delay taking title until the end of the OT.
  - The contractor assumes the risk of loss.

4

# Considerations (continued)

- When an OT has fixed payments made based on accomplishment of technical performance milestones and has no cost share:
  - There is no requirement for taking title to property unless it is defined as a deliverable.
  - There is no requirement for adequate property control systems.

5

# Considerations (continued)

- Where property is a major element of the OT, include an explanation in the vision statement (Article I).
- Do not acquire property to facilitate manufacturing under OTs unless specifically necessary.
- If necessary, allow use of both streamlined commercial practices and existing government practices.

6

# Rights to Property when Acquired Under a Cost-Shared OTFR

Where acquisition of property is determined necessary in a cost-shared-payments OTFR:

* Contractors acquire title upon acquisition.
  - Exception: property with acquisition value > $5K or as determined by government
* The government retains contract right to participate in the property disposition determination.
  - Joint government/contractor process

7

# Disposition Options

* Purchase by contractor at an agreed-to price representing fair market value, with proceeds returned to the government.
  - NRP's cost share is already considered in the price.
* Transfer to a government research facility, with title and ownership transferred to the government.
* Donate to a mutually agreed-upon university or technical learning center for research purposes.
* Follow any other agency-approved disposition procedure.

8

# Disposition Rationale

* Prevent unfair competitive advantages.
* Incur significant commercial benefits.

9

This page is intentionally left almost blank.

# Foreign Access to Technology Created Under Other Transactions NIH

Other Transaction Authority (OTA) Training
Part H

H

# Road Map

1. Use of OTs for Foreign Requirements
2. Introduction to Foreign Access to Technology in OTs
3. Transfer of Technology to Foreign Firms
4. Examples

2

# Foreign Firms

* Foreign firms are defined by the same limitations as US firms.
  - OTs for Research—Nontraditional Research Performers (NSP)
  - OTs for Prototypes–Nontraditional Research Performers (NSP)
* In most cases, NIH would be trying to have technology transferred into NIH's mission needs.

3

# Definitions

* Foreign firm or institution: A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions
* Know-how: All information including, but not limited to, discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus, and machines
* Technology: Discoveries, innovations, know-how, and inventions, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue

4

# Existing Statutory and Regulatory Requirements

* International Traffic in Arms Regulation (ITAR), 22 CFR Part 121 et seq.
* DoD Industrial Security Regulation, DoD 5220.22-R
* Department of Commerce Export Regulation, 15 CFR Part 770 et seq.

5

H

# Foreign Access to Technology Article

* Include the Foreign Access to Technology article in agreements to restrict the flow of technology to foreign sources for a specified term.
* This is a good policy because primary or substantial economic benefits flow to the United States as a result.

6

# Transfer of Technology to Foreign Firms

* What is considered a transfer of technology to foreign firms?
  - Sale of a company
  - Sales or licensing of technology
  - Foreign access to technology without prior agency approval

7

# Transfer of Technology to Foreign Firms (continued)

* What is not considered a transfer of technology to a foreign firm?
  - Sale of products or components
  - License of the software or documentation related to the sale of a product
  - Transfer to foreign subsidiaries of the awardee for purposes related to the agreement
  - Transfer to an approved source for the conduct of research or to create a source of supply (limited transfer)

8

# Process for Handling Transfer of Technology to Foreign Firms

* Pre- or post-award approvals: "Disputes" article in the OT can be used if the agency withholds approval.
* If transfer occurs without agency approval:
  - Government funds are returned to the agency.
  - The government gets a license to reuse the technology within the United States to accomplish the intent of a specific agreement.

9

H

# Example 1

* U.S. company
  - Manufactures in the United States only
  - Sells both in the United States and abroad
* Answer: This is okay because the technology is available within the United States.

10

# Example 2

* U.S. company
  - Manufactures abroad only
  - Sells both in the United States and abroad
* Answer: This is not okay because the technology and the resulting manufacturing jobs are not available in the United States.

11

# Example 3

* U.S. company
  - Manufactures in the United States for domestic sales only
  - Manufactures abroad for foreign sales
* Answer: This is okay because the technology is available within the United States.

12

# Example 4

* U.S. company
  - Manufactures a component abroad
  - Inserts the component into a higher-value product manufactured in the United States
  - Sells the product both in the United States and abroad
* Answer: This is okay because the technology for the higher-value product is available within the United States. This is very common practice in commercial sales in a global market.

13



# Example 5

* U.S. company
  - Plans to build manufacturing plants in the United States and abroad
  - Wants no foreign access restrictions
* Answer: This is not okay because there is no definition of what will happen; therefore, the government's investment is not protected.

14

This page is intentionally left almost blank.

# Other Transactions: A Summary

Other Transaction Authority (OTA) Training
Part I

# Why OTs?

- Flexibility of Ts & Cs for fluid programs
- Flexibility of Ts & Cs for nontraditional management reviews
- Flexibility of Ts & Cs where consortia management applies
- Predominantly nontraditional companies need to participate in government programs; for example—
  - Biotech industry
  - Industries related to information technology
  - Materials manufacturers
  - Big Pharma

2

# Characteristics and Comparison of Types of OTs

| | OTs for Research (OTFRs) | OTs for Prototype Projects (OTFPPs) |
|---|---|---|
| Use | Support and stimulation; research | Buying goods and services; purely government needs |
| Products | Prototypes (products) consumed in testing | Prototypes potentially to remain in inventory |
| Teaming | Co-managed; articles of collaboration; changeable | Generally prime/sub relationship because of focus on prototypes, but team is bound together for overall goals |
| Cost Share | Higher based on commercial market potential | None or low, depending on potential spin-off |

3

# Characteristics and Comparison of Types of OTs (continued)

| | OTFRs | OTFPPs |
|---|---|---|
| Intellectual Property | More rights to private parties; based on strength of resource sharing; imperative to commercialization | Focus on what is necessary in operation and support (O&S) of prototypes |
| Property | Greater rights conveyed if resource share is higher | Focus on what is necessary in O&S of prototypes |
| Solicitation | Broad Agency Announcements and Research Announcements, asking for unique and innovative solutions | Broad Agency Announcements and Program Solicitations, directed at solving specific agency needs |
| Pricing | More like financing or investing | Obtaining value for specific accomplishments |

4

# Key Elements of Effective Use of OT Authority

* Top-level management interest and support
* Technical managers who understand OT authority and see opportunities to use it
* Positive attitude and close cooperation among legal and contracting personnel in government and industry

5

# Lessons Learned

* FAR-based solicitations lack flexibility to attract nontraditional contractors and encourage innovative terms and conditions.
  - Make flexibility known in solicitations for OT agreements.
  - Write your own provisions or leave it to industry.

6

# Lessons Learned (continued)

* When negotiating IP rights, know what you want and ask for only that.
* Ensure the OT clearly describes how to handle sensitive/proprietary commercial or business information.

7

# Lessons Learned (continued)

* Everyone must be involved
  - OT Agreements Officer, users, technical, legal counsel, and industry
  - Because OTs offer significant flexibility, it is critical for the government to assign qualified personnel and train the negotiators.

8

# Lessons Learned (continued)

* Ensure the team is cohesive and thoroughly committed to the agreement goals.
* The selection of partners or team members is critical to the success of an OT.
* The industry team should designate one member (person with best vision) to be firmly in charge.
  - Represents the team to the government
  - Maintains the program vision

9

# Lessons Learned (continued)

* Carefully construct the OT agreement to help ensure a successful partnership between government and industry.
* Ensure complete and consistent file organization, as the foundation for "telling the story" of an OT award.

10

# Lessons Learned (continued)

* Beginning the negotiation of terms and conditions in advance of the source selection decision can save time.
* When seeking proposals for an OT, allow as much response time as practicable.
* Develop model solicitations and generally applicable terms and conditions in advance for use as a starting point when drafting OT agreements.

11

# Lessons Learned (continued)

* The government's post-award role is different in OTFRs and early stages of OTFPPs.
  - Team is responsible for technical and financial oversight.
  - Government's role is as part of that team, not traditional contract administration.
* Some consortia lack sufficient oversight of financial and payment issues; government business manager must ensure these matters are discussed as part of their management duties.

12

# Lessons Learned (continued)

* IR&D costs that are allowable under OTs can be a powerful motivator to traditional government industry and government when commingled with government funds.
* Ensure the agreed-upon payment arrangement is specified clearly and accurately.
* Watch use of the term "best efforts" (cost-type).

13

# Lessons Learned (continued)

* Pricing
  - Agreement must identify type of payment structure selected.
  - Agreement Terms and Conditions (Ts & Cs) must be consistent with identified payment structure.
  - All milestones must have associated dollars and dates.
  - Exit criteria should be reasonable to preclude unnecessary technical and business risks.
* Audits and oversight have their role in OTs but should not be allowed to undermine the collaborative nature of these agreements.

14

# Lessons Learned (continued)

* Many features of the OT process facilitate participation by nontraditional firms; use them.
* Combined use of OT authority and the Integrated Process Team enables a positive, collaborative relationship with open communication and collaboration.
* Substantive participation by government personnel is necessary.

15

# Lessons Learned (continued)

* Significant leverage can be gained by allowing competing design contractors to treat the program as an externally funded IR&D activity.
* OT awardees should be encouraged to focus on both positive and negative information provided during their debriefing to prepare them for competition in later phases.

16

# Lessons Learned (continued)

* Cultural change is necessary: ultimate success depends on cultural change by government and industry causing acceptance of and commitment to an integrated, OT approach.

17

# A Final Thought: Introducing Change

Machiavelli was right when he said—

> Nothing is more difficult … than to introduce a new order. Because the innovator has for enemies all those who have done well under the old conditions and lukewarm defenders in those who may do well under the new.
>
> --*The Prince*, 1513

18

This page is intentionally left almost blank.

# J. POLICY DOCUMENTS

work is within the purpose, mission, and general scope of effort of such center as established in the sponsoring agreement of the Department of Defense with such center.

(b) EXCEPTION FOR APPLIED SCIENTIFIC RESEARCH.—This section does not apply to a federally funded research and development center that performs applied scientific research under laboratory conditions.

(c) LIMITATION ON CREATION OF NEW CENTERS.—(1) The head of an agency may not obligate or expend amounts appropriated to the Department of Defense for purposes of operating a federally funded research center that was not in existence before June 2, 1986, until—

(A) the head of the agency submits to Congress a report with respect to such center that describes the purpose, mission, and general scope of effort of the center; and

(B) a period of 60 days beginning on the date such report is received by Congress has elapsed.

(2) In this subsection, the term ''head of an agency'' has the meaning given such term in section 2302(1) of this title.

(d) IDENTIFICATION TO CONGRESS OF FFRDC WORKLOAD EFFORT.—After the close of a fiscal year, and not later than January 1 of the next year, the Secretary shall submit to the Committee on Armed Services and the Committee on Appropriations of the Senate and the Committee on Armed Services and the Committee on Appropriations of the House of Representatives a report setting forth the actual obligations and the actual man-years of effort expended at each federally funded research and development center during that fiscal year.

(Added Pub. L. 99–500, § 101(c) [title X, § 912(a)(1)], Oct. 18, 1986, 100 Stat. 1783–82, 1783–146, and Pub. L. 99–591, § 101(c) [title X, § 912(a)(1)], Oct. 30, 1986, 100 Stat. 3341–82, 3341–146; Pub. L. 99–661, div. A, title IX, formerly title IV, § 912(a)(1), Nov. 14, 1986, 100 Stat. 3925, renumbered title IX, Pub. L. 100–26, § 3(5), Apr. 21, 1987, 101 Stat. 273; amended Pub. L. 102–190, div. A, title II, § 256(a)(1), Dec. 5, 1991, 105 Stat. 1330; Pub. L. 104–106, div. A, title XV, § 1502(a)(9), Feb. 10, 1996, 110 Stat. 503; Pub. L. 106–65, div. A, title X, § 1067(1), Oct. 5, 1999, 113 Stat. 774; Pub. L. 107–314, div. A, title X, § 1041(a)(12), Dec. 2, 2002, 116 Stat. 2645.)

CODIFICATION

Pub. L. 99–591 is a corrected version of Pub. L. 99–500. Pub. L. 99–500, Pub. L. 99–591, and Pub. L. 99–661 added identical sections.

AMENDMENTS

2002—Subsec. (d). Pub. L. 107–314, § 1041(a)(12), struck out designations for pars. (1) and (2) and text of par. (1). Prior to amendment par. (1) read as follows: ''In the documents provided to Congress by the Secretary of Defense in support of the budget submitted by the President under section 1105 of title 31 for any fiscal year, the Secretary shall set forth the proposed amount of the man-years of effort to be funded by the Department of Defense for each federally funded research and development center for the fiscal year covered by that budget.''

1999—Subsec. (d)(2). Pub. L. 106–65 substituted ''and the Committee on Armed Services'' for ''and the Committee on National Security''.

1996—Subsec. (d)(2). Pub. L. 104–106 substituted ''the Committee on Armed Services and the Committee on Appropriations of the Senate and the Committee on National Security and the Committee on Appropriations of the'' for ''the Committees on Armed Services and the Committees on Appropriations of the Senate and''.

1991—Subsec. (d). Pub. L. 102–190 added subsec. (d).

EFFECTIVE DATE OF 1991 AMENDMENT

Section 256(a)(2) of Pub. L. 102–190 provided that:

''(A) Paragraph (1) of subsection (d) of section 2367 of title 10, United States Code, as added by paragraph (1), shall take effect with respect to the budget submitted for fiscal year 1994.

''(B) Paragraph (2) of such subsection shall take effect with respect to fiscal year 1992.''

GAO STUDY; REPORT

Section 101(c) [title X, § 912(b), (c)] of Pub. L. 99–500 and Pub. L. 99–591, and section 912(b), (c) of title IX, formerly title IV, of Pub. L. 99–661, renumbered title IX, Pub. L. 100–26, § 3(5), Apr. 21, 1987, 101 Stat. 273, directed Comptroller General to conduct a study of national defense role of federally funded research and development centers and submit a report to Congress not later than one year after Oct. 18, 1986.

**[§ 2368. Repealed. Pub. L. 102–190, div. A, title VIII, § 821(c)(1), Dec. 5, 1991, 105 Stat. 1431]**

Section, added Pub. L. 100–456, div. A, title VIII, § 823(a)(1), Sept. 29, 1988, 102 Stat. 2018; amended Pub. L. 101–189, div. A, title VIII, § 841(c)(1), Nov. 29, 1989, 103 Stat. 1514; Pub. L. 102–25, title VII, § 701(g)(1), Apr. 6, 1991, 105 Stat. 115, authorized studies in fields of research and development essential to development of critical technologies.

**[§ 2369. Repealed. Pub. L. 103–355, title III, § 3062(a), Oct. 13, 1994, 108 Stat. 3336]**

Section, added Pub. L. 100–456, div. A, title VIII, § 842(a), Sept. 29, 1988, 102 Stat. 2026; amended Pub. L. 103–160, div. A, title IX, § 904(d)(1), Nov. 30, 1993, 107 Stat. 1728, related to program for supervision and coordination of product evaluation activities within the Department of Defense.

**[§ 2370. Repealed. Pub. L. 104–106, div. A, title X, § 1061(j)(1), Feb. 10, 1996, 110 Stat. 443]**

Section, added Pub. L. 101–510, div. A, title II, § 241(a), Nov. 5, 1990, 104 Stat. 1516, required annual report to Congress on Biological Defense Research Program.

**[§ 2370a. Repealed. Pub. L. 108–375, div. A, title X, § 1005(a), Oct. 28, 2004, 118 Stat. 2036]**

Section, added Pub. L. 103–160, div. A, title II, § 214(a), Nov. 30, 1993, 107 Stat. 1586, related to medical countermeasures against biowarfare threats and allocation of funding between near-term and other threats.

**§ 2371. Research projects: transactions other than contracts and grants**

(a) ADDITIONAL FORMS OF TRANSACTIONS AUTHORIZED.—The Secretary of Defense and the Secretary of each military department may enter into transactions (other than contracts, cooperative agreements, and grants) under the authority of this subsection in carrying out basic, applied, and advanced research projects. The authority under this subsection is in addition to the authority provided in section 2358 of this title to use contracts, cooperative agreements, and grants in carrying out such projects.

(b) EXERCISE OF AUTHORITY BY SECRETARY OF DEFENSE.—In any exercise of the authority in

J

subsection (a), the Secretary of Defense shall act through the Defense Advanced Research Projects Agency or any other element of the Department of Defense that the Secretary may designate.

(c) ADVANCE PAYMENTS.—The authority provided under subsection (a) may be exercised without regard to section 3324 of title 31.

(d) RECOVERY OF FUNDS.—(1) A cooperative agreement for performance of basic, applied, or advanced research authorized by section 2358 of this title and a transaction authorized by subsection (a) may include a clause that requires a person or other entity to make payments to the Department of Defense or any other department or agency of the Federal Government as a condition for receiving support under the agreement or other transaction.

(2) The amount of any payment received by the Federal Government pursuant to a requirement imposed under paragraph (1) may be credited, to the extent authorized by the Secretary of Defense, to the appropriate account established under subsection (f). Amounts so credited shall be merged with other funds in the account and shall be available for the same purposes and the same period for which other funds in such account are available.

(e) CONDITIONS.—(1) The Secretary of Defense shall ensure that—

(A) to the maximum extent practicable, no cooperative agreement containing a clause under subsection (d) and no transaction entered into under subsection (a) provides for research that duplicates research being conducted under existing programs carried out by the Department of Defense; and

(B) to the extent that the Secretary determines practicable, the funds provided by the Government under a cooperative agreement containing a clause under subsection (d) or a transaction authorized by subsection (a) do not exceed the total amount provided by other parties to the cooperative agreement or other transaction.

(2) A cooperative agreement containing a clause under subsection (d) or a transaction authorized by subsection (a) may be used for a research project when the use of a standard contract, grant, or cooperative agreement for such project is not feasible or appropriate.

(f) SUPPORT ACCOUNTS.—There is hereby established on the books of the Treasury separate accounts for each of the military departments and the Defense Advanced Research Projects Agency for support of research projects and development projects provided for in cooperative agreements containing a clause under subsection (d) and research projects provided for in transactions entered into under subsection (a). Funds in those accounts shall be available for the payment of such support.

(g) REGULATIONS.—The Secretary of Defense shall prescribe regulations to carry out this section.

(h) ANNUAL REPORT.—(1) Not later than 90 days after the end of each fiscal year, the Secretary of Defense shall submit to the Committee on Armed Services of the Senate and the Committee on Armed Services of the House of Representatives a report on the use by the Department of Defense during such fiscal year of—

(A) cooperative agreements authorized under section 2358 of this title that contain a clause under subsection (d); and

(B) transactions authorized by subsection (a).

(2) The report shall include, with respect to the cooperative agreements and other transactions covered by the report, the following:

(A) The technology areas in which research projects were conducted under such agreements or other transactions.

(B) The extent of the cost-sharing among Federal Government and non-Federal sources.

(C) The extent to which the use of the cooperative agreements and other transactions—

(i) has contributed to a broadening of the technology and industrial base available for meeting Department of Defense needs; and

(ii) has fostered within the technology and industrial base new relationships and practices that support the national security of the United States.

(D) The total amount of payments, if any, that were received by the Federal Government during the fiscal year covered by the report pursuant to a clause described in subsection (d) that was included in the cooperative agreements and other transactions, and the amount of such payments, if any, that were credited to each account established under subsection (f).

(3) No report is required under this subsection for a fiscal year after fiscal year 2006.

(i) PROTECTION OF CERTAIN INFORMATION FROM DISCLOSURE.—(1) Disclosure of information described in paragraph (2) is not required, and may not be compelled, under section 552 of title 5 for five years after the date on which the information is received by the Department of Defense.

(2)(A) Paragraph (1) applies to information described in subparagraph (B) that is in the records of the Department of Defense if the information was submitted to the Department in a competitive or noncompetitive process having the potential for resulting in an award, to the party submitting the information, of a cooperative agreement for performance of basic, applied, or advanced research authorized by section 2358 of this title or another transaction authorized by subsection (a).

(B) The information referred to in subparagraph (A) is the following:

(i) A proposal, proposal abstract, and supporting documents.

(ii) A business plan submitted on a confidential basis.

(iii) Technical information submitted on a confidential basis.

(Added Pub. L. 101–189, div. A, title II, §251(a)(1), Nov. 29, 1989, 103 Stat. 1403; amended Pub. L. 101–510, div. A, title XIV, §1484(k)(9), Nov. 5, 1990, 104 Stat. 1719; Pub. L. 102–190, div. A, title VIII, §826, Dec. 5, 1991, 105 Stat. 1442; Pub. L. 102–484, div. A, title II, §217, Oct. 23, 1992, 106 Stat. 2352; Pub. L. 103–35, title II, §201(c)(4), May 31, 1993, 107 Stat. 98; Pub. L. 103–160, div. A, title VIII, §827(b), title XI, §1182(a)(6), Nov. 30, 1993, 107 Stat. 1712, 1771; Pub. L. 103–355, title I, §1301(b), Oct. 13, 1994, 108 Stat. 3285; Pub. L. 104–106, div. A, title XV, §1502(a)(1), Feb. 10, 1996, 110 Stat.

502; Pub. L. 104–201, div. A, title II, § 267(a)–(c)(1)(A), title X, § 1073(e)(1)(B), Sept. 23, 1996, 110 Stat. 2467, 2468, 2658; Pub. L. 105–85, div. A, title VIII, § 832, Nov. 18, 1997, 111 Stat. 1842; Pub. L. 105–261, div. A, title VIII, § 817, Oct. 17, 1998, 112 Stat. 2089; Pub. L. 106–65, div. A, title X, § 1067(1), Oct. 5, 1999, 113 Stat. 774; Pub. L. 108–136, div. A, title X, § 1031(a)(19), Nov. 24, 2003, 117 Stat. 1597.)

AMENDMENTS

2003—Subsec. (h)(3). Pub. L. 108–136 added par. (3).

1999—Subsec. (h)(1). Pub. L. 106–65 substituted ''and the Committee on Armed Services'' for ''and the Committee on National Security'' in introductory provisions.

1998—Subsec. (i)(2)(A). Pub. L. 105–261 substituted ''cooperative agreement for performance of basic, applied, or advanced research authorized by section 2358 of this title'' for ''cooperative agreement that includes a clause described in subsection (d)''.

1997—Subsec. (i). Pub. L. 105–85 added subsec. (i).

1996—Subsec. (b). Pub. L. 104–201, § 1073(e)(1)(B), inserted ''Defense'' before ''Advanced Research Projects Agency''.

Subsec. (e). Pub. L. 104–201, § 267(a), inserted ''(1)'' before ''The Secretary of Defense'', redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, inserted ''and'' after semicolon at end of subpar. (A), substituted a period for ''; and'' at end of subpar. (B), added par. (2), and struck out par. (3) which read as follows: ''a cooperative agreement containing a clause under subsection (d) or a transaction authorized under subsection (a) is used for a research project only when the use of a standard contract, grant, or cooperative agreement for such project is not feasible or appropriate.''

Subsec. (f). Pub. L. 104–201, § 1073(e)(1)(B), inserted ''Defense'' before ''Advanced Research Projects Agency''.

Subsec. (h). Pub. L. 104–201, § 267(b), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: ''Not later than 60 days after the end of each fiscal year, the Secretary of Defense shall submit to the Committee on Armed Services of the Senate and the Committee on National Security of the House of Representatives a report on all cooperative agreements entered into under section 2358 of this title during such fiscal year that contain a clause authorized by subsection (d) and on all transactions entered into under subsection (a) during such fiscal year. The report shall contain, with respect to each such cooperative agreement and transaction, the following:

''(1) A general description of the cooperative agreement or other transaction (as the case may be), including the technologies for which research is provided for under such agreement or transaction.

''(2) The potential military and, if any, commercial utility of such technologies.

''(3) The reasons for not using a contract or grant to provide support for such research.

''(4) The amount of the payments, if any, that were received by the Federal Government during the fiscal year covered by the report pursuant to a clause included in such cooperative agreement or other transaction pursuant to subsection (d).

''(5) The amount of the payments reported under paragraph (4), if any, that were credited to each account established under subsection (f).''

Pub. L. 104–106 substituted ''Committee on Armed Services of the Senate and the Committee on National Security of the House of Representatives'' for ''Committees on Armed Services of the Senate and House of Representatives''.

Subsec. (i). Pub. L. 104–201, § 1073(e)(1)(B), which directed amendment of subsec. (i) by inserting ''Defense'' before ''Advanced Research Projects Agency'', could not be executed because of the renumbering of subsec. (i) as section 2371a of this title by Pub. L. 104–201, § 267(c)(1)(A). See below.

Pub. L. 104–201, § 267(c)(1)(A), renumbered subsec. (i) of this section as section 2371a of this title.

1994—Pub. L. 103–355 amended section generally. Prior to amendment section related to cooperative agreements and other transactions for advanced research projects.

1993—Subsec. (a). Pub. L. 103–160, § 827(b)(1)(C), substituted ''section 2358 of this title'' for ''subsection (a)'' in par. (1) and ''subsection (d)'' for ''subsection (e)'' in par. (2).

Pub. L. 103–160, § 827(b)(1)(A), (B), redesignated subsec. (b) as (a) and struck out former subsec. (a), as amended by Pub. L. 103–160, § 1182(a)(6), (h), which read as follows: ''The Secretary of Defense, in carrying out advanced research projects through the Advanced Research Projects Agency, and the Secretary of each military department, in carrying out advanced research projects, may enter into cooperative agreements and other transactions with any person, any agency or instrumentality of the United States, any unit of State or local government, any educational institution, and any other entity.''

Pub. L. 103–160, § 1182(a)(6), substituted ''Advanced Research Projects Agency'' for ''Defense Advanced Research Projects Agency''.

Subsec. (b). Pub. L. 103–160, § 827(b)(1)(B), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Subsec. (c). Pub. L. 103–160, § 827(b)(1)(B), (2)(A), redesignated subsec. (d) as (c) and inserted ''and development'' after ''research'' in two places in par. (1). Former subsec. (c) redesignated (b).

Subsec. (d). Pub. L. 103–160, § 827(b)(1)(B), (D), (2)(B), redesignated subsec. (e), as amended by Pub. L. 103–160, § 1182(a)(6), (h), as (d) and substituted ''section 2358 of this title'' for ''subsection (a)'' and ''research and development'' for ''advanced research''. Former subsec. (d) redesignated (c).

Subsec. (e). Pub. L. 103–160, § 827(b)(1)(B), (E), (2)(B), (C), redesignated subsec. (f) as (e), in par. (1) substituted ''research and development are'' for ''advanced research is'', in par. (3) substituted ''research and development'' for ''advanced research'', in par. (4) substituted ''subsection (a)'' for ''subsection (b)'', and in par. (5) substituted ''subsection (d)'' for ''subsection (e)''. Former subsec. (e) redesignated (d).

Pub. L. 103–160, § 1182(a)(6), substituted ''Advanced Research Projects Agency'' for ''Defense Advanced Research Projects Agency''.

Subsec. (f). Pub. L. 103–160, § 827(b)(1)(B), redesignated subsec. (g), as amended by Pub. L. 103–160, § 1182(a)(6), (h), as (f). Former subsec. (f) redesignated (e).

Subsec. (g). Pub. L. 103–160, § 827(b)(1)(B), redesignated subsec. (g), as amended by Pub. L. 103–160, § 1182(a)(6), (h), as (f).

Pub. L. 103–160, § 1182(a)(6), substituted ''Advanced Research Projects Agency'' for ''Defense Advanced Research Projects Agency''.

Pub. L. 103–35 substituted ''granted by section 12'' for ''granted by section 11'' and ''provisions of sections 11 and 12'' for ''provisions of sections 10 and 11''.

1992—Subsec. (g). Pub. L. 102–484 added subsec. (g).

1991—Subsec. (a). Pub. L. 102–190, § 826(a), inserted ''and the Secretary of each military department, in carrying out advanced research projects,''.

Subsec. (b)(1). Pub. L. 102–190, § 826(b)(1)(A), struck out ''by the Secretary'' after ''transactions entered into''.

Subsec. (b)(2). Pub. L. 102–190, § 826(b)(1)(B), substituted ''to the appropriate account'' for ''to the account''.

Subsec. (d). Pub. L. 102–190, § 826(b)(2), substituted ''The Secretary of Defense'' for ''The Secretary'' in introductory provisions.

Subsec. (e). Pub. L. 102–190, § 826(b)(3), substituted ''separate accounts for each of the military departments and the Defense Advanced Research Projects Agency'' for ''an account'' and ''those accounts'' for ''such account''.

J

Subsec. (f)(5). Pub. L. 102–190, §826(b)(4), substituted ''each account'' for ''the account''.

Subsec. (g). Pub. L. 102–190, §826(c), struck out subsec. (g) which read as follows: ''The authority of the Secretary to enter into cooperative agreements and other transactions under this section expires at the close of September 30, 1991.''

1990—Subsec. (f). Pub. L. 101–510 substituted ''Committees on'' for ''Committees of'' in introductory provisions.

EFFECTIVE DATE OF 1994 AMENDMENT

For effective date and applicability of amendment by Pub. L. 103–355, see section 10001 of Pub. L. 103–355, set out as a note under section 2302 of this title.

AUTHORITY OF DEFENSE ADVANCED RESEARCH PROJECTS AGENCY TO CARRY OUT CERTAIN PROTOTYPE PROJECTS

Pub. L. 103–160, div. A, title VIII, §845, Nov. 30, 1993, 107 Stat. 1721, as amended by Pub. L. 104–201, div. A, title VIII, §804, title X, §1073(e)(1)(D), (2)(A), Sept. 23, 1996, 110 Stat. 2605, 2658; Pub. L. 105–261, div. A, title II, §241, Oct. 17, 1998, 112 Stat. 1954; Pub. L. 106–65, div. A, title VIII, §801, title X, §1066(d)(6), Oct. 5, 1999, 113 Stat. 700, 773; Pub. L. 106–398, §1 [[div. A], title VIII, §§803, 804(a)], Oct. 30, 2000, 114 Stat. 1654, 1654A–205, 1654A–206; Pub. L. 107–107, div. A, title VIII, §822, title X, §1048(i)(2), Dec. 28, 2001, 115 Stat. 1182, 1229; Pub. L. 108–136, div. A, title VIII, §847, Nov. 24, 2003, 117 Stat. 1554; Pub. L. 109–163, div. A, title VIII, §823, Jan. 6, 2006, 119 Stat. 3387; Pub. L. 109–364, div. A, title VIII, §855, Oct. 17, 2006, 120 Stat. 2347; Pub. L. 110–181, div. A, title VIII, §823, title X, §1063(h), Jan. 28, 2008, 122 Stat. 226, 324; Pub. L. 110–417, [div. A], title VIII, §824, Oct. 14, 2008, 122 Stat. 4533; Pub. L. 111–383, div. A, title VIII, §§826, 866(g)(2), Jan. 7, 2011, 124 Stat. 4270, 4298, provided that:

''(a) AUTHORITY.—(1) Subject to paragraph (2), the Director of the Defense Advanced Research Projects Agency, the Secretary of a military department, or any other official designated by the Secretary of Defense may, under the authority of section 2371 of title 10, United States Code, carry out prototype projects that are directly relevant to weapons or weapon systems proposed to be acquired or developed by the Department of Defense, or to improvement of weapons or weapon systems in use by the Armed Forces.

''(2) The authority of this section—

''(A) may be exercised for a prototype project that is expected to cost the Department of Defense in excess of $20,000,000 but not in excess of $100,000,000 (including all options) only upon a written determination by the senior procurement executive for the agency (as designated for the purpose of section 16(c) of the Office of Federal Procurement Policy Act [former] (41 U.S.C. 414(c)) [now 41 U.S.C. 1702(c)] or, for the Defense Advanced Research Projects Agency or the Missile Defense Agency, the director of the agency that—

''(i) the requirements of subsection (d) will be met; and

''(ii) the use of the authority of this section is essential to promoting the success of the prototype project; and

''(B) may be exercised for a prototype project that is expected to cost the Department of Defense in excess of $100,000,000 (including all options) only if—

''(i) the Under Secretary of Defense for Acquisition, Technology, and Logistics determines in writing that—

''(I) the requirements of subsection (d) will be met; and

''(II) the use of the authority of this section is essential to meet critical national security objectives; and

''(ii) the congressional defense committees [Committees on Armed Services and Appropriations of the Senate and the House of Representatives] are notified in writing at least 30 days before such authority is exercised.

''(3) The authority of a senior procurement executive or director of the Defense Advanced Research Projects Agency or Missile Defense Agency under paragraph (2)(A), and the authority of the Under Secretary of Defense for Acquisition, Technology, and Logistics under paragraph (2)(B), may not be delegated.

''(b) EXERCISE OF AUTHORITY.—(1) Subsections (e)(1)(B) and (e)(2) of such section 2371 shall not apply to projects carried out under subsection (a).

''(2) To the maximum extent practicable, competitive procedures shall be used when entering into agreements to carry out projects under subsection (a).

''(c) COMPTROLLER GENERAL REVIEW.—(1) Each agreement entered into by an official referred to in subsection (a) to carry out a project under that subsection that provides for payments in a total amount in excess of $5,000,000 shall include a clause that provides for the Comptroller General, in the discretion of the Comptroller General, to examine the records of any party to the agreement or any entity that participates in the performance of the agreement.

''(2) The requirement in paragraph (1) shall not apply with respect to a party or entity, or a subordinate element of a party or entity, that has not entered into any other agreement that provides for audit access by a Government entity in the year prior to the date of the agreement.

''(3)(A) The right provided to the Comptroller General in a clause of an agreement under paragraph (1) is limited as provided in subparagraph (B) in the case of a party to the agreement, an entity that participates in the performance of the agreement, or a subordinate element of that party or entity if the only agreements or other transactions that the party, entity, or subordinate element entered into with Government entities in the year prior to the date of that agreement are cooperative agreements or transactions that were entered into under this section or section 2371 of title 10, United States Code.

''(B) The only records of a party, other entity, or subordinate element referred to in subparagraph (A) that the Comptroller General may examine in the exercise of the right referred to in that subparagraph are records of the same type as the records that the Government has had the right to examine under the audit access clauses of the previous agreements or transactions referred to in such subparagraph that were entered into by that particular party, entity, or subordinate element.

''(4) The head of the contracting activity that is carrying out the agreement may waive the applicability of the requirement in paragraph (1) to the agreement if the head of the contracting activity determines that it would not be in the public interest to apply the requirement to the agreement. The waiver shall be effective with respect to the agreement only if the head of the contracting activity transmits a notification of the waiver to Congress and the Comptroller General before entering into the agreement. The notification shall include the rationale for the determination.

''(5) The Comptroller General may not examine records pursuant to a clause included in an agreement under paragraph (1) more than three years after the final payment is made by the United States under the agreement.

''(d) APPROPRIATE USE OF AUTHORITY.—(1) The Secretary of Defense shall ensure that no official of an agency enters into a transaction (other than a contract, grant, or cooperative agreement) for a prototype project under the authority of this section unless—

''(A) there is at least one nontraditional defense contractor participating to a significant extent in the prototype project; or

''(B) no nontraditional defense contractor is participating to a significant extent in the prototype project, but at least one of the following circumstances exists:

''(i) At least one third of the total cost of the prototype project is to be paid out of funds provided

by parties to the transaction other than the Federal Government.

''(ii) The senior procurement executive for the agency (as designated for the purposes of section 16(3) of the Office of Federal Procurement Policy Act ([former] 41 U.S.C. 414(3))) [see 41 U.S.C. 1702(c)] determines in writing that exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a contract.

''(2)(A) Except as provided in subparagraph (B), the amounts counted for the purposes of this subsection as being provided, or to be provided, by a party to a transaction with respect to a prototype project that is entered into under this section other than the Federal Government do not include costs that were incurred before the date on which the transaction becomes effective.

''(B) Costs that were incurred for a prototype project by a party after the beginning of negotiations resulting in a transaction (other than a contract, grant, or cooperative agreement) with respect to the project before the date on which the transaction becomes effective may be counted for purposes of this subsection as being provided, or to be provided, by the party to the transaction if and to the extent that the official responsible for entering into the transaction determines in writing that—

''(i) the party incurred the costs in anticipation of entering into the transaction; and

''(ii) it was appropriate for the party to incur the costs before the transaction became effective in order to ensure the successful implementation of the transaction.

''(e) PILOT PROGRAM FOR TRANSITION TO FOLLOW-ON CONTRACTS.—(1) The Secretary of Defense is authorized to carry out a pilot program for follow-on contracting for the production of items or processes developed under prototype projects carried out under this section or research projects carried out pursuant to section 2371 of title 10, United States Code.

''(2) Under the pilot program—

''(A) a qualifying contract for the procurement of such an item or process, or a qualifying subcontract under a contract for the procurement of such an item or process, may be treated as a contract or subcontract, respectively, for the procurement of commercial items, as defined in section 4(12) of the Office of Federal Procurement Policy Act ([former] 41 U.S.C. 403(12)) [see 41 U.S.C. 103]; and

''(B) the item or process may be treated as an item or process, respectively, that is developed in part with Federal funds and in part at private expense for the purposes of section 2320 of title 10, United States Code.

''(3) For the purposes of the pilot program, a qualifying contract or subcontract is a contract or subcontract, respectively, with a nontraditional defense contractor that—

''(A) does not exceed $50,000,000 (including all options); and

''(B) is either—

''(i) a firm, fixed-price contract or subcontract; or

''(ii) a fixed-price contract or subcontract with economic price adjustment.

''(4) The authority to conduct a pilot program under this subsection shall terminate on September 30, 2010. The termination of the authority shall not affect the validity of contracts or subcontracts that are awarded or modified during the period of the pilot program, without regard to whether the contracts or subcontracts are performed during the period.

''(f) NONTRADITIONAL DEFENSE CONTRACTOR DEFINED.—In this section, the term 'nontraditional defense contractor' has the meaning provided by section 2302(9) of title 10, United States Code.

''(g) FOLLOW-ON PRODUCTION CONTRACTS.—(1) A transaction entered into under this section for a prototype project that satisfies the conditions set forth in subsection (d)(1)(B)(i) may provide for the award of a follow-on production contract to the participants in the transaction for a specific number of units at specific target prices. The number of units specified in the transaction shall be determined on the basis of a balancing of the level of the investment made in the project by the participants other than the Federal Government with the interest of the Federal Government in having competition among sources in the acquisition of the product or products prototyped under the project.

''(2) A follow-on production contract provided for in a transaction under paragraph (1) may be awarded to the participants in the transaction without the use of competitive procedures, notwithstanding the requirements of section 2304 of title 10, United States Code, if—

''(A) competitive procedures were used for the selection of parties for participation in the transaction;

''(B) the participants in the transaction successfully completed the prototype project provided for in the transaction;

''(C) the number of units provided for in the follow-on production contract does not exceed the number of units specified in the transaction for such a follow-on production contract; and

''(D) the prices established in the follow-on production contract do not exceed the target prices specified in the transaction for such a follow-on production contract.

''(h) APPLICABILITY OF PROCUREMENT ETHICS REQUIREMENTS.—An agreement entered into under the authority of this section shall be treated as a Federal agency procurement for the purposes of section 27 of the Office of Federal Procurement Policy Act ([former] 41 U.S.C. 423) [now 41 U.S.C. 2101 et seq.].

''(i) PERIOD OF AUTHORITY.—The authority to carry out projects under subsection (a) shall terminate at the end of September 30, 2013.''

### § 2371a. Cooperative research and development agreements under Stevenson-Wydler Technology Innovation Act of 1980

The Secretary of Defense, in carrying out research projects through the Defense Advanced Research Projects Agency, and the Secretary of each military department, in carrying out research projects, may permit the director of any federally funded research and development center to enter into cooperative research and development agreements with any person, any agency or instrumentality of the United States, any unit of State or local government, and any other entity under the authority granted by section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a). Technology may be transferred to a non-Federal party to such an agreement consistent with the provisions of sections 11 and 12 of such Act (15 U.S.C. 3710, 3710a).

(Added and amended Pub. L. 104–201, div. A, title II, § 267(c)(1)(A), (B), Sept. 23, 1996, 110 Stat. 2468; Pub. L. 105–85, div. A, title X, § 1073(a)(50), Nov. 18, 1997, 111 Stat. 1903.)

CODIFICATION

The text of section 2371(i) of this title, which was transferred to this section, redesignated as text of section, and amended by Pub. L. 104–201, § 267(c)(1)(A), (B), was based on Pub. L. 103–355, title I, § 1301(b), Oct. 13, 1994, 108 Stat. 3286.

AMENDMENTS

1997—Pub. L. 105–85 inserted ''Defense'' before ''Advanced Research Projects Agency''.

1996—Pub. L. 104–201 transferred section 2371(i) of this title to this section, added section catchline, and

J

This page is intentionally left almost blank.

# Appendix II: Agencies Authorized to Use Other Transaction Agreements and their Statutory Authorities

| Agency | Other transaction authority as currently enacted[a] | Public Law providing initial authorization |
|---|---|---|
| Department of Defense (DOD) | | |
| *For research, development, and demonstration activities* | 10 U.S.C. § 2371 | Pub. L. No. 101-189, § 251 (1989) |
| *For prototype activities* | 10 U.S.C. § 2371 note | Pub L. No. 103-160, § 845 (1993) |
| Department of Energy (DOE) | 42 U.S.C. § 7256 | Pub. L. No. 109-58, § 1007 (2005) |
| Advanced Research Projects Agency-Energy (ARPA-E) | 42 U.S.C. § 16538 | Pub. L. No. 111-358, § 904 (2011) |
| Department of Health and Human Services (HHS) | 42 U.S.C. § 247d-7e | Pub. L. No. 109-417, § 401 (2006) |
| National Institutes of Health (NIH) | | |
| *For National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program* | 42 U.S.C. § 285b-3 | Pub. L. No. 92-423, § 3 (1972) |
| *For Common Fund* | | |
| *For certain demonstration projects* | Consolidated Appropriations Act, 2015, Pub. L No. 113-235,div. G, title II, § 213,128 Stat. 2487 | Pub. L. No. 108-199, div. E, title II, § 221, 118 Stat. 256 (2004) |
| *For Cures Acceleration Network* | 42 U.S.C. § 284n | Pub. L. No. 109-482, § 105 (2007) |
| | 42 U.S.C. § 287a | Pub L. No. 111-148, § 10409 (2010) |
| Department of Homeland Security (DHS) | 6 U.S.C. § 391 | Pub. L. No. 107-296, § 831 (2002) |
| Domestic Nuclear Detection Office (DNDO) | 6 U.S.C.§ 596 | Pub. L. No. 109-347, § 501 (2006) |
| Transportation Security Administration (TSA) | 49 U.S.C. § 114(m) | Pub. L. No. 107-71, § 101 (2002) |
| Department of Transportation (DOT) | 49 U.S.C. § 5312 | Pub. L. No. 105-178, § 3015 (1998) |
| Federal Aviation Administration (FAA) | 49 U.S.C. § 106(l) | Pub L. No. 104-264, § 226 (1996) |
| National Aeronautics and Space Administration (NASA) | 51 U.S.C. § 20113(e) | Pub. L. No. 85-568, § 203(c) (1958) |

Sources: GAO analysis of U.S. code and public laws. | GAO-16-209

[a]As of September 30, 2015.

J

# 42 U.S. Code § 285b–3 - National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program; administrative provisions

(a)

(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the "Program") may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of and rehabilitation from such diseases;

(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

(G) the education (including continuing education) and training of scientists, clinical investigators, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and the use of blood and blood products and the management of blood resources;

(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

(J) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director

of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.
(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—
(1) may, after consultation with the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;
(2)
(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;
(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and
(C) may, in consultation with the advisory council for the Institute, acquire, without regard to section 8141 of title 40, by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;
(3) subject to section 284 (b)(2) of this title and without regard to section 3324 of title 31 and section 6101 of title 41, may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions;
(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects; and
(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and education programs, including continuing education and laboratory and clinical research training programs.
Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

*LII has no control over and does not endorse any external Internet site that contains links to or references LII.*

About LII

Contact us

Advertise here

Help

## (2) Goals, priorities, and methods; interagency collaboration

### Terms Used In 42 USC 284n

**fiscal year**: The fiscal year is the accounting period for the government. For the federal government, this begins on October 1 and ends on September 30. The fiscal year is designated by the calendar year in which it ends; for example, fiscal year 2006 begins on October 1, 2005 and ends on September 30, 2006.

**Secretary**: means the Secretary of Health and Human Services. See

The Secretary shall establish goals, priorities, and methods of evaluation for research under paragraph (1), and shall provide for interagency collaboration with respect to such research. In developing such goals, priorities, and methods, the Secretary shall ensure that–

(A) the research reflects the vision of innovation and higher risk with long-term payoffs; and

(B) the research includes a wide spectrum of projects, funded at various levels, with varying timeframes.

## (3) Peer review

A grant may be made under paragraph (1) only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title or has been reviewed by an advisory council composed of representatives from appropriate scientific disciplines who can fully evaluate the applicant.

# (b) High-risk, high-reward research

## (1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary, acting through the Director of NIH, may allocate funds for the national research institutes and national centers to make awards of grants or contracts or to engage in

LawSERVER

Custom Search

Search


> > > > > § 284n

# 42 USC 284n – Certain demonstration projects

Current as of: 2015 | *Check for updates* | *Other versions*

## (a) Bridging the sciences

### (1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary of Health and Human Services, acting through the Director of NIH, (in this subsection referred to as the "Secretary") in consultation with the Director of the National Science Foundation, the Secretary of Energy, and other agency heads when necessary, may allocate funds for the national research institutes and national centers to make grants for the purpose of improving the public health through demonstration projects for biomedical research at the interface between the biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences.

J

other transactions for demonstration projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. The head of a national research institute or national center may conduct or support such high-impact, cutting-edge research (with funds allocated under the preceding sentence or otherwise available for such purpose) if the institute or center gives notice to the Director of NIH beforehand and submits a report to the Director of NIH on an annual basis on the activities of the institute or center relating to such research.

### (2) Special consideration

In carrying out the program under paragraph (1), the Director of NIH shall give special consideration to coordinating activities with national research institutes whose budgets are substantial relative to a majority of the other institutes.

### (3) Administration of program

Activities relating to research described in paragraph (1) shall be designed by the Director of NIH or the head of a national research institute or national center, as applicable, to enable such research to be carried out with maximum flexibility and speed.

### (4) Public-private partnerships

In providing for research described in paragraph (1), the Director of NIH or the head of a national research institute or national center, as applicable, shall seek to facilitate partnerships between public and private entities and shall coordinate when appropriate with the Foundation for the National Institutes of Health.

### (5) Peer review

A grant for research described in paragraph (1) may be made only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title.

## (c) Report to Congress

Not later than the end of fiscal year 2009, the Secretary, acting through the Director of NIH, shall conduct an evaluation of the activities under this section and submit a report to the Congress on the results of such evaluation.

## (d) Definitions

For purposes of this section, the terms "Director of NIH", "national research institute", and "national center" have the meanings given such terms in section 281 of this title.

Ask a question

Subject

Question

Featured Attorneys

42 USC 287a – Cures Acceleration Network

A

B....

Supporting innovation: To carry out the purposes described in this section, the Director of the Center shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to–(A) promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies.(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product

(iii) Matching funds

As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of $1 for every $3 awarded under clauses (i) and (ii), except that the Director of the Center may waive or modify such matching requirement in any case where the Director determines that the goals and objectives of this section cannot adequately be carried out unless such requirement is waived.

(C) The cures acceleration flexible research awards

If the Director of the Center determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of the Center shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.

# K. OT
# POLICY GUIDE

K

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**NATIONAL INSTITUTES OF HEALTH**

# "OTHER TRANSACTIONS" (OT)
# POLICY GUIDE

**May 22, 2017**

TABLE OF CONTENTS


| | Page |
|---|---|
| Table of Contents | 2 |
| Introduction | 4 |
| I – General Information | 5 |
| A. - Legal Authority for the Use of OT | 5 |
| B. – Roles and Responsibilities | 5 |
| C. – Other Relevant Legal Authorities | 6 |
| --- | |
| II - Agreement Planning and Execution | 7 |
| A. - Agreement Planning | 7 |
| B. - Metrics | 8 |
| C. - Intellectual Property | 9 |
| D. - Agreement Funding | 10 |
| E. - Flow Down | 11 |
| F. - Price Reasonableness | 11 |
| G. - Allowable Costs | 11 |
| H. - Accounting and Management Systems | 11 |
| I. - Audit | 12 |
| J. - Cost Sharing | 13 |
| K. - Payments | 14 |
| L. - Property | 14 |
| M. - Changes | 15 |
| N. - Disputes | 15 |
| O. - Termination | 15 |
| P. – Reporting, Administration, and Close-Out | 16 |

Q. – Documentation of Standard Operating Procedures 17

---

APPENDICES

Appendix 1 - Statutes Applicable to "Other Transactions" 18

Appendix 2 – Statutes Inapplicable to "Other Transactions" 28

Appendix 3 – Sample OT Agreement Table of Content 29

## INTRODUCTION

"Other Transactions" (OT) refers to the authority to enter into transactions other than contracts, grants or cooperative agreements. When NIH, or a specific NIH Institute, Center or Office (ICO), has legal authority to award OT agreements (OTAs) and to design an OT award program, it must differentiate OTs from existing assistance/acquisition mechanisms. Requirements for awards issued under OT authorities are generally included in the authorizing language or budgetary appropriation for such awards.

While OTs come with fewer restrictions than other types of awards, they still must be awarded in a manner that ensures proper stewardship of Federal funds and comply with requirements applicable to all Federal funding (regardless of funding mechanism). For this reason, ICOs must be sure that their OT requirements are fully documented and consistently applied. They also must comply with the policy requirements discussed throughout this document, as appropriate.

OTs offer greater flexibility for NIH to develop programs that meet the rapidly advancing needs of biomedical research and may appeal to non-traditional partners that might not typically apply for grants, cooperative agreements, and contracts. ICOs are encouraged to think creatively when designing programs to take advantage of this flexibility.

# I. GENERAL INFORMATION

## A. LEGAL AUTHORITY FOR THE USE OF OTHER TRANSACTIONS

Before pursuing use of an OT funding instrument, it is important to determine whether specific legal authority exists to support use of OT for the designated purpose. Over the years, there have been several examples of specific OT authorities that exist, or have existed, for NIH or for specific ICOs in U.S. public law. It is important to note that authorities may expire, be revised, or be repealed, and must be accompanied by a Congressional appropriation of funding for that purpose. As a result, before developing a biomedical research program for which an OT may be used, consultation with the NIH Legal Advisor's Office (also known as the NIH Branch of the HHS Office of the General Counsel) and the applicable Office of Budget is strongly recommended to confirm that sufficient legal authorization and funding exists.

## B. OTHER RELEVANT LEGAL AUTHORITIES

"Other Transactions" are not required to comply with the Federal Acquisition Regulation (FAR), its supplements, or laws that are limited in applicability to procurement contracts, such as the Truth in Negotiations Act, the Competition in Contracting Act, the Contract Disputes Act, and Cost Accounting Standards (CAS). Similarly, OTs are not subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (Uniform Regulations) (45 CFR Part 75), which are limited in applicability to grants, cooperative agreements, or other forms of Federal financial assistance, nor are OTs subject to the NIH Grants Policy Statement. Although these laws and regulations do not apply to OTs, NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds. The statutes specified in this Policy Guide set many of those standards. This information is provided for guidance only and is not intended to be definitive; other laws may be determined to apply generally to all NIH OTs, or specifically to a particular award depending on the terms of the OT. Thus, it is essential that ICOs consult with the NIH Legal Advisor's office and other relevant offices to ensure the appropriate legal authorities have been addressed.

## C. ROLES AND RESPONSIBILITIES

1. Agreements Officer. Individual responsible for legally committing the government to an OT agreement, and for the administrative and financial aspects of the award.

Agreements Officers must be either warranted contracting officers (at Level III) or grants management officers (at Level III or above) with a level of responsibility, formal training, business acumen, and judgment that enables them to operate in this relatively unstructured environment. Agreements Officers may bind the government only to the extent of the authority delegated to them by the Other Transaction Agreement warrant granted with concurrent approval by the NIH Office of Acquisition Management and Policy and the Office of Policy for Extramural Research Administration.

When negotiating financial and administrative requirements for OT awards, the Agreements

Officer should consider typical FAR procedures and clauses, principles from the Uniform Regulations, grants policies, commercial business practices, as well as other OT agreements; but ultimately is responsible for negotiating clauses and terms of award that appropriately reflect the risk to be undertaken by all parties on their particular project. If a policy or procedure, or a particular strategy or practice, is in the best interest of the government and is not specifically addressed in this Guide, nor prohibited by law or Executive Order, the government team should not assume it is prohibited. The Agreements Officer should take the lead in encouraging business process innovations and ensuring that business decisions are made on an informed basis, in good faith, and in the honest belief that actions are taken in the best interests of the government.

2. Staff Coordination. While Agreement Officers and Program/Project Managers are expected to work collaboratively on all aspects of an OTA award program, their roles may differ depending on the design of the OT program.

3. Training and Workforce Needs. To ensure the proper management of awards, NIH will develop appropriate training for OTA staff and conduct data-driven workforce assessments to identify the number, skills, location, and competencies of the OTA staff.

## II. AGREEMENT PLANNING AND EXECUTION

### A. AGREEMENT PLANNING

1. Appropriate Safeguards. OT authority provides flexibility to negotiate terms and conditions appropriate for the agreement. This includes assurances that the cost to the government is allocable, necessary, reasonable and realistically reflects the work that will be accomplished, the schedule and other requirements are enforceable, and the payment arrangements promote on-time performance. It is the responsibility of both the Agreements Officer and Program Manager to ensure the terms and conditions negotiated are appropriate for the particular project, and they should consider expected follow-on program needs.

There is a public expectation that Federal funding opportunities are made widely available to all parties and that open competition ensures only the most qualified applicants receive funding. Therefore, ICOs are encouraged to make OT funding opportunities known to a wide audience and to allow potential applicants to compete for funds to the maximum extent practicable. Examples of competitive announcements are in the forms of Funding Opportunity Announcements (FOAs), Broad Agency Announcements (BAAs) and Research Announcements (RAs). If competition is not practicable or appropriate for a given ICO or program, the Agreements Officer should document the file accordingly.

2. Peer Review. Current peer review regulations (42 CFR Part 52h) and the Public Health Service Act (as enacted in section 492 (42 U.S.C. 289a)) apply specifically to grants (and by definition, cooperative agreements), as well as contracts. While these authorities do not apply directly to OT awards, historically some NIH OT authorities have required some level of peer review to occur. Consultation with the NIH Legal Advisor's Office is recommended to determine whether and to what extent peer review requirements apply to a particular proposed OT program.

3. NIH Legal Advisor's Review. OTA staff should submit the agreement to the NIH Legal Advisor's office before execution to ensure compliance with applicable statutes, regulations, and policies. ICOs are also encouraged to discuss new solicitations and OTA policies with the NIH Legal Advisor's office, as appropriate.

4. Negotiated Agreement and Award. Prior to issuing an agreement, an ICO must document its rationale for using an OT, as opposed to a conventional funding instrument, and track circumstances throughout the life of the agreement to ensure the use of OT authority continues to be appropriate. Reasons to use OT authority may include, among others:

- Seeking participation by nontraditional research performers, such as:
    - Small businesses, patient advocacy organizations, educational institutions, pharmaceutical companies, foreign entities, or other organizations that are typically not inclined to work with the federal government;
    - Consortia comprised of the entities above who collaborate as peers with the government to manage the project and share its costs;
    - Non-profit entities that have an interest in the goals of the OT program; and

- Individuals.

- Requiring fluid implementation of a program - awards may need to begin quickly on a small scale, with additional funds added later if particular milestones are met, or awards may need to be downsized or discontinued.

- Nontraditional review and award management practices are needed because the science is expected to be highly evolving, with requirements for additional aims or expertise added to, or removed from, the project throughout the award period.

- The requirement for collaborative involvement by the government in the technical direction and oversight of the research, which can be akin to partnering. Examples of involvement can include participation in progress reviews and decisions on future efforts or direction. The government may also be a voting or non-voting member of the consortium.

Second, the ICO should document internal controls for assessing the risks associated with meeting the project objectives, including estimating the risk's significance, assessing the likelihood for the risk to occur, and deciding how to manage the risks and what specific actions to undertake. The documentation should address project-specific risks, such as fairness and reasonableness of cost estimates, but may also rely on broader risk management policies to inform overarching issues.

Third, the ICO's internal documentation should include a determination that the proposed awardee is a responsible party and is not on the excluded parties list in the System for Award Management (SAM), or otherwise prohibited from receiving federal appropriations.

Finally, the ICO's internal documentation must also address the reasonableness of the anticipated cost and applicable terms and conditions. This should include highlighting the key agreement clauses and explain why the proposed terms and conditions provide adequate safeguards to the government and are appropriate for the project.

ICOs should periodically review their internal processes to ensure that they include the defined elements identified within this section in their OTA files.

## B. METRICS

Agreements Officers and Program Managers should establish and track any metrics that measure the value or benefits directly attributed to the use of the OT authority. Since OTs are too distinct from other funding approaches to perform a statistical comparison, traditional metrics, such as cost growth, schedule slips and performance shortfalls, are generally inappropriate. Therefore, such metrics must be specifically tailored to the objectives of the OT in question.

If OTA staff establish other metrics that could be used across the board to measure the value or benefits directly attributed to the use of the OT authority, they are encouraged to submit this information to the relevant policy offices in the NIH Office of the Director, such as the NIH

Office of Acquisition Management and Policy and the Office of Policy for Extramural Research Administration.

C. INTELLECTUAL PROPERTY

1. General. Agreements Officers can negotiate terms and conditions different from those typically used in other extramural funding instruments. However, in negotiating these clauses, the Agreements Officer must consider other laws that affect the government's use and handling of intellectual property, such as the Bayh-Dole Act (35 U.S.C. 200-212); the Trade Secrets Act (18 U.S.C. 1905); the Freedom of Information Act (5 U.S.C. 552); 10 U.S.C. 130; 28 U.S.C. 1498; 35 U.S.C. 205 and 207-209; and the Lanham Act, partially codified at 15 U.S.C. 1114 and 1122. Flexibility in the negotiation of IP rights is one of the rationales for using an OT.

1.1. Intellectual property (IP) collectively refers to rights governed by a variety of different laws, such as patent, copyright, trademark, data, and trade secret laws. Due to the complexity of intellectual property law and the critical role of intellectual property created under research projects, OTA staff should obtain the assistance of the NIH Legal Advisor's office, the appropriate technology transfer office representative, or the OPERA Division of Extramural Inventions and Technology Resources, as appropriate, as early as possible in the negotiation process.

1.2. OTA staff should assess the impact of intellectual property rights on the government's total life cycle cost of the research. Obtaining Insufficient intellectual property rights hinder the government's ability to adapt the developed research for use outside the initial scope of the project. Conversely, where the government overestimates the intellectual property rights it will need, the government's attempt to negotiate for unnecessary or unused rights may dissuade parties from entering into an Agreement and increase the cost of the project. Bearing this in mind, the OTA staff should carefully assess the intellectual property needs of the government. The negotiation should focus on acquiring only those rights and deliverables necessary to satisfy the government's need.

1.3. The negotiated intellectual property clauses should facilitate the agreement's strategy and balance the relative investments and risks borne by the parties. Due to the complex nature of intellectual property clauses, it may be advisable to incorporate the clauses in full text.

1.4. OTA staff should ensure that the disputes clause included in the agreement can accommodate specialized disputes arising under the intellectual property clauses, such as the exercise of intellectual property "march-in rights," reporting requirements, or the validation of restrictions on technical data, computer software or other rights provided to the Government.

1.5. OTA staff should consider how the intellectual property clauses applicable to the awardee flow down to others, including whether to allow others to submit any applicable intellectual property licenses directly to the government.

1.6. OTA staff should consider restricting awardees from licensing research developed under the Agreement to domestic or foreign firms under circumstances that would hinder potential domestic manufacture or use of the research. Such restrictions need to be consistent with NIH's public access and data policies or a waiver should be submitted. Consideration

should be given to whether a restriction facilitates the commercial development or research use of products or services that will benefit public health. If a restriction on future research by the Government, non-profits, or for-profits is necessary, a justification for such restrictions on future research should be developed by the ICO OTA staff and submitted to the OPERA Division of Extramural Inventions and Technology Resources. The Agreements Officer must also be aware that export restrictions prohibit awardees from disclosing or licensing certain research to foreign firms.

1.7. Additional Matters. OTA staff should consider including in the intellectual property clauses any additional rights available to the government in the case of inability or refusal of the private party or consortium to continue to perform the Agreement. It may also be appropriate to consider negotiating time periods after which the government will automatically obtain greater rights.

1.8. Enforcement and "March-in Rights." The Agreements Officer should consider negotiating enforcement rights similar to the "march-in rights" set forth in the Bayh-Dole Act (see 35 U.S.C. 203), or other remedies enforceable by the government should the awardee fail to comply with the use or restriction of the intellectual property rights in the OTA (e.g., fail to commercialize the results of the research, make the research results publicly available as required under the OTA, or make them available in the case of an exigent public health need).

D. AGREEMENT FUNDING

1. Funding Requirements. Federal funding requirements are applicable to OTs and are contained in agency fiscal regulations. No Agreements Officer or employee of the government may create or authorize an obligation in excess of the funds available, or in advance of appropriations (Anti-Deficiency Act, 31 U.S.C. 1341), unless otherwise authorized by law.

2. Funding Restrictions. Examples of laws not applicable to NIH OTs include the Buy American Act (41 U.S.C. 8303) and the Berry Amendment (10 U.S.C. 2533a). However, Agreements Officers should consult with legal counsel to determine the applicability of funding restrictions found in appropriations acts.

3. Limits on Government Liability. In accordance with appropriations law, when agreements provide for incremental funding or include cost-reimbursement characteristics, the Agreements Officer should include appropriate clauses that address the limits on government obligations.

E. FLOW DOWN

OTA staff should consider which of the OT clauses the awardee should be required to flow down to participants of the agreement. In making this decision, both the needs of the government (e.g., audits) and the protections (e.g., intellectual property) that should be afforded to all participants should be considered.

F. PRICE REASONABLENESS

The government must be able to determine that the amount of the agreement is fair and reasonable. The ICO may require the awardees to provide whatever data is needed to establish price reasonableness, including commercial pricing data, market data, parametric data, or cost information. However, OTA staff should attempt to establish price reasonableness through other means before requesting cost information. If cost information is needed to establish price reasonableness, the government should obtain the minimum cost information needed to determine that the amount of the agreement is fair and reasonable.

G. ALLOWABLE COSTS

1. General. This section applies only when the agreement uses amounts generated from the awardee's financial or cost records as the basis for payment (e.g., interim or actual cost reimbursement including payable milestones that provide for adjustment based on amounts generated from the awardee's financial or cost records).

2. Use of Funds. The agreement should stipulate that federal funds and the OT awardee's cost sharing funds, if any, are to be used only for costs that a reasonable and prudent person would incur in carrying out the project.

3. Allowable Costs Requirements. In determining whether to include some or all of the allowable cost requirements contained in the Cost Principles (48 CFR Part 31) or Uniform Regulations (45 CFR Part 75), the Agreements Officer should consider the guidance contained in the section entitled "Accounting Systems."

4. Profit/Fee. Profit or fee may be permitted for awardees of OTs, but since most OTAs implement collaborative partnerships to advance research, it may not be considered appropriate for an OTA to be a profit or fee bearing instrument.

5. Travel, Transportation and Subsistence Expenses. Generally, an appropriation may not be used for travel, transportation, and subsistence expenses of non-federal individuals for a meeting unless specifically provided by law. 31 U.S.C. 1345. While procurement laws and the FAR, including the costs principles applicable under the FAR, do not apply to OT awards, the obligation of federal funds remains subject to federal appropriations laws. For guidance on when appropriated funds may be used to pay for such expenses, Agreement Officers should refer to applicable NIH policies (e.g. NIH Travel Policies and Procedures (Manual Chapter 1500)).

H. ACCOUNTING AND MANAGEMENT SYSTEMS

1. General. An important component of the use of OT agreements is the ability for awardees

to use appropriate accounting and management systems that may differ from those used for other award types. While not all agreements may require this option, the flexibility is available and the Agreements Officer should ensure it is addressed in the award document.

2. Applicability. This section applies only when the agreement uses amounts generated from the awardee's financial or cost records as the basis for payment (e.g., interim or actual cost reimbursement including payable milestones that provide for adjustment based on amounts generated from the awardee's financial or cost records). In these cases, the Agreements Officer should consider including a clause that requires the awardee to consider their accounting and management system capabilities when the awardee is expected to receive payments exceeding the Truth in Negotiations Act (TINA) threshold, as adjusted for inflation (41 U.S.C. 1908 and 41 U.S.C. 1502(b)(1)(B)), that will be based on amounts generated from their financial or cost records.

3. Financial System Capability. When structuring the agreement, the Agreements Officer must consider the capability of the awardee's accounting and management systems in accordance with Generally Accepted Accounting Principles (GAAP). Agreements should require that adequate records be maintained to account for federal funds received and cost-sharing, if any. The Agreements Officer should not enter into an agreement that provides for payment based on amounts generated from the awardee's financial or cost records if the awardee does not have an accounting and management system capable of identifying and accumulating the amounts/costs to individual agreements. Any system that segregates direct costs from indirect costs, identifies and accumulates direct costs by project and provides for an equitable and consistent allocation of indirect costs to intermediate and final cost objectives is acceptable.

3.1. When the awardee has a system capable of identifying the amounts/costs, the agreement should utilize the awardee's existing accounting and management system to the maximum extent practical. The agreement should include a clause that documents the basis for determining the interim or actual amounts/costs, i.e., what constitutes direct versus indirect costs and the basis for allocating indirect costs.

I. AUDIT.

1. General. Where appropriate, Agreements Officers should include audit access clauses in the agreement. In addition, Agreements Officers should require the awardee to insert an appropriate audit access clause in awards to key participants.

2. Frequency of Audits. Audits of agreements will normally be performed only when the OTA staff determine it is necessary to verify awardee compliance with the terms of the agreement.

2.1. Indirect Cost Rate Agreements. In the event a cost reimbursable payment schedule is utilized for the OTA, the NIH Division of Financial Advisory Services (DFAS) within OAMP, or the cognizant audit group, should be consulted to establish negotiated indirect cost rates.

3. Means of accomplishing any required audits. The provisions of the Single Audit Amendments Act of 1996 (31 U.S.C. 7501 *et seq.*) should be followed when the awardee is a state government, local government, or nonprofit organization whose federal procurement

contracts and financial assistance agreements are subject to that Act. The Single Audit Act is implemented by Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 200). The Single Audit Act is intended to minimize duplication of audit activity and provides for the use of independent public accountants, to conduct annual audits of state or local governments and educational or other nonprofit institutions.

4. Length and extent of access. Agreements should provide for the Agreements Officer's authorized representative to have direct access to sufficient records to ensure full accountability for all government funding or cost share under the agreement for a specified period of time after final payment, unless notified otherwise by the Agreements Officer.

## J. COST SHARING

1. General. Cost sharing is an option as an administrative requirement, unless the authorizing legislation for the particular OT program specifies otherwise. If included, it shall be stated in the application instructions/guidance for each particular OT program. When the potential awardee willingly offers cost sharing, or when the government requires it for a specific project, the NIH Agreements Officer may include it in the negotiated agreement. The two types of cost sharing are "cash" – outlays of funds to support the total project, and "in-kind" – value of equipment, materials, or other property used in performance of the work. "In-kind" contributions and IP are calculated at reasonable fair market value and the burden of proof is with industry.

2. Restrictions.

2.1. Costs Incurred Before OT Agreement. The non-federal amounts counted as provided, or to be provided, by a party to the OT agreement (including any entity that participates in the performance of the agreement or a subordinate element of the party or entities) may not include costs that were incurred before the date on which the OT agreement becomes effective. Costs that were incurred by a party, entity or subordinate element after the beginning of negotiations, but prior to the date the OT agreement becomes effective may be counted for purposes of this subsection as being provided, or to be provided, by the party, entity or subordinate element to the OT agreement if and to the extent that the Agreements Officer determines in writing that (i) the party, entity or subordinate element incurred the costs in anticipation of entering into the OT agreement; and (ii) it was appropriate for the party, entity or subordinate element to incur the costs before the OT agreement became effective in order to ensure the successful implementation of the OT agreement.

2.2. Other Constraints. The cost share cannot include foregone profit/fee, cost of money, or the cost of prior research.

3. Nature of cost-share. The Agreements Officer should understand and evaluate the nature of the cost share. Any part of the cost share that includes an amount for a fully depreciated asset should be limited to a reasonable usage charge. In determining the reasonable usage charge, the Agreements Officer should consider the original cost of the asset, total estimated remaining useful life at the time of negotiations, the effect of any increased maintenance charges or decreased efficiency due to age, and the amount of depreciation previously charged to

procurement contracts and subcontracts. In determining the amount of cost sharing, the agreement should not count, as part of the awardee's cost share, the cost of government-funded research, prior R&D, or indirect costs that are not allocable to the "other transaction."

4. Equity when sharing costs. OTAs that require cost sharing should generally provide for adjustment of government or private sector investment or some other remedy if the other party is not able to make its required investment. Such agreements should also address the procedures for verifying cost share contributions, the conditions that will trigger an adjustment and the procedures for making the adjustment.

K. PAYMENTS

1. General. There are three primary payable milestone options available for OTs: fixed, adjustable (cost reimbursable), and a hybrid approach that combines these two options. The agreement must identify clearly the basis and procedures for payment. Consider the following in drafting the agreement payment clauses:

- Are payments based on amounts generated from the awardee's financial or cost records? In determining whether the agreement should provide for reimbursement based on the awardee's financial or cost records, the Agreements Officer should consider the guidance contained in the section entitled "Accounting and Management Systems".

- Are the payment amounts subject to adjustment during the period of performance?

- If the payments can be adjusted, what is the basis and process for the adjustment?

- What are the conditions and procedures for final payment and agreement close-out?

- Is an interim or final audit of costs needed?

2. Payable Milestones. There is not one uniform clause or set of procedures for payable milestones. Payable milestone procedures vary, depending on the inherent nature of the agreement.

2.1. Fixed payable milestones. Agreements with fixed price characteristics may contain payable milestone clauses that do not provide for adjustment based on amounts generated from the awardee's financial or cost records. In these cases, this fact should be clear in the agreement and the negotiated payable milestone values should be commensurate with the estimated value of the milestone events.

2.2. Adjustable payable milestones. Alternatively, agreements may provide for payable milestones to be adjusted based on amounts generated from the awardee's financial or cost records. When this is the case, the agreement must address the procedures for adjusting the payable milestones, including consideration of the guidance contained in the section entitled "Accounting and Management Systems". Payable milestones should be adjusted as soon as it is reasonably evident that adjustment is required under the terms of the agreement.

3. Provisional Indirect Rates on Interim Payments. When the agreement provides for interim

reimbursement based on amounts generated from the awardee's financial or cost records, any indirect rates used for the purpose of that interim reimbursement should be no higher than the awardee's provisionally approved indirect rates, when such rates are available.

L. PROPERTY

The government is not required to take title to property (not including intellectual property) acquired or produced by a private party signatory to an OTA except property the agreement identifies as deliverable property. In deciding whether or not to take title to property under an OT, the government should consider whether known or future efforts may be fostered by government ownership of the property.

M. CHANGES

1. Method of change. The agreement should address how changes will be handled, including notification requirements. The Agreements Officer should consider whether the government should have the right to make a unilateral change to the agreement, or whether all changes should be bilateral. A process for managing unauthorized changes that have not been previously agreed to by the parties must also be established in the OT agreement.

2. Need for unilateral change. The government may need the right to make a unilateral change to the agreement to ensure that critical requirements are met, or to efficiently manage minor, administrative changes. The fact that unilateral changes may lead to disputes and claims, particularly in agreements with fixed-priced characteristics, should be considered.

3. Accounting Systems. In determining the method to be used to compute the amount of the equitable adjustment (monies due as a result of a change), the Agreements Officer should consider the guidance contained in the section entitled, Accounting and Management Systems.

N. PROTESTS AND DISPUTES

1. General. Agreements Officers should ensure each OT addresses the basis and procedures for resolving disputes. The Agreements Officer may negotiate disputes language that provides for final resolution to be made at a higher level, either jointly or by a Government official.

2. Disputes arising before the award is issued. The Government Accountability Office (GAO) protest rules do not apply to OTs. GAO's bid protest jurisdiction is limited to determining whether an agency has statutory authority to enter into an OTA and whether the OTA at issue falls within the agency's specified statutory authority. Solicitations and announcements that envision the use of an OT should stipulate the offerors'/ applicants' rights and procedures for filing a protest with the agency, using either the agency's established agency-level protest procedure or an OT-specific procedure. This stipulation could include a statement that there is no right of protest/appeal.

3. Disputes arising after the award is issued. Although OTs are not subject to the Contract Disputes Act (41 U.S.C. 7101-7109), an OT dispute can be the subject of an injunction action in the U.S. Court of Federal Claims. Agreements Officers should seek to reduce the risk of costly litigation by negotiating disputes clauses which maximize the use of Alternative Dispute Resolution when possible and appropriate.

Although OTs are not subject to GAO's bid protest jurisdiction, GAO may review the propriety of the agency's use of OT authority and challenge the decision not to use a traditional procurement instrument.

## O. TERMINATION

1. Basis for termination. OTA staff should consider termination clauses (both for convenience and for cause) in light of the circumstances of the particular OT project. A unilateral government termination right is appropriate. In cases in which there is an apportionment of risk allocation and cost shares, it could be appropriate to allow an awardee termination right as well. Either party may terminate in this scenario per the terms of the agreement between the parties. Such a termination could occur in instances in which an awardee discovers that the expected commercial value of the research does not justify continued investment or the government fails to provide funding in accordance with the agreement. Termination clauses should identify the conditions that would permit terminations and include the procedures for deciding termination settlements.

2. Remedies. Agreements Officers should consider whether the government should be provided the opportunity to terminate the award, tailoring clauses to discourage defaults in line with the agreement's overall allocations of risk. When agreements provide the government the right to terminate or provide the awardee the right to terminate, the agreement should address what remedies are due to the government.

3. Accounting Systems. If termination settlement costs are expected to be the subject of negotiation based on amounts generated from the awardee's financial or cost records, then the Agreements Officer should consider the guidance contained in the sections entitled Allowable Costs, Accounting and Management Systems and Audit.

## P. REPORTING, ADMINISTRATION, AND CLOSEOUT

1. Performance Reporting. The awardee is responsible for managing and monitoring each project and all participants. The solicitation and resulting agreement should identify the frequency and type of performance reports necessary to support effective management. Effective performance reporting addresses cost, schedule and technical/scientific progress, and may also include reporting of subject inventions. It discusses the progress achieved compared to the anticipated progress, as well as the budgeted and actual costs. It is vital that Agreements Officers receive all pertinent documentation to ensure the effective administration of the agreement.

1.1. Teaming Arrangements. If an awardee is teaming with other companies (e.g., consortium, joint venture) for the project, the Agreements Officer should consider if performance reporting on all team members would be appropriate.

1.2. Forms and Formats for Reporting. Any collection of information from ten or more people or organizations, including performance and financial reporting, must be approved by OMB before the collection can occur unless a statutory exemption is determined to apply. While

the Research Performance Progress Report (RPPR) has been approved for this use with OT agreements, OTA staff may utilize other forms or formats for reporting as long as they have received any necessary OMB approval for the requested reports.

2. Link to Payment. OTA staff, should consider whether reports required of the OT awardee are important enough to warrant establishment of line items or separate payable milestones, or if report requirements should be incorporated as a part of a larger line item or payable milestone.

3. Corrective action. It is the Agreements Officer's responsibility to ensure that all terms and conditions of the agreement are being satisfied. If the OT awardee has failed to comply with any term of the agreement, the Agreements Officer must take timely, appropriate action to remedy the situation.

4. Agreement Close-out. Standard close-out procedures used by the NIH acquisition and assistance communities may be utilized for OTAs and the requirements listed in the award document.

Q. Documentation of Standard Operating Procedures

1. Developing ICO-Specific OTA Policies. The requirements listed in this Policy Guide are not intended to address every issue OT programs will encounter. ICOs retain the authority to include additional requirements on OTA awardees and to provide further guidance on specific issues than what is provided in this Policy Guide. Where additional requirements are included in an ICO-specific OTA policy, the ICO should make clear to potential and current awardees that such additional requirements apply as part of the terms of award.

2. Documentation and Consistent Treatment. All ICO-specific policies and procedures must be fully documented and implemented consistently among all OTA awards issued by the ICO for a particular program, and must comply with the requirements of this Policy Guide.

## APPENDIX 1

## LAWS THAT MAY BE APPLICABLE TO "OTHER TRANSACTIONS"

For the purposes of identifying public policy requirements and appropriations laws that may be applicable to all NIH funding, this document highlights variouspublic policies and appropriations language that is applicable to NIH grants/cooperative agreements or other award types. However, please note that Other Transactions are not grants, cooperative agreements, nor contracts and therefore, the public policies that are outlined in this Appendix may not be applicable to Other Transactions unless the agency, in consultation, with the Office of General Counsel (OGC) states otherwise based on the specific OT program requirements and its applicable laws that govern the OT, which will vary depending on the nature of the OT program. Similarly, other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms of the OTA. In the interest of maintaining as much flexibility as feasible, programs may consult with OGC to discuss whether incorporation of the requirements outlined within this Appendix, or other requirements, are warranted under applicable program legislation.

### Debarment and Suspension

HHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for HHS' nonprocurement programs and activities. A "nonprocurement transaction" means any transaction, regardless of type (excluding procurement contracts), including but not limited to grants, cooperative agreements, scholarships, fellowships, and loans (2 CFR 180.970). NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, awardees of NIH OT awards are required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in a covered transaction prior to entering into the covered transaction.

### Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:

1. Airline "Open Skies" Agreement. A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States.

   The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued

Guidance October 6, 2010. Pursuant to the amendment, federal contractors and awardees (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and awardees must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the European Union. For additional information, please see the text of the Amendment and GSA Bulletin FTR 11-02. For information on other "open skies" agreements in which the United States has entered, refer to GSA's Web site: http://www.gsa.gov/portal/content/103191.

2. Involuntary Rerouting. Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.

3. Travel To and From the U.S. Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

4. Travel Between Points Outside the U.S. Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

5. Short Distance Travel. For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

**Metric System**

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and awardee-prepared reports, publications, and OT award-related documents should be in metric.

**National Environmental Policy Act**

All NIH OT awards, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires Federal agencies to consider the reasonably foreseeable environmental consequences of all OT-supported activities. As part of NIH's implementation of this Act, awardees are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from OT-supported activities, or certify that no such impacts will arise upon receipt of an OT award. In addition, NIH has determined that most NIH OT awards are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

**Pro-Children Act of 1994**

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH OT awards are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may

result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.
Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH OT award should be directed to the AO.

- **Research Misconduct**

  Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" specifies awardee responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity, and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities (http://www.ori.dhhs.gov).

- **Research Involving Recombinant or Synthetic Nucleic Acid Molecules**

  *The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* (November 2013 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the *NIH Guidelines* is available at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelinesOT Policy Guide Draft - 150930 NCO.doc.

  According to the *NIH Guidelines*, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3)molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

  Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. Two specific requirements of the *NIH Guidelines* are discussed below, but the awardee should carefully review the *NIH Guidelines* in their entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.
  Recombinant or synthetic nucleic acid research involving select agents also is subject to

pertinent CDC and USDA regulations, 42 CFR 73, Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins.

- **Select Agents**

  Domestic awardees who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR 73 and 9 CFR 121 and Section 3 of 7 CFR 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

- **USA Patriot Act**

  The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. Chapter 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. “Restricted persons,” as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent.

- **Salary Cap/Salary Limitation**

  None of the funds appropriated in the governing appropriation Act for the NIH shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is on the NIH Office of Extramural Research Salary Cap Summary webpage.

- **Gun Control**

  NIH funds may not be used, in whole or in part, to advocate or promote gun control.

- **Lobbying Prohibition**

  NIH appropriations have in the past included restrictions similar to the following text from the 2016 appropriation:

(a) No part of any appropriation contained in the Consolidated Appropriations Act, 2016, or transferred pursuant to Section 4002 of Public Law 111–148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself,

or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

(b) No part of any appropriation contained in this Act or transferred pursuant to Section 4002 of Public Law 111–148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

(c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

**Restriction on Abortion Funding**

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term ‘‘health benefits coverage’’ means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

**Exceptions to Restrictions on Abortions**

(a) The limitations established in the preceding section shall not apply to an abortion— (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.
(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).
(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).
(d) (1) None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. (2) In this subsection, the term ‘‘health care entity’’ includes an individual physician or other health

care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

- **ClinicalTrials.gov Requirements**

  Applicants and awardees should familiarize themselves with the requirements regarding ClinicalTrials.gov, including the authorizing statute, as amended (42 U.S.C. 282(j)), the implementing regulations (42 CFR Part 11), and the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. In particular, awardees should be aware that if an applicable clinical trial is funded in whole or in part by an NIH OT award, any application or progress report shall include a certification that the Responsible Party has made all required submissions to ClinicalTrials.gov. For additional information, see https://clinicaltrials.gov/.

- **Human Stem Cell Research**

  Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, effective July 7, 2009, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

  For the purpose of the NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. Induced pluripotent stem cells are human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.

  NIH awardees may use hESCs that have been approved by NIH in accord with the NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry, or may establish eligibility of specific cell lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and awardees must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/awardee must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used.

- **Human Embryo Research and Cloning Ban**

  NIH funds may not be used to support human embryo research. NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term “human

embryo or embryos" includes any organism not protected as a human subject under 45 CFR 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In addition to the statutory restrictions on human fetal research under subsection 498(b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

- **Human Fetal Tissue Research**

  Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

  Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects. 45 C.F.R. 46.204 and 46.206 may be specifically relevant.

  The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements, particularly Section 498B. When an application involving human fetal tissue research is submitted to NIH, the AOR's signature certifies that researchers using these tissues are in compliance with Section 498B of the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

  Current federal laws and regulations require informed consent for research involving the transplantation of human fetal tissue and for research with human fetal material associated with information that can identify a living individual. Most states require informed consent for the use of fetal tissue in research. Accordingly, NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.

  When obtaining primary human fetal tissue for research purposes, NIH expects awardees of NIH OT awards to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

- **Research on Transplantation of Human Fetal Tissue**

  Sections 498A and 498B of the Public Health Service Act, 42 USC 289g-1 and 289g-2,

contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:
  - for therapeutic transplantation research,
  - without any restriction regarding the identity of individuals who may receive the transplantation, and
  - without the donor knowing the identity of the recipient.
- The attending physician must sign a statement that he/she has:
  - obtained the tissue in accordance with the donor's signed statement and
  - fully disclosed to the donor his or her intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.
- In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that he/she:
  - obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
  - did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
  - performed the abortion in accordance with applicable State and local laws.
- The PD/PI must sign a statement certifying that he/she is aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The PD/PI must certify in writing that he/she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the AOR that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the OT award, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the OT awardee. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA has jurisdiction over fetal cells and tissues intended for use in humans and requests that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm105857.htm.

- **Human Subjects Protections**

  The HHS regulations for the protection of human subjects, in 45 CFR 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the NIH or other HHS components.

  The HHS regulations stipulate that the awardee organization(s), whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in HHS-supported activities (46.101(a) and 46.103(a)). Awardee organization(s) "engaged" in human subjects research must obtain a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects.

- **Animal Welfare Requirements**

  The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all awardee organizations receiving PHS support for research or related activities using live vertebrate animals. Awardee organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

  The PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the awardee to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495).

- **Promotion or Legalization of Controlled Substances**

  Awardees are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by Section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the awardee notifies the AO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine

therapeutic advantage.

- **Dissemination of False or Deliberately Misleading Information**

  None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

- **Restriction on Distribution of Sterile Needles**

  NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

- **Restriction of Pornography on Computer Networks**

  NIH appropriations since FY2014 have included the following restriction:

  a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

  b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities."

- **Trafficking in Persons, 22 US Code 7104**

  Agencies are authorized to terminate awards, without penalty, if the recipient or a subrecipient —

  1. Engages in severe forms of trafficking in persons during the period of time that the award is in effect;
  2. Procures a commercial sex act during the period of time that the award is in effect; or
  3. Uses forced labor in the performance of the award or subawards under the award.

- **Federal Information Security Management Act**

  All information systems, electronic or hard copy, which contain Federal data need to be protected from unauthorized access.

- **Comptroller General Access**

  OT agreements that provide for total government payments in excess of $5,000,000 must include the following clause to provide for Comptroller General access to records.

*"To the extent that the total Government payment under this Agreement exceeds $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any entity that participates in the performance of this Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any entity that has already entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that grants audit access by a Government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement."*

## APPENDIX 2

## LAWS THAT MAY BE INAPPLICABLE TO "OTHER TRANSACTIONS"

This list of laws that apply to procurement contracts, but that are not necessarily applicable to OTs, is provided for guidance only and is not intended to be definitive. To the extent that a particular requirement is a funding or program requirement, or is not tied to the type of instrument used, it would generally apply to an OT, e.g., fiscal and property laws. Each law must be reviewed carefully to ensure it does or does not apply to a particular funding arrangement using an OT. This appendix may be updated periodically, as needed.[1]

1. Sections 202-204 of the Bayh-Dole Act, 35 U.S.C. 202-204 - Prescribes government's rights in patentable inventions made with government funds.

2. Competition in Contracting Act, Pub. L. No. 98-369 (1984), as amended, 10 U.S.C. 2304 and 41 U.S.C. 3301 - Promotes the use of competitive procurement procedures and prescribes uniform government-wide policies and procedures regarding contract formation, award, publication, and cost or pricing data.

3. Contract Disputes Act, Pub. L. No. 95-563 (1987), as amended, 41 U.S.C. 601 et seq. - Provides for the resolution of claims and disputes relating to government contracts.

4. Procurement Protest System, Subtitle D of Competition in Contracting Act, Pub. L. No. 98-369 (1984), 31 U.S.C. 3551 et seq. - Provides legal basis for procurement protests by interested parties to the Comptroller General.

5. 31 U.S.C. 1352. Limitation on the use of appropriated funds to influence certain Federal contracting and financial transactions - Prohibits use of funds to influence or attempt to influence government officials or members of Congress in connection with the award of contracts, grants, loans, or cooperative agreements.

6. Antikickback Act of 1986, 41 U.S.C. 51-58 - Prohibits kickbacks in connection with government contracts; provides civil and criminal penalties.

7. Procurement Integrity Provisions, section 27 of the Office of Federal Procurement Policy Act, 41 U.S.C. 423 - Imposes civil, criminal, and administrative sanctions against individuals who inappropriately disclose or obtain source selection information or contractor bid and proposal information.

8. Service Contract Act, 41 U.S.C. 351 et seq., Walsh Healey Act, 41 U.S.C. 35-45; Fair Labor Standards Act, 29 U.S.C. 201-219 - Provide protections for contractor employees by establishing minimum wage and benefit requirements.

9. Drug-Free Workplace Act of 1988, 41 U.S.C. 701-707 - Applies to contracts and grants.

[1] This list is derived from GAO-05-136, *Homeland Security: Further Action Needed to Promote Successful Use of Special DHS Acquisition Authority* (Dec. 2004), at p.6, Table 1.

10. Buy American Act, 41 U.S.C. 10a-d. Provides preferences for domestic end products in production.

## APPENDIX 3

## SAMPLE OT AGREEMENT TABLE OF CONTENT

ARTICLE 1 PARTIES
ARTICLE 2 LEGAL AUTHORITY
ARTICLE 3 SCOPE OF THE AGREEMENT
ARTICLE 4 EFFECTIVE DATE AND TERM
ARTICLE 5 STATEMENT OF OBJECTIVES AND MILESTONES
ARTICLE 6 AGREEMENT ADMINISTRATION
ARTICLE 7 CHANGES, MODIFICATIONS
ARTICLE 8 PUBLICATION AND ACADEMIC RIGHTS
ARTICLE 9 INTELLECTUAL PROPERTY
ARTICLE 10 FOREIGN ACCESS TO TECHNOLOGY
ARTICLE 11 GOVERNMENT FURNISHED EQUIPMENT, PROPERTY, INFORMATION, FACILITIES, AND SERVICES
ARTICLE 12 FUNDING AND PAYMENT
ARTICLE 13 COST SHARING
ARTICLE 14 ACCOUNTING AND MANAGEMENT SYSTEMS
ARTICLE 15 REPORTING REQUIREMENTS
ARTICLE 16 AUDITS
ARTICLE 17 TERMINATION
ARTICLE 18 DISPUTES
ARTICLE 19 CIVIL RIGHTS ACT
ARTICLE 20 SECURITY
ARTICLE 21 GENERAL TERMS AND PROVISIONS
ARTICLE 22 INCORPORATION BY REFERENCE
ARTICLE 23 ORDER OF PRECEDENCE
ARTICLE 24 CONSTRUCTION OF THE AGREEMENT

ATTACHMENT 1 DEFINITIONS
ATTACHMENT 2 SCHEDULE OF PAYMENTS AND MILESTONES
ATTACHMENT 3 CONSORTIUM MEMBERS

# L. OTAO DESKTOP GUIDE

L

# OTAO's Desktop Guide

## OT AGREEMENT STRUCTURE AND DISCUSSION

## Scope of this Guide

THE FOLLOWING DISCUSSION INCLUDES STRUCTURE OF AGREEMENTS AND NUMBERS OF ARTICLES, AND SOME MODEL/SAMPLE LANGUAGE FOR ARTICLES. ALL MATTERS SHOULD BE SUBSTANTIALLY REVISED DEPENDING ON THE FACTS OF EACH AGREEMENT AND BECAUSE OF THE COMPLEXITY OF THE AGREEMENTS ALL ARTICLES SHOULD BE IN FULL TEXT.

FOR ADDITIONAL DISCUSSION ON MANY OF THESE ISSUES, OTAO'S SHOULD CONSULT THE NIH OT POLICY GUIDE DATED 22MAY 2017

THE ATTACHED ADDENDUM IS A "LIBRARY" OF ADDITIONAL SAMPLE LANGUAGE BY ARTICLES

# FRONT PAGE OF THE OT AGREEMENT

OT's not require any standard government forms

Start with a blank sheet of paper and address critical first information to frame the OT. Think about what the outsiders to OT would expect to see

- OT number
- Name of the contractual parties
- Title of project or work to be performed
- OT authority
- Funds obligated and total financial commitments made by the parties
- Signatures by authorized individuals of the parties

See "Library of Samples" for ideas

# Model Agreement Articles

Since OT's are different than federal contracts, grants, and cooperative agreement, early users within DoD using the OT authority made a decision to not use terms those instruments and this included construction of the OT agreement. They used Articles. This not mandatory, but agencies have adopted this approach.

The following is a sample Table of Contents. Its order and organization is not mandatory, it is used in this desktop guide

# Model Agreement Articles

| | Page Number | Addendum Page Number |
|---|---|---|
| Article I: Scope of the Agreement | 208 | 226 |
| Article II: Term | 209 | 231 |
| Article III: Management of the Project | 210 | 235 |
| Article IV: Modifications | 211 | 238 |
| Article V: Obligation and Payment | 212 | 239 |
| Article VI: Disputes | 214 | 246 |
| Article VII: Patent Rights | 215 | 251 |
| Article VIII: Data Rights | 215 | 257 |
| Article IX: Foreign Access to Technology | 217 | 260 |
| Article X: Title to, and Disposition of, Property | 219 | 262 |
| Article XI: Civil Rights Act | 220 | 264 |
| Article XII: Subcontracting | 220 | N/A |
| Article XIII Execution and Order Of Precedence | 221 | |
| Article XIV: Special Clauses | 221 | |

5

L

# Model Agreement Articles (Continued)

| | Page Number | Addendum Page Number |
|---|---|---|
| **Attachments** | **222** | |
| Attachment 1: Statement of Work | 223 | 274 |
| Attachment 2: Report Requirements | | 275 |
| Attachment 3: Schedule of Payments and Payable Milestones | | 292 |
| Attachment 4: Funding Schedule, if needed | | N/A |
| Attachment 5: List of Government and (INSERT COMPANY NAME) Representatives | | 295 |

See sample provided in handout materials

6

## Article I—Scope of the Agreement

**Vision Statement :**Describes the scope of the project and explains:

- Expectation of the parties for a successful outcome
- Goals, including the individual goals of each party and their joint goals
- Nature of the research effort involved
- Respective obligations of the parties to each other
- Prospects for both Government and commercial benefits

- If there are non-traditional research partners (NRP) so who are they and why wouldn't they accept a contract, grant or cooperative agreement?
- How is the NRP' contributing to a significant extent in the overall agreement
- Does this program required rapid implementation with small phases followed by larger ones if early phases are successful?
- Is partnering between industry and government necessary for the successful completion of the NIH's goals?

7

## Article I—Scope of the Agreement

**Definitions:** Insert key definitions

**Scope of the Project:** Describes the Work to be done during this phase of the project and explains:

- Addresses Statement of Objectives (SOO)

Cost sharing arrangement and its underlying rationale should discussed

8

# Article II—Term, Termination and option to extend

Paragraph A Term:

- This article sets forth the term/period of performance of the agreement. Most NIH agreements will have a term of one or two years.
- It is important to match the term to any established deliverables. For example if a final report is a key element of the program, its delivery date should established.

9

L

# Article II—Paragraph B: Termination

Advanced R&D Contracts have Termination clause ( Convenience and Default are included) that might not be appropriate in OTs

Termination provision in the OT Article II – **Term should address issues like:**

- Allows either party to terminate the agreement after consultation between the parties.
- Must be based upon a reasonable determination that continuing will not produce beneficial results commensurate with the expenditure of resources.
- No further payment for work beyond the last payable milestone completed, if the awardee terminates the effort.
- Allocation of intellectual property rights upon termination, either by the Government or the awardee, is an important consideration to be worked out.

10

# Paragraph C. Extending the Term

A separate article may be needed if the parties wish to design more specific language as to when how and why of any option

The sample language is simple and reserves the right of the parties to agreement

Any extension must be within Article I, "Vision"

# Article III—Management /Teaming

Advanced R&D Contracts have single firms, as a prime with subcontractors involvement or a Joint Ventures (new company made up of equals)

OTs have flexibility in teaming. Unique consortia made be formed to do your project. *Consortium* means: A group of performers who are participating as team members in the performance of the project. All of the performers will be directly involved in:

- Developing and revising plans for the Research effort,
- Performing technical effort
- Reviewing technical progress, and/or
- Overseeing financial and other business matters

12

# Article III—Management /Teaming

Article III must tell how the project will be managed

- Establishes relative responsibilities of the Government and the awardee, alone or with partners/teammates
- Key coverage deals with planning at time of award and possible revisions to those plans based upon technology development results
- Rules on how they will management themselves must be established and reviewed by the OTAO. Those rules sometimes called Article of Collaboration must address:
  - What are the names of the consortium members, and what cost share will each contribute?
  - What will be each member's responsibilities for the program?
    - Detailed list of each member's tasks and rewards should appear here, rather than in OT agreement
  - Who will manage and govern the consortium?
  - Who will conduct billing, and how will members be paid?
  - How will IP be handled?

L

# Article IV—Modifications

Advanced R&D (S&T) Contracts contain a changes clause that permits **only** the CO to make unilateral changes, in designated areas, within the general scope of the contract

Article IV Modifications is really a **Changes** provision in OTs

The sample language excludes the Government's right to act unilaterally and direct the awardee to change any matters without first a bilaterally signed modification to the agreement

14

# Article V—Obligations, Payments and Audits

This article addresses treatment of funds, payments offices issues, cost principles if any, and audits.

Audit provisions can be simple or complex depending on nature of payments or nature of the awardee

Instructions concerning invoice preparation and submittal should covered.

GAO Assess to Records language must be part of every agreement is over $5 M

Milestone Payment schedule could be inserted here or as an attachment to the agreement.

15

# Article V—Obligations, Payments and Audits continued

Cost sharing

- Cost sharing is encouraged by NIH policy, but only to the extent deemed practicable
- Cost sharing discussions can be in Article I or V or both and generally reflected in Attachment 3 and 4

16

# Article V—Obligations, Payments and Audits, continued

Payment Types Suitable for OTs

- Fixed-price payable milestones
- Adjustable (Cost–based) payable milestones
  - If adjustable, what cost principles apply and who and when will audits be done
  - NIH's restrictions on salaries paid under a adjustable payable milestone agreement is one of those cost principles
- A hybrid approach that combines these two options is possible , but difficult

Payable Milestones : Covered in Articles I, V and Attachments 3 and 4

- Agreement must identify type of payment structure selected
- Agreement articles must be consistent with identified payment structure
- Milestones and exit criteria
- All milestones must have associated dollars and dates
- Exit criteria should be reasonable to preclude unnecessary technical and business risks

17

L

# Article V—Obligations, Payments and Audits, continued

Consider the following in drafting the agreement payment clauses:

- Are payments based on amounts generated from the awardee's financial or cost records?
  - In determining whether the agreement should provide for reimbursement based on the awardee's financial or cost records, the Agreements Officer should consider the guidance contained in the section entitled "Accounting and Management Systems".
- Are the payment amounts subject to adjustment during the period of performance?
- If the payments can be adjusted, what is the basis and process for the adjustment?
- What are the conditions and procedures for final payment and agreement close-out?
- Is an interim or final audit of costs needed?

# Article V—Obligations, Payments and Audits, continued

Final milestone payment

- For adjustable payable milestones, the final payment is made when the total contribution by both parties has been expended
- For fixed milestones, the final payment is made when the final milestone exit criteria have been satisfied, regardless of the total expenditure under the agreement

19

# Article VI—Disputes

Although OTs are not subject to the Contract Disputes Act (41 U.S.C. 7101-7109), an OT dispute can be the subject of an injunction action in the U.S. Court of Federal Claims.

Agreements Officers should seek to reduce the risk of costly litigation by negotiating disputes clauses which maximize the use of Alternative Dispute Resolution when possible and appropriate.

Model article discussed how disagreements should be address

- Beginning with a the lowest level
- Ending with a decision by a senior government officials

Push back from potential awardees has happened in the past. Negotiations of the model terms should be considered

20

# Article VII and VIII Intellectual Property (IP)

Intellectual property (IP) collectively refers to rights governed by a variety of different laws, such as patent, copyright, trademark, data, and trade secret laws.

Due to the complexity of intellectual property law and the critical role of intellectual property created under research projects, OTAO should obtain as appropriate, as early as possible in the negotiation process, the assistance of:

- the NIH Legal Advisor's office,
- the appropriate technology transfer office representative, or
- the OPERA Division of Extramural Inventions and Technology Resources,

L

# Article VII and VIII Intellectual Property (IP)(Continued

Agreements Officers can negotiate terms and conditions different from those typically used in other extramural funding instruments. Regarding patents, the Bayh-Dole Act (35 U.S.C. 200-212); does not apply

However, in negotiating these clauses, the Agreements Officer must consider other laws that affect the government's use and handling of, or disclosure of intellectual property

- Trade Secrets Act (18 U.S.C. 1905);
- Freedom of Information Act (5 U.S.C. 552); 10 U.S.C. 130; 28 U.S.C. 1498; 35 U.S.C. 205 and 207-209; and
- Lanham Act, partially codified at 15 U.S.C. 1114 and 1122.

Flexibility in the negotiation of IP rights is one of the rationales for using an OT.

# Article VII and VIII Intellectual Property (IP)(Continued

Article VII and VIII of Model Agreement covers IP: Patents and Data

- These articles are patterned after "traditional IP language". OTAO should revise to meet NIH's needs prior to sharing with potential awardees. The Agreement Analysis in the agreement file should document the rationale behind changes to the standard going-in position

Past OT agreements have included

- Waiver of government license for a period of years
- Allowed protection of materials as trade secrets
- Negotiation of a new definition to "Practical Application".

The negotiated intellectual property clauses should facilitate the agreement's strategy and balance the relative investments and risks borne by the parties.

Negotiations should start with Identifying the IP you need to meet the program and agency goals and missions

23

# Article VII and VIII Intellectual Property (IP)(Continued

With data, determine what data the project/program needs delivered and ask for only that, then define the license rights you need and negotiate a reasonable deal

Cost savings are possible by limiting the government's need for data license rights

The government's need for data and license rights may changes based on program phases

- When many competitors exist, the need for data rights is reduced

Make your flexibility in IP known in BAAs or others solicitations

24

# Article VII and VIII Intellectual Property (IP)(Continued)

Know the technology and standard rights in industry

Take into account the performers investment through both cost-sharing and previous investments

Always keep in mind the goals of both the performer and the government set out in and their commercialization plan and the Project Strategy

Remember that there are no standard/required approaches

25

L

# Article IX—Foreign Access to Technology

Concept begins in the Patent Clause – US manufacturing

Include the Foreign Access to Technology article in agreements to restricted the flow of technology to foreign sources without prior review and approval

Good policy because primary or substantial economic benefits flow to the United States as a result

26

# Article IX—Foreign Access to Technology

Article IX restrictions are in addition to existing Statutory and Regulatory Requirements, such as;

International Traffic in Arms Regulation (ITAR),
22 CFR Part 121 et seq.

DoD Industrial Security Regulation,
DoD 5220.22-R

Department of Commerce Export Regulation,
15 CFR Part 770 et seq.



# Article IX—Foreign Access to Technology

This article contains a proposed process for Handling Transfer of Technology to Foreign Firms

- Pre- or post-award approvals: "Disputes" article in the OT can be used if the agency withholds approval
- If transfer occurs without agency approval:
  - Government funds are returned to the agency.
  - The government gets a license to reuse the technology within the United States to accomplish the intent of a specific agreement .

# Article X—Property Acquired under an OT

Definition - Property: Any tangible personal property other than:

- Property actually consumed during the execution of work under OT or
- Delivered under the agreement

Policy - Where the government owns or takes title, the property is subject to the Federal Property and Administrative Services Act.

In deciding whether or not to take ownership under an OT, the OTAO should consider whether known or future efforts may be fostered by government ownership of the property.

If ownership at the end on the OT's is deemed necessary, three approaches apply –

- If possible, acquire property outside of the OT:
  - Have the awardee use its cost share to acquire property.
- If the government is completely funding the OT effort and property is acquired—
  - The government takes title in a cost-type arrangement unless the property is determined insignificant.
- If the government is cost sharing the effort and property is acquired
  - The government may delay taking title until the end of the OT; the contractor assumes the risk of loss.

29

# Article X—Property Disposition Options

Sample language addresses four methods for disposition of property acquired in the course of OT

- Purchase by contractor at an agreed-to price representing fair market value, with proceeds returned to the government
- Transfer to a government research facility, with title and ownership transferred to the government
- Donate to a mutually agreed-upon university or technical learning center for research purposes
- Follow any other agency-approved disposition procedure

30

# Article XI: Civil Rights Act

Statutes of general applicability apply to OT's. Here is an example

ARTICLE XI: CIVIL **RIGHTS ACT**

This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. Each Consortium Member company has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act. The Parties recognize that since the Consortium has no employees, that compliance is-the responsibility of each Consortium Member.

# Article XII: Subcontracting

Subcontracts, whatever there form should always contain flow down provisions passing on all flexibility of the OT and restrictions, especially to nontraditional Research Performers (NRP)s

## Article XIII Execution and Order Of Precedence

Where there official agreements among the parties/teams/consortia that impact the management or performance an order of precedence article may be needed. Here is suggested language:

A sample article is included in the OTAO's Desktop Guide Library

L

## Article XIV: Special Clauses

NIH has determined that several laws may be applicable to NIH OTs

OTAO's should consider the guidance in NIH OT Policy Guide and construct language that is appropriate and negotiate their inclusion if the OT maybe in this Article

A sample Special Clauses article is included in the OTAO's Desktop Guide Library

# Attachments

The number and size of attachments to OT's is subject to the complexity of the program/program

Attachment 1 is where complex and detailed statements of work or objectives would inserted. It could be created by the offerors or government and should aligned with the Vision in Article I, delivery requirements in Article II, and the payable milestones descriptions

Attachment 2 Report Requirements is where all information concerning interim and final report draft submissions, review by the government, and distribution is found. Also, the quarterly technical and business status reporting is found. These report are the foundation of all post award oversight by OTAO's representatives

A sample listing of potential attachments is as follows:

# Attachments

| | |
|---|---|
| ATTACHMENT 1 | Statement of Work *(Statement of Objectives)* should be tied to Payable Milestones |
| ATTACHMENT 2 | Report Requirements |
| ATTACHMENT 3 | Schedule of Payments and Payable Milestones |
| ATTACHMENT 4 | Funding Schedule |
| ATTACHMENT 5 | List of Government and (INSERT COMPANY/ CONSORTIUM NAME) Representatives |

36

# OTAO DESK GUIDE ADDENDUM
# OT AGREEMENT LIBRARY
# SAMPLE ARTICLE LANGUAGE



*(Sample Front Page of an OT that Includes Multiple Partners/Teammates)*

OTHER TRANSACTION AGREEMENT (OTA)
BETWEEN

(*Insert consortium's name and address*)

AND

*(Insert the government agency's name and address)*

CONCERNING

*(Insert research and development effort)*

Agreement No.:
Requisition/Purchase Request Order No.: .
Total Amount of the Agreement: $ *(includes consortium and government funding)*
Total Estimated Government Funding of the Agreement: $
Funds Obligated: $
Authority: *Insert the appropriate OTA authority*
Line of Appropriation:

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by THE NATIONAL INSTITUTES OF HEALTH (NIH) and the (INSERT CONSORTIUM NAME) pursuant to and under U.S. Federal law.

| FOR *(insert consortium name)* | FOR THE UNITED STATES OF AMERICA<br>THE NATIONAL INSTITUTES<br>OF HEALTH (NIH) |
|---|---|
| _____ | _____ |
| (Signature) | (Signature) |
| _____ | _____ |
| (Name, Title) (Date) | (Name, Title) |

AGREEMENT

(Date)

*Sample table of contents lists all the main topics that are the basis of the agreement between the parties. It should be tailored to meet the needs of the project, teams and the parties.*

**TABLE OF CONTENTS**


| **ARTICLES** | | **PAGE** |
|---|---|---|
| ARTICLE I | Scope of the Agreement | |
| ARTICLE II | Term | |
| ARTICLE III | Management of the Project | |
| ARTICLE IV | Modifications | |
| ARTICLE V | Obligation and Payment | |
| ARTICLE VI | Disputes | |
| ARTICLE VII | Patent Rights | |
| ARTICLE VIII | Data Rights | |
| ARTICLE IX | Foreign Access to Technology | |
| ARTICLE X | Title to and Disposition of Property | |
| ARTICLE XI | Civil Rights Act | |
| ARTICLE XII | Subcontracting | |
| ARTICLE XIII | Execution and Order of Precedence | |
| ARTICLE XIV | Special Provisions | |

| ATTACHMENTS | |
|---|---|
| ATTACHMENT 1 | Statement of Work *(Statement of Objectives)* |
| ATTACHMENT 2 | Report Requirements |
| ATTACHMENT 3 | Schedule of Payments and Payable Milestones |
| ATTACHMENT 4 | Funding Schedule |
| ATTACHMENT 5 | List of Government and (INSERT COMPANY/ CONSORTIUM NAME) Representatives |

# Other possible articles titles that have been used in other agreement:



| | |
|---|---|
| ARTICLE 1 | PARTIES |
| ARTICLE 2 | LEGAL AUTHORITY |
| ARTICLE 3 | SCOPE OF THE AGREEMENT |
| ARTICLE 4 | EFFECTIVE DATE AND TERM |
| ARTICLE 5 | STATEMENT OF OBJECTIVES AND MILESTONES |
| ARTICLE 6 | AGREEMENT ADMINISTRATION |
| ARTICLE 7 | CHANGES, MODIFICATIONS |
| ARTICLE 8 | PUBLICATION AND ACADEMIC RIGHTS |
| ARTICLE 9 | INTELLECTUAL PROPERTY |
| ARTICLE 10 | FOREIGN ACCESS TO TECHNOLOGY |
| ARTICLE 11 | GOVERNMENT FURNISHED EQUIPMENT, PROPERTY, INFORMATION, FACILITIES, AND SERVICES |
| ARTICLE 12 | FUNDING AND PAYMENT |
| ARTICLE 13 | COST SHARING |
| ARTICLE 14 | ACCOUNTING AND MANAGEMENT SYSTEMS |
| ARTICLE 15 | REPORTING REQUIREMENTS |
| ARTICLE 16 | AUDITS |
| ARTICLE 17 | TERMINATION |
| ARTICLE 18 | DISPUTES |
| ARTICLE 19 | CIVIL RIGHTS ACT |
| ARTICLE 20 | SECURITY |
| ARTICLE 21 | GENERAL TERMS AND PROVISIONS |
| ARTICLE 22 | INCORPORATION BY REFERENCE |
| ARTICLE 23 | ORDER OF PRECEDENCE |
| ARTICLE 24 | CONSTRUCTION OF THE AGREEMENT |

AGREEMENT

## ARTICLE I

*Article I sets the tone for the agreement. It tells why the parties are working together, what they hope to accomplish, the scope of the project, as well as the scope of the agreement.*

A. VISION AND BACKGROUND

*This paragraph(s) describes the vision of the program and should answer the following questions:*

1. What is the agreement all about?
2. What is the current technological situation?
3. What makes this program a "critical technology" effort?
4. Why is the current technology not sufficient?
5. Why is it necessary for the government to support industry in addressing this situation?
6. What are the issues of particular importance to the issuing agency?
7. What are the dual-use (government and commercial) applications?
8. What is the market potential?
9. What are the commercialization goals?
10. If there are nontraditional research partners (NRPs), who are they and why wouldn't they accept a contract, grant, or cooperative agreement?
11. Does this program required rapid implementation with small phases followed by larger ones if early phases are successful?
12. Is partnering between industry and government necessary for the successful completion of the NIH's goals?
13. If the program is successful, then what? Where do we go from here? If this collaboration is successful, what will we have accomplished?)

# Sample language from other agreements:

Agreement A

XXXX, Inc. has conceived of a new technology which may have wide-ranging military and civilian applications. The vision is to bring this technology to fruition for multiple applications as an underlying "technology platform" which leads to improvements in various areas, e.g., the advanced sniper rifle, land mines, etc. Under the NIH program, the goal is to develop and demonstrate the technology and transition it to programs that will take on multiple manufacturers as early as possible. The success of this agreement will be evidenced by development of prototypes which may enter limited usage and the licensing of the technology to manufacturers for end-use. Although XXXX does not currently intend to manufacture any system applications/systems developed under the NIH program, XXXX reserves its right to decide to manufacture in the future.

or

# Agreement B

The objective of this Other Transaction Agreement (OTA) is to create a framework for collaboration between AstraZeneca and the Biomedical Advanced Research and Development Authority (BARDA) to evaluate the efficacy and safety of a portfolio of selected AstraZeneca antibacterial assets in treating hospital and biothreat infections. Many pharmaceutical companies have stopped developing new antibiotics due to a diminished return on investment. Formation of public-private partnerships with industry helps to sustain research in this area where new drugs are desperately needed to address the growing rate of antibiotic resistance. This Agreement addresses this issue by permitting BARDA to share in the expense of clinical trials for ATM-AVI, along with any additional antibiotics that may be added to the Agreement by mutual consent of the parties. This Agreement will help ensure that at least one experienced pharmaceutical company will remain engaged in antibacterial development to combat the threat of antibiotic resistance. Furthermore, the ability of the Government to enter into an agreement with consortia is a compelling factor for selecting an OTA as the appropriate funding mechanism. In addition, portfolio-based product development reduces risk by allowing for the reallocation of resources across activities and drug candidates if technical or business risks materialize. An agreement that allows for the funding of a portfolio of products instead of just one increases the probability of bringing a successful drug to market.

To support this objective, AstraZeneca will support regulatory approval of each selected product. This includes nonclinical, clinical, and drug manufacturing activities supporting regulatory approval. In addition, data to support biothreat indications will also be generated where agreed to. By mutual consent of AstraZeneca and BARDA, preclinical candidates may be included in order to facilitate their progress into the clinical portfolio. This framework will provide BARDA and AstraZeneca the flexibility to execute a portfolio approach to funding in the complex and uncertain environment of drug development.

The initial work under this Agreement will support regulatory approval of aztreonam- avibactam (ATM-AVI), an antibiotic designed to treat serious infections caused by multi- drug-resistant Gram-negative organisms.

Or

# Agreement C

DHS’s Counter-Man-Portable Air Defense Systems (MANPADS) program is using system engineering, prototype development, and deployment testing of a protective system for U.S. commercial aircraft against shoulder-fired missiles. While there is no credible, specific intelligence information about planned MANPADS attacks against U.S. commercial aircraft, the program is pursuing countermeasures technology development to counter this potential threat.

The Counter-MANPADS program is adapting existing and evolving military technology for commercial aviation use, which is challenging. The military counter-MANPADS systems work on limited numbers of aircraft in confined and centrally located airports, highly sensitive technologies are easily protectable. The systems are in controlled maintenance and logistics environments. False alarms and notifications of such to the public are not an important issue. While in the U.S. commercial airline industry there are more than 400 airports and more than 6,000 aircraft in the commercial fleet. Many aircraft are foreign built, and maintenance is more and more done overseas. Maintenance costs, i.e., reliability and mean-time between failures, must be greatly increased if this technology will possible in the commercial marketplace.

**DHS Counter-MANPADS Program Acquisition Strategy**

The multi-phase approach of the Homeland Security Counter-MANPADS program was defined. It envisioned teaming of traditional government contractors, who had developed or were developing the required technology, with nontraditional government contractors who provide goods or services in the commercial airline industry. This combining of the technologists, manufacturers and users into effective teams was a critical overall strategy of the program. It was also a critical factor in the selection of the use of the Other Transaction Authority.

# B. DEFINITIONS- Example

**Agreement:** The body of this Agreement and Attachments 1 – *(correct number)***,** which are expressly incorporated in and made a part of the Agreement.

**Computer Software:**

Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Does not include computer databases or computer software documentation.

**Consortium:** A team formed under Articles of Collaboration to perform the responsibilities of an agreement.

**Consortium Administrator:** Individual authorized by the Consortium's Articles of Collaboration represent and binding the consortium.

**Data:** Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, and trade secrets made in

the performance of work under this Agreement within the Field. The term does not include financial, administrative, cost, pricing or management information.

**Foreign Firm or Institution:** A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals. Specifically excluded from the definition of Foreign Firm or Institution are the entities listed on Attachment 4 along with their non-US affiliates.

**Government:** The United States of America, as represented by *xxxx*.

**Government Purpose Rights:** The rights to use, duplicate, or disclose data, in whole or in part and in any manner, for government purposes only, and to have or permit others to do so for government purposes only.

**Invention:** Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

**Know-How:** Information, practical knowledge, techniques, and skill development by Recipient in the performance of work under this Agreement necessary for the Practical Application of a Subject Invention with the Field.

**Limited Rights:** The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. DHHS will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

**Non-Traditional Research Participant(s) (NRP)**:

**Other Transaction (OT)**: A legally binding, non-acquisition instrument (generally called "an agreement") used in instances where the principal purpose is facilitating NIH's mission.

**Other Transaction Agreement Officer (OTAO):** The responsible government official authorized to bind the government by signing this Agreement and bilateral modifications.

**Other Transaction Agreement Specialist (OTAS):** A supporting official that executes agreement modifications on behalf of the Other Transaction Agreement Officer.

**Other Transaction Agreement Technical Representative (OTTR):** The primary government official for all technical matters on the Agreement.

**Practical Application:** With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public.

**Program:** Research and development being conducted by the Parties pursuant to this Agreement.

**Property:** Any tangible personal property other than property consumed during the execution of work under this Agreement.

**Recipient/Awardee/Contractor/Consortium:** The entity awarded this agreement.

**Subrecipient/Subawardee/Subcontractor:** Entities with a sub contractual relationship with Recipient/ Awardee/Contractor.

**Subject Invention:** Any Invention conceived in the performance of work under this Agreement (as defined below) within the Field for which Recipient pursues a patent.

**Technology:** Discoveries, innovations, Know-How, and Subject Inventions, whether patentable or not, conceived in the performance of work under this Agreement, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights developed under this Agreement.

# C. EFFORTS REQUIRED BY THIS AGREEMENT- EXAMPLE

1. Consortium ABC (ABC) shall perform a research and development program (Program) designed to develop (*insert research and development effort under this agreement period*). The research shall be carried out in accordance with the Statement of Work incorporated in this Agreement as Attachment 1. ABC shall submit or otherwise provide all documentation required by Attachment 2, Report Requirements.

2. ABC shall be paid for each Payable Milestone accomplished in accordance with the Schedule of Payments and Payable Milestones set forth in Attachment 3 and the procedures of Article V. The parties recognize that the nature of the Payable Milestones is fixed and subject to revision only in accordance with Article IV Modifications. While fixed, the parties recognize that the Payable Milestones are constructed using the concept of "Substantial Compliance" where variable outcomes possible and acceptable.

***(Insert if cost sharing applies)***

3. The Government and ABC (Parties) estimate that the Statement of Work of this Agreement can only be accomplished with an ABC aggregate resource contribution of $ (*insert dollar amount*) from the effective date of this Agreement through (*insert number of months*) ( ) months thereafter. ABC intends and, by entering into this Agreement, undertakes to cause these funds to be provided. ABC contributions will be provided as detailed in the Funding Schedule set forth in Attachment 4.



# D. GOALS / OBJECTIVES - EXAMPLE

1. The goal of this (program) is/are [insert goal(s)] and therefore within the scope of the agreement.

2. The Government will have continuous involvement with ABC. The Government will also obtain access to research results and certain rights in data and patents pursuant to Articles VII and VIII. NIH and ABC are bound to each other by a duty of good faith and best research effort in achieving the goals of the Program.

3. This Agreement is an "other transaction" pursuant to (the OTAO must pick the correct authority)

Section 402(b)(7) or 402(b)(12) of the Public Health Service (PHS) Act or,

Section 480(e)(3)(C) of the PHS, 42 U.S.C. 287a(e)(3)(C or,

42 U.S.C. 284n(b), or,

The National Heart, Blood Vessel, Lung, and Blood Act of 1972, Pub. L. No. 92-423, 86 Stat. 679 (1972), or, H.R.6, The 21st Century Cures Act (Cures Act),

4. The Parties agree that the principal purpose of this Agreement is for the Government to support and stimulate ABC to advanced research and technology development and not for the acquisition of property or services for the direct benefit or use of the Government. The *Federal Acquisition Regulation* (FAR) and *Federal Assistance Regulations* apply only as specifically referenced herein. This Agreement is not a procurement contract or grant agreement for purposes of FAR section 31.205-18.

## ARTICLE II: TERM

A. THE TERM OF THIS AGREEMENT

The Program commences upon the date of the last signature hereon and continues for *(insert number of months)* ( ) months. If all funds are expended prior to the *(insert number of months)* ( )-month duration, the Parties have no obligation to continue performance and may elect to cease development at that point. Provisions of this Agreement. which by their express terms or by necessary

implication apply for periods of time other than specified herein, shall be given effect notwithstanding this Article.

# Term - ANOTHER EXAMPLE

A. TERM OF THIS AGREEMENT

The term of this Agreement commences upon the date of the last signature. This Agreement commences with a five-year base period and four options. The period of performance is a base period of five (5) years during which clinical, non-clinical, manufacturing and development activities supporting the registration of ATM-AVI will be conducted as set forth in Attachment 1. The parties may exercise two one-year option periods to permit the continuation of ATM-AVI development activities. In addition, the parties may agree to two additional one-year option periods to add additional antibacterial candidates to the Agreement for preclinical, clinical, manufacturing and development activities. The option periods may run concurrently or consecutively within the base period.

The Government will give the Recipient a preliminary written notice of its desire to exercise an option at least ninety (90) days before the expiration of one year following the commencement of the Agreement (for the first option) and each option term thereafter, as applicable. The Recipient may decline any option. The Parties may also agree mutually to extend the term of this Agreement and its options by written agreement on or before the expiration of the Agreement. The Government will give the Recipient a preliminary written notice of its desire to extend at least ninety (90) days before the five (5) year period expires. The preliminary notice does not commit the Government to an extension.

B. TERMINATION PROVISIONS

Subject to a reasonable determination that the program will not produce beneficial results commensurate with the expenditure of resources, either Party may terminate this Agreement by written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement. shall be in accordance with the provisions set forth in Article VIII,Data Rights. The Government. acting through the Agreements Officer, and the Consortium, acting through its Consortium Management Committee, will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties because of termination. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VI, Disputes. The Government has no obligation to reimburse the Consortium beyond the last completed and paid milestone if the Consortium, acting through its Consortium Management Committee, decides to terminate.

# ANOTHER EXAMPLE (adjustable milestones apply)

Either Party may terminate this Agreement for convenience by providing at least ninety (90) days prior written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement shall be in accordance with the provisions set forth in Article IX, Data Rights. In the event of termination by either Party, the Recipient's and Government termination costs shall be reimbursable pursuant to the terms of Article VI. For purposes of this clause, termination costs shall be those costs identified in *Federal Acquisition Regulation* 31.205-42 but does not include reprocurement costs unless foreign access to technology Article XI is applicable. The Government and the Recipient will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties because of termination, including disposition of animals acquired for research use. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VIII, Disputes. In the event of termination, neither party shall have any continuing obligations to perform under the Program except as otherwise specified herein.



C. EXTENDING THE TERM

The Parties may extend by mutual written agreement the term of this Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the OTAO and the Consortium Administrator.

# ANOTHER EXAMPLE

TERMINATION

1. This agreement may be terminated by either party within __insert__ days upon receipt of written notice by the other party. Termination shall not affect obligations incurred under this agreement by either party before the effective date of termination. If termination is effected by NIH, it will not become final until the NRPs has been afforded reasonable notice; however, NIH may suspend this agreement pending the outcome if it is determines that such action is necessary in order to prevent substantial harm to the interests of the United States.

2. Subject to a reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this agreement or a specific project, in whole or in part, if the NIH determines that a termination is in the Government's interest. NIH shall terminate by delivering to the NRPs through its designated agent a Notice of Termination specifying the extent of termination and the effective date.
3. After receipt of a Notice of Termination, and except as directed by NIH, the NRPs in through its designated agent shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:
    i. Stop work and direct its partners to stop work as specified in the notice.
    ii. Place no further agreements or orders for materials, services, or facilities, except as necessary to complete the continued portion of the agreement or project.
    iii. Terminate all agreements or orders to the extent they relate to the work terminated.
    iv. Assign to the Government, as directed by NIH, all right, title, and interest of the terminated work performed under the agreement, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.
    v. With approval or ratification to the extent required by NIH, settle all outstanding liabilities and termination settlement proposals arising from the termination of agreements or orders; the approval or ratification will be final for purposes of this clause.
    vi. As directed by NIH, obtain from partners under the terminated portion of the agreement a transfer of title to the following where applicable and deliver to the Government --

        (i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the work had been completed, would have been required to be furnished to the Government.

vii. Complete performance of any work not terminated, if applicable.

viii. Take any action that may be necessary, or that NIH may direct, for the protection and preservation of the property related to this agreement that is in the possession of the NRPs and in which the Government has or may acquire an interest.

ix. The proceeds of any transfer or disposition of such property will be applied to reduce any payments to be made by the Government under this agreement, including credited to the price or cost of the work, or paid in any other manner directed by NIH.



4. In the event of a termination of the Agreement, the Government shall have patent rights as described in this agreement. Failure of the Parties to agree to an equitable adjustment shall be resolved pursuant to this agreement.

## ARTICLE III: MANAGEMENT OF THE PROJECT

*(Note: this article should be substantially revised depending on the facts of each agreement.)*

The following example is where the parties see a long-term relationship and envision revision to the scope work will be required and the work will be paid by fixed payments.

A. MANAGEMENT AND PROGRAM STRUCTURE

ABC shall be responsible for the overall technical and program management of the Program, and technical planning and execution shall remain with ABC. The Program Manager shall provide recommendations to Program developments and technical collaboration and be responsible for the review and verification of the Payable Milestones.

B. PROGRAM MANAGEMENT PLANNING PROCESS

Program planning will consist of an Annual Program Plan with inputs and review from ABC and NI

H management, containing the detailed schedule of research activities and payable milestones. The Annual Program Plan will consolidate quarterly adjustments in the research schedule, including revisions/modification to payable milestones.

1. Initial Program Plan: ABC will follow the initial program plan that is contained in the Statement of Work (Attachment 1), and the Schedule of Payments and Payable Milestones (Attachment 3).

2. Overall Program Plan Annual Review

(a) ABC, with NIH Program Manager review, will prepare an overall Annual Program Plan in the first quarter of each Agreement year. (For this purpose, each consecutive twelve (12) month period from (and including) the month of execution of this Agreement during which this Agreement shall remain in effect shall be considered an "Agreement Year".) The Annual Program Plan will be presented and reviewed at an annual site review which will be attended by ABC Management, the NIH Program Manager, Senior NIH management as appropriate, and other NIH program managers and personnel as appropriate. ABC, with NIH participation and review, will prepare a final Annual Program Plan.

(b) The Annual Program Plan provides a detailed schedule of research activities, commits ABC to meet specific performance objectives, includes forecasted expenditures and describes the Payable Milestones. The Annual Program Plan will consolidate all prior adjustments in the research schedule, including revisions/modifications to payable milestones. Recommendations for changes, revisions or modifications to the Agreement which result from the Annual Review shall be made in accordance with the provisions of Article IV.

(c) The OTAO or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this Agreement.

C.

## (This example envisions cost payable milestones.)

B(2)(b) The Annual Program Plan provides a detailed schedule of research activities, commits ABC to use its best efforts to meet specific performance objectives, includes forecasted expenditures and describes the Payable Milestones. The Annual Program Plan will consolidate all prior adjustments in the research schedule, including revisions/modifications to payable milestones. Recommendations for changes, revisions or modifications to the Agreement which result from the Annual Review shall be made in accordance with the provisions of Article III, Section C.

# ANOTHER EXAMPLE (BARDA)

## ARTICLE III: MANAGEMENT OF THE PROJECT

A. RECIPIENT/BARDA JOINT OTAR OVERSIGHT COMMITTEE

1. Recipient/BARDA Joint OTAR Oversight Committee (JOC) is comprised of three senior level members from Recipient, three senior level BARDA participants, and the Other Transaction Agreement Officer (OTAO). Assuming no objection by the other party, additional external advisors may also be included in this body on an ad hoc basis, as dictated by the circumstances. Either party may substitute alternate senior level representatives, on either a temporary or ongoing basis, by providing advance written notice.

Oversight Committee Members:

| | |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |

*Another example for Article III*

I. MILESTONES

Initial activities shall be accomplished according to the following milestones. (*Or, reference attachment*.)

| MILESTONE | COMPLETION DATE | RESPONSIBLE PARTY | PERFORMANCE METRICS | PAYMENT DUE UPON COMPLETION |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

# ANOTHER EXAMPLE (Deliverables)

**ARTICLE III: MANAGEMENT OF THE PROJECT**

**PAYABLE EVENT SCHEDULE, DELIVERABLES AND COMPLETION CRITERIA**

A. PAYMENT SCHEDULE

UAL shall perform the work required by SOW. UAL shall be paid for each Payable Milestone accomplished and delivered in accordance with the Schedule of Payments and Payable Milestones set forth below. Both the Schedule of Payments and the Funding Schedule set forth below may be revised or modified in accordance with subparagraph C of this article.

B. SCHEDULE OF PAYMENTS AND PAYABLE MILESTONES

| Payable Milestone | Milestone Date | Milestone Amount | Exit Criteria |
|---|---|---|---|
| 1 - Boeing 757 systems classroom training and simulator session | Prior to 30 November 2XX5 | | Training complete |
| 2- Utilization of Boeing 757 Simulators | Prior to 31 March 2XX6 | | Completion of 52 hours of simulators use |
| 3- Utilization of Airbus 320 Simulators | Prior to 31 May 2XX6 | | Completion of 8 hours of simulators use |
| 4- Boeing 757 Throttles-Only-Control Flight Evaluation | Prior to 30 April 2XX6 | | Completion of two 3- hour demonstration flights |
| 5- Deliverables/Reporting Requirements | On or about 31 May 2XX6 | | Receipt of Deliverables per Attachment II |

## ARTICLE IV: MODIFICATIONS

MODIFICATIONS

1. Because of quarterly meetings, annual reviews, or at any time during the term of the Agreement, research progress or results may indicate that a

change in the Statement of Work and/or the Payable Milestones, would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the Statement of Work and/or the Payable Milestones, will be documented in a letter and submitted by ABC to the NIH Program Manager with a copy to the NIH Agreements Officer. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the research program. ABC shall approve any Agreement modification. The Government is not obligated to pay for additional or revised Payable Milestones until the Payable Milestones Schedule (Attachment 3) is formally revised by the NIH Agreements Officer and made part of this Agreement.



2. The NIH Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement Statement of Work, Schedule of Payments or Payable Milestones, or other proposed changes to the terms and conditions of this Agreement.

3. For minor or administrative Agreement modifications (e.g. changes in the paying office or appropriation data, changes to Government or ABC personnel identified in the Agreement, etc.) no signature is required by ABC.

## ARTICLE V: OBLIGATION AND PAYMENT

A. OBLIGATIONS

*This area of the agreement should define the government's limitations to proceed without obligated funds. OTAOs should keep in mind the Anti-Deficiency Act. Here are a couple of examples:*

1. Obligation

The Government's liability to make payments to the Recipient is limited to only those funds obligated under the Agreement or by modification to the Agreement. The Government's obligated funds for the Base Period only. The contractor is not obligated to perform work in absence of new funding.

*Or*

1. Obligation

The Government's liability to make payments to the Consortium is limited to only those funds obligated under this Agreement or by modification to the Agreement. NIH may incrementally fund this Agreement.

B. ADJUSTABLE MILESTONES PAYMENTS

1. ABC has an established and agrees to maintain an established accounting system which complies with Generally Accepted Accounting Principles and the requirements of this Agreement. An acceptable accounting system is one in

which all cash receipts and disbursements are controlled and documented properly.

2. ABC shall document the accomplishments of each Payable Milestone by submitting or otherwise providing the Payable Milestones Report required by Attachment 2, Part D. ABC shall submit an original and one (1) copy of all invoices to the OTAO for payment approval. After written verification of the accomplishment of the Payable Milestone by the NIH Program Manager, and approval by the Agreements Officer, the invoices will be forwarded to the payment office within fifteen (15) calendar days of receipt of the invoices at NIH. Payment approval for the final Payable Milestone will be made after a determination by NIH that agreement results equals value of the accumulated government funds and ABC contributions. Payments will be made by xxxxx within fifteen (15) calendar days of NIH's transmittal. Subject to change only through written Agreement modification, payment shall be made to the address of the ABC Administrator set forth below.

3. Address of Payee: (*INSERT NAME AND ADDRESS OF PAYEE)*

4. Limitation of Funds: In no case shall the Government's financial liability exceed the amount obligated under this Agreement.

5. Financial Records and Reports: ABC shall maintain adequate records to account for all funding under this Agreement, including ABC's funding provided under this Agreement. Upon completion or termination of this Agreement, whichever occurs earlier, the ABC Administrator shall furnish to the OTAO a copy of the Final Report required by Attachment 2, Part E. ABC's relevant financial records are subject to examination or audit on behalf of NIH by the Government for a period not to exceed three (3) years after expiration of the term of this Agreement. The OTAO or designee shall have direct access to sufficient records and information of ABC, to ensure full accountability for all funding under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party.

## REQUIRED IN EVERY AGREEMENT WITH A VALUE OF $5.0 MILLION OR MORE

The Comptroller General, at its discretion, shall have access to and the right to examine records of any party to the agreement or any entity that participates in the performance of this agreement that directly pertain to, and involve transactions relating to, the agreement.

- Excepted from this requirement is any party to this agreement or any entity that participates in the performance of the agreement, or any subordinate element of such party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other

transaction") that provides for audit access by a government entity in the year prior to the date of the agreement.

- This clause shall not be construed to require any party or entity, or any subordinate element of such party or entity, that participates in the performance of the agreement, to create or maintain any record that is not otherwise maintained in the ordinary course of business or pursuant to a provision of law.
- The Comptroller General shall have access to these records until three years after the date the final payment is made by the United States.
    a. All the terms of the clause shall be included in all subagreements to the agreement.



## ANOTHER EXAMPLE (Adjustable Milestone Payment)

B. PAYMENTS

Payments herein are adjustable during the life of the agreement. A target payable milestone has been established and will be paid with accomplishment of tasks with the criteria listed in Attachment 3. However, they can be revised prospectively and retrospectively based on research results. To change these payments, use of costs accumulated is necessary. Therefore, costs must be accumulated in accordance with cost principles by the nature of the businesses involved in this agreement. At a minimum, each member of the consortium must have and agrees to maintain an established accounting system which complies with Generally Accepted Accounting Principles, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds. An acceptable accounting system is one in which all costs, cash receipts and disbursements are controlled and documented properly. The same cost principles and processes that apply to entities that have existing government business and have already established accounting systems that comply with Government Accepted Accounting Principles apply under this agreement.

## ANOTHER EXAMPLE (Adjustable Milestone Payment)

B. PAYMENTS

The Recipient will invoice the Government monthly. The Recipient's shared costs incurred during the reporting period shall be reported in the Financial Status Report, Attachment 2, Paragraph B and monthly invoice. The Recipient properly prepared invoice(s) will be submitted for payment not more than once per month in Adobe Acrobat (.pdf) format.

The invoice shall be uploaded to a shared electronic file server, with an email copy to the OTAO, OTAS and OTR cited below. As directed by the OTAO, the invoice shall be accompanied by adequate documentation to support the payment.

AGREEMENT

After verification of the accomplishment of the work for which reimbursement is sought by the OTAO, the OTAS and OTR will forward the invoice(s) to the. Program Support Center (PSC). Each invoice must contain the following information to be deemed properly prepared:

1. Name and address of Recipient
2. Invoice Date and Invoice Number
3. Agreement Number
4. Description, quantity, unit of measure, unit price, and extended price
5. Recipient Cost Share
6. Name and address of OTAR official to whom voucher is to l;>e sent
7. Name, title, phone number, and mailing address of person to notify in the event of a defective invoice.
8. Taxpayer Identification Number (TJN)
9. Electronic funds transfer (EFT) banking information.

Documents should be delivered electronically to the OTAO, OTAS, OTTR, PSC, and e-room electronically. Unless otherwise specified by the OTAO all eliverables and reports furnished to the Government under the resultant Agreement (including invoices) shall be addressed as follows:

**NAME**
Carl Newman (OTAO)
carl.newman@hhs.gov
and
Juan Wooten (OTAS)
Juan.Wooten@hhs.gov

**HHS/ASPR/AMCG**
330 Independence Avenue, S.W.,
Room G640
Washington, DC 20201 Email:
Name@hhs.gov

**NAME**
Christopher Houchens (OTTR)
christopher.houchens@hhs.gov

**HHS/ASPR/BARDA**
330 Independence Avenue, S.W.
Room G640
Washington, DC 20201
Email: Name@hhs.gov

Email invoices to:

PSC lnvoices@psc.hhs.gov

and

E-Room:

Link: TBD

Monthly invoices must include the cumulative total costs submitted for reimbursement to date, adjusted (as applicable) to show any amounts suspended by the Government.

The Recipient will convert foreign currency costs to US dollars each month using the closing spot exchange rate published by Reuters on the last working day of each month at: http://www.reuters.com/finance/currencies/

## ANOTHER EXAMPLE (Cost Principle)

Salary Rate Limitation

1. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate more than the Federal Executive Schedule Level II in effect on the date an expense is incurred is an unallowable cost under this Agreement.

2. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under the OT. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also. referred to as indirect costs or facilities and administrative [F&A] costs).



**Note:** The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract, order, or OTAR; it merely limits the portion of that salary that may be paid with Federal funds.

3. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year OTAR, it may be subject to unilateral modification by the OTAO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

4. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

## ANOTHER EXAMPLE (adjustable milestones are negotiated*)*

B. LIMITATION OF PAYMENTS

It is herein understood and agreed that Government funds are to be used solely for this Agreement and must be reasonable in nature and amount. The following cost principles are effective under this agreement for determining the allowability of costs for which reimbursement is sought under this Agreement. The cost principles are not applicable to Recipient's contribution and the Financial Status Report.

1. Allocability shall be determined in accordance with the standards set forth in FAR § 31.201-4. The Cost Accounting Standards do not apply to the Recipient or any Subrecipient. Costs shall be accounted for in accordance with the Recipient's or Subrecipient's commercial accounting practices.

2. To be reasonable, a cost must be generally recognized as an ordinary or necessary part of the business; follow sound business practices; follow what a prudent business person would accept; comply with federal, state, and local laws; and be consistent with the Recipient's or Subrecipient's established practices.

3. In addition, Recipient's costs that are passed onto the Government for reimbursement shall comply with the procedures and cost principles set forth in this paragraph:

   (a) Reimbursement is subject to restrictions on allowable costs listed in Attachment 5. It is anticipated that this list will require revision and the Government, and the Recipient agree to update this list in a timely manner.

   (b) The cost principles set forth in subparagraphs (a) shall only apply to the reimbursement of direct costs under cost-type subAgreements. These cost principles will be applicable to the pricing of fixed-priced subAgreements only to the extent required by FAR 31.102.

   (c) A cost-type subRecipient will propose indirect rates as a component of its proposal to Recipient. The Government will review these indirect rates as part of the subRecipient approval process set forth in Article XII. The Government's approval to issue the subAgreement constitutes the Government's agreement that the proposed indirect rate(s) may be used during the performance of the subAgreement to determine the subRecipient's reimbursable indirect costs. The apprnved indirect rate(s) will not be subject to audit or adjustment based upon the subRecipient's actual cost experience during the performance of the subAgreement.

C. The Recipient agrees to promptly notify the OTAO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base segment or any option segment{s) and the reasons for the variance.

# Examples of Audits Provisions

**Sample 1**: *Clause for awardees (insert name, if desired) that have a contract, grant, or cooperative agreement subject to the Single Audit Act*

The awardee shall comply with all aspects of the Single Audit Act.

**Sample 2**: *Clause for awardees (insert name, if desired) that are not subject to the Single Audit Act but have a contract subject to Cost Principles and/or Cost Accounting Standards*

The Other Transaction Agreement Officer (OTAO), or an authorized representative, shall have the right to examine or audit awardee records during the period of the agreement and for three years after final payment is made, unless notified otherwise by the Other Transaction Agreement Officer. The OTAO, or an authorized representative, shall have direct access to sufficient records to ensure full accountability for all Government funding or to verify statutorily required cost share under the agreement.



**Sample 3**: *Clause for awardees (insert name, if desired) that are not subject to the Single Audit Act, do not have a procurement contract subject to Cost Principles (48 CFR Part 31) and/or Cost Accounting Standards (48 CFR Part 99), and refuse to accept Government access to their records*

The Other Transaction Agreement Officer or an authorized representative, shall have the right to request an examination or audit of the awardee's records during the period of the agreement and for three years after final payment is made, unless notified otherwise by the Other Transaction Agreement Officer. The audits will be conducted by an Independent Public Accountant (IPA), subject to the following conditions:

1) The audit shall be performed in accordance with Generally Accepted Government Auditing Standards (GAGAS).

2) The Other Transaction Agreement Officer's authorized representative shall have the right to examine the IPA's audit report and working papers for three years after final payment, unless notified otherwise by the Other Transaction Agreement Officer. The IPA shall report instances of suspected fraud directly to the DHS Inspector General and shall inform the Other Transaction Agreement Officer.

4) When the Other Transaction Agreement Officer determines (subject to appeal under the Disputes Article of the agreement) that the audit has not been performed within twelve months of the date requested by the Other Transaction Agreement Officer, or has not been performed in accordance with GAGAS or other pertinent provisions of the agreement (if any), the Government shall have the right to require corrective action by the awardee.

The awardee may take corrective action by having the IPA correct any deficiencies identified by the Other Transaction Agreement Officer, by having another IPA perform the audit, or by electing to have the Government perform the audit. If corrective action is not taken, the Other Transaction Agreement Officer shall have the right to take one or more of the following actions:

(a) Withhold or disallow a percentage of costs until the audit is satisfactorily completed;

(b) Suspend performance until the audit is satisfactorily completed; and/or

(c) Terminate the OT agreement.

5) If it is found that the awardee was performing a procurement contract subject to Cost Principles (48 CFR Part 31) and/or Cost Accounting Standards (48 CFR 99) at the time of agreement award, the Other Transaction Agreement Officer, or an authorized representative, shall have the right to audit sufficient records of the awardee to ensure full accountability for all Government funding or to verify statutorily required cost share under the agreement. The awardee shall retain such records for three years after final payment, unless notified otherwise by the Other Transaction Agreement Officer.

**Sample 4:** *Clause for all awardees for flowing down requirements*

The awardee shall flow down the applicable audit access requirements, when key participants contribute towards statutory cost share requirements or will receive total payments exceeding $300,000 that are based on amounts generated from cost or financial records, and request audits of key participants when the Other Transaction Agreement Officer advises that audits are necessary. The Other Transaction Agreement Officer will provide sample audit access clauses to the awardee. Unless otherwise permitted by the Other Transaction Agreement Officer, the awardee shall alter the sample clauses only as necessary to properly identify the contracting parties and the Other Transaction Agreement Officer.

The awardee shall provide a statement to the Other Transaction Agreement Officer when a business unit meets the conditions for use of an Independent Public Accountant (other than pursuant to the Single Audit Act) for any needed audits. The statement shall include the business unit's name, address, expected value of its award, and state that the business unit is not currently performing on a procurement contract subject to the Cost Principles (48 CFR Part 31) and/or Cost Accounting Standards (48 CFR Part 99) and refuses to accept Government access to its records. Where the awardee and key participant agree, the key participant may provide this statement directly to the Other Transaction Agreement Officer.

## ARTICLE VI: DISPUTES

A. GENERAL

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

B. DISPUTE RESOLUTION PROCEDURES

1. Any disagreement, claim or dispute between NIH and ABC concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or

misunderstanding which arose more than three (3) months prior to the notification made under subparagraph B.3 of this article constitute the basis for relief under this article unless the Director of NIH in the interests of justice waives this requirement.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the NIH OTAO or Consortium Administrator, as the case may be) in writing of the relevant facts, identify unresolved issues, and specify the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the NIH's Special Assistant for Acquisition and senior executive (no lower than *(insert a level of executive far enough removed from the program to maintain a greater level of impartiality)* level) appointed by ABC. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Deputy Director for Management and the senior executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, upon written request to the Director of NIH, made within thirty (30) calendar days of the expiration of the time for a decision under subparagraph B.3 above, the dispute shall be further reviewed. The Director of NIH may elect to conduct this review personally or through a designee or jointly with a senior executive (no lower than (*insert a level of executive far enough removed from the program to maintain a greater level of impartiality*) level) appointed by ABC. Following the review, the Director of NIH or designee will resolve the issue(s)and notify the Parties in writing. Such resolution is not subject to further administrative review and, to the extent permitted by law, shall be final and binding.

(5. Subject only to this article and 41 U.S.C. § 321-322, if not satisfied with the results of completing the above process, either Party may within thirty (30) calendar days of receipt of the notice in subparagraph B.4 above pursue any right and remedy in a court of competent jurisdiction. *Note: this paragraph should not be included in this agreement unless this issue is raised by the company*.)

C. LIMITATION OF DAMAGES

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of NIH funding disbursed as of the time the dispute arises. In no event shall NIH be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, or other indirect damages. (ABC disclaims any liability for consequential, indirect, or special damages, except when such damages are caused by willful misconduct of ABC personnel. In no event shall ABC's liability under this

Agreement exceed the funding it has received up to the time of incurring such liability. (*Note: this part of the paragraph should not be included in this agreement unless the issue is raised by ABC.*)

# ANOTHER EXAMPLE

## ARTICLE VI: DISPUTES

a. The responsibility of the Recipient/BARDA Joint OTAR Oversight Committee·is to mutually interrogate risks and progress of assets covered under this Agreement, endorse potential new assets and agree on modifications to the allocation of funding across activities covered under the Agreement. This Committee will also jointly evaluate achievement of Portfolio Progress Milestones.

b. The Recipient/BARDA Joint OTAR Oversight Committee will meet approximately every six (6) months to review progress. The Committee will recommend the strategy to be covered under this Agreement during the subsequent funding period, as well as how Government and Recipient funding will be allocated across these activities. The recommendations would be submitted, as appropriate, to the relevant Recipient governance board(s) for endorsement and decision. If endorsed by the relevant Recipient governance boards and by BARDA, the recommendations will be incorporated into the Statement of Work and this Agreement through modifications as described in ARTICLE III.

**4. Project Meetings**

a. Weekly Teleconferences. A conference call between the OTTR and the Recipient's principal investigator shall occur every two (2) weeks or as directed by the OTTR. During this call, the principal investigator will discuss the activities· during the reporting period, any problems that have arisen, and the activities planned for the ensuing reporting period. The principal investigator may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the OTTR. On an as-needed basis, the OTTR or principal investigator may assign this responsibility to a delegate.

b. Kick-off and Quarterly Meetings. The Recipient and the Government shall participate in Project Meetings to coordinate the performance of the Agreement. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Recipient and its subrecipients. Such

meetings may include, but are not limited to, meetings of the Recipient (and subrecipients invited by the Recipient) to discuss study designs, site visits to the Recipients and subrecipient's facilities, and meetings with the Recipient and HHS officials to discuss the technical, financial, regulatory and ethical aspects of the program. These meetings will also formulate and endorse the activities for the subsequent three months. In order to facilitate review of agreement activities, it is expected that the Recipient will provide data, reports, and presentations to groups of outside experts (subject to appropriate agreements to protect confidential or proprietary data) and Government personnel as requested by the OTTR. The Recipient shall provide an itinerary/agenda at least five (5) business days in advance of a face-to-face meeting. Subject to other provisions specified in this Agreement (see for example Attachment 2), the Recipient shall notify the OTTR of formal and informal correspondence with the Food and Drug Administration (FDA) or, other regulatory agencies as specified in Attachment 2.



c. In Process Review Meeting (IPR). On an annual or event driven basis, prior to the exercise of Agreement options, the Government will invite the Recipient to give a presentation at an In Process Review Meeting attended by BARDA, AMCG, and select, invited interagency representatives and other interested parties, as needed. The Recipient will present data generated under the Agreement. Progress against Portfolio Progress Milestones will be assessed. Successes and challenges of the program will be discussed and plans for the coming year will be presented. With respect to ATM-AVI, the Recipient will also provide updates on the separate COMBACTE-CARE project involving a Phase II and the European component of the Phase Ill trial in Europe.

**5. Document Review**

The Recipient shall provide BARDA sufficient opportunity to review study protocols, reports, and regulatory correspondence. BARDA's comments on these documents will be viewed as advisory in nature. Specific timelines for document review and responses are outline in Attachment 2 - Reporting Requirements.

# ANOTHER EXAMPLE

I. DISPUTES

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising dispute issues under this Article.

1. Dispute Resolution Procedures: Any disagreement, claim or dispute between NIH and the NRPss concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may be raised only under this Article.
2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than __insert__ months prior to the notification made under this article constitute the basis for relief under this article unless NIH in the interest of justice waives this requirement.
3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. The other Party shall submit a written position on the matter(s) in dispute within __insert__ working days after receiving such notification. The Agreement Officer will conduct a review of the matter(s) in dispute and render a decision in writing within __insert__ working days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.
4. If requested within thirty (30) calendar days of the Agreement Officer's decision, further review will be conducted by the Agreement Officer. In the event of, or in an absence of, a decision within sixty (60) calendar days of referral to the Agreement Officer, either party may pursue any right or remedy provided by law. If the parties are unable to jointly resolve a dispute within a reasonable period of time the parties agree to explore and consider such Alternate Disputes Resolution options as may be available to them before pursing litigation.
5. Limitation of Liability and Damages: In no event shall the liability of the NRPs or any other entity performing research activities under this agreement, exceed the funding such entity has received for their performance of the specific work under which the dispute arises.

6. No Party shall be liable to any other Party for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct. Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.
7. The NRPs agrees to indemnify and hold harmless the Government, its agents and employees from every claim or liability, including attorneys fees, court costs, and expenses, arising out of, or in any way related to, the misuse or unauthorized modification, reproduction, release, performance, display, or disclosure of proprietary data it received from the Government.



8. If the Agreement Officer finds that any of the assurances or representation made by the NRPs in connection with the Agreement are incomplete or incorrect in any material respect or that there has been a failure by the NRPs to comply with any of the provisions of this Agreement or applicable Federal law or Regulations, he/she may take such action short of termination as may be necessary to protect the interest of the United States. Such action may include withholding payments to be made to the NRPs until adequate documentation thereof is provided, or requiring that the NRPs reimburse NIH for any payments made or any payments which NIH has become obligated to make as a result of the NRPs's incomplete or incorrect statements or violations of provisions of this Agreement or applicable Federal law or Regulations.

## ARTICLE VII: PATENT RIGHTS

*(Note: This article can be concise, defining and describing march-in rights and any other appropriate terms.)*

A. DEFINITIONS

1. "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.
2. "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

3. "Practical application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

4. "Subject invention" means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

B. ALLOCATION OF PRINCIPAL RIGHTS

Unless ABC shall have notified NIH (in accordance with subparagraph C.2 below) that ABC does not intend to retain title, ABC shall retain the entire right, title, and interest throughout the world to each subject invention consistent with the provisions of this Article and 35 U.S.C. § 202. With respect to any subject invention in which ABC retains title, NIH shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the subject invention throughout the world.

C. INVENTION DISCLOSURE, ELECTION OF TITLE, AND FILING OF PATENT APPLICATION

*(Time extensions may be applicable depending upon your program.)*

1. ABC shall disclose each subject invention to NIH within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to NIH shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. ABC shall also submit to NIH an annual listing of subject inventions.

2. If ABC determines that it does not intend to retain title to any such invention, ABC shall notify NIH, in writing, within eight (8) months of disclosure to NIH. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by NIH to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

3. ABC shall file its initial patent application on a subject invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. ABC may

elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

4. *Requests for extension of the time for disclosure election, and filing under Article VII, paragraph C, may, at the discretion of NIH, and after considering the position of ABC, be granted.*

Further, the NRPs is responsible for timely filing patent applications and reporting inventions and patents via NIH's iEdison website.

D. CONDITIONS WHEN THE GOVERNMENT MAY OBTAIN TITLE

Upon NIH's written request, ABC shall convey title to any subject invention to NIH under any of the following conditions:

1. If ABC fails to disclose or elects not to retain title to the subject invention within the times specified in paragraph C of this Article; provided, that NIH may only request title within sixty (60) calendar days after learning of the failure of ABC to disclose or elect within the specified times.

2. In those countries in which ABC fails to file patent applications within the times specified in paragraph C of this Article; provided, that if ABC has filed a patent application in a country after the times specified in paragraph C of this Article, but prior to its receipt of the written request by NIH, ABC shall continue to retain title in that country; or

3. In any country in which ABC decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a subject invention.

E. MINIMUM RIGHTS TO ABC AND PROTECTION OF ABC'S RIGHT TO FILE

1. ABC shall retain a nonexclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title, except if ABC fails to disclose the invention within the times specified in paragraph C of this Article. The ABC license extends to the domestic (including Canada) subsidiaries and affiliates, if any, within the corporate structure of which ABC is a party and includes the right to grant licenses of the same scope to the extent that ABC was legally obligated to do so at the time the Agreement was awarded. The license is transferable only with the approval of NIH, except when transferred to the successor of that part of the business to which the invention pertains. NIH approval for license transfer shall not be unreasonably withheld.

2. The ABC domestic license may be revoked or modified by NIH to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which ABC has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of NIH to the extent ABC, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

3. Before revocation or modification of the license, NIH shall furnish ABC a written notice of its intention to revoke or modify the license, and ABC shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

F. ACTION TO PROTECT THE GOVERNMENT'S INTEREST

1. ABC agrees to execute or to have executed and promptly deliver to NIH all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which ABC elects to retain title, and (ii) convey title to NIH when requested under paragraph D of this Article and to enable the Government to obtain patent protection throughout the world in that subject invention.

2. ABC agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by ABC each subject invention made under this Agreement in order that ABC can comply with the disclosure provisions of paragraph C of this Article. ABC shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U. S. or foreign statutory bars.

3. ABC shall notify NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

4. ABC shall include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made with Government support under Agreement No. awarded by NIH. The Government has certain rights in the invention."

G. LOWER TIER AGREEMENTS

ABC shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

H. REPORTING ON UTILIZATION OF SUBJECT INVENTIONS

ABC agrees to submit, during the term of the Agreement, an annual report on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by ABC or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by ABC, and such other data and information as the agency may reasonably specify. ABC also agrees to provide additional reports as may be requested by NIH about any march-in proceedings undertaken by NIH in accordance with paragraph J of this Article. Consistent with 35 U.S.C. § 202(c)(5), NIH agrees it shall not disclose such information to persons outside the Government without permission of ABC.

I. PREFERENCE FOR AMERICAN INDUSTRY

Notwithstanding any other provision of this clause, ABC agrees that it shall not grant to any person the exclusive right to use or sell any subject invention in the United States or Canada unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by NIH upon a showing by ABC that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

J. MARCH-IN RIGHTS

ABC agrees that, with respect to any subject invention in which it has retained title, NIH has the right to require ABC, an assignee, or exclusive licensee of a subject invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if ABC, assignee, or exclusive licensee refuses such a request, NIH has the right to grant such a license itself if NIH determines that:

1. Such action is necessary because ABC or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the subject invention;

2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by ABC, assignee, or their licensees;

3. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by ABC, assignee, or licensees; or

4. Such action is necessary because the agreement required by paragraph (I) of this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such Agreement.

# A BARDA Example

A. ALLOCATION OF PRINCIPAL RIGHTS

Unless Recipient shall have notified HHS (in accordance with subparagraph C.2 below) that Recipient does not intend to retain title, in which case title shall vest with the Government, Recipient shall retain the entire right, title, and interest throughout the world to each Subject Invention developed under this Agreement, consistent with the provisions of this Article and 35 U.S. § 202. With respect to any Subject Invention developed under this Agreement, in which Recipient retains title, HHS shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. For any Subject Invention relating to ATM-AVI,

this license is restricted to practice of such Subject Invention for use in the development of antibacterial assets to treat hospital and biothreat infections.

H. The Recipient agrees that, with respect to any Subject Invention in which it has retained title, HHS. has the right to require Recipient, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license within the Field to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Recipient, assignee, or exclusive licensee refuses such a request, HHS has the right to grant such a license in the development of antibacterial assets to treat hospital and biothreat infections itself if HHS determines that:

1. Such action is necessary because Recipient or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve Practical Application of the Subject Invention; or

2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by Recipient, assignee, or their licensees.



## ARTICLE VIII: DATA RIGHTS

*(Note: this article may be substantially revised depending on the facts of each agreement.)*

A. DEFINITIONS

1. "Government Purpose Rights", as used in this article, means rights to use, duplicate, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

2. "Unlimited Rights", as used in this article, means rights to use, duplicate, release, or disclose, Data in whole or in part, in any manner and for any purposes whatsoever, and to have or permit others to do so.

3. "Data", as used in this article, means recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, trade secrets, and mask works. The term does not include financial, administrative, cost, pricing or management information and does not include subject inventions included under Article VII.

B. ALLOCATION OF PRINCIPAL RIGHTS

1. This Agreement shall be performed with mixed Government and ABC funding. The Parties agree that in consideration for Government funding, ABC intends to reduce to practical application items, components and processes developed under this Agreement.

2. ABC agrees to retain and maintain in good condition until (*insert number of year*) ( ) years after completion or termination of this Agreement, all

Data necessary to achieve practical application. In the event of exercise of the Government's March-in Rights as set forth under Article VII or subparagraph B.3 of this article, ABC agrees, upon written request from the Government, to deliver at no additional cost to the Government, all Data necessary to achieve practical application within sixty (60) calendar days from the date of the written request. The Government shall retain Unlimited Rights, as defined in paragraph A above, to this delivered Data.

3. ABC agrees that, with respect to Data necessary to achieve practical application, NIH has the right to require ABC to deliver all such Data to NIH in accordance with its reasonable directions if NIH determines that:

(a) Such action is necessary because ABC or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the technology developed during the performance of this Agreement;

(b) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by ABC, assignee, or their licensees; or

(c) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by ABC, assignee, or licensees.

4. With respect to Data delivered pursuant to Attachment 2 (and listed below), the Government shall receive Government Purpose Rights, as defined in paragraph A above. With respect to all Data delivered, in the event of the Government's exercise of its right under subparagraph B.2 of this article, the Government shall receive Unlimited Rights.

C. MARKING OF DATA

Pursuant to paragraph B above, any Data delivered under this Agreement shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in Agreement XXXX between the Government and ABC.

D. LOWER-TIER AGREEMENTS

ABC shall include this Article, suitably modified to identify the Parties, in all subcontracts or lower-tier agreements, regardless of tier, for experimental, developmental, or research work.

## Another example

DATA

1. The NRPs reserves the right to protect by copyright original works developed under this agreement. Further, the NRPs is responsible for timely

filing patent applications and reporting inventions and patents via NIH's iEdison website.

2. The NRPs hereby grants to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.



3. In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work, and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.

Identification and Disposition of Data

Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

As to Data first produced by the Government in carrying out the Government's responsibilities under this agreement and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the NRPs, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the NRPs to whom disclosed for a period of ***insert number)*** years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the NRPs, including its respective employees or subcontractors, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

Government Prior Technology: In the event it is necessary for the Government to furnish the NRPs, including their respective employees or their sub-awardees and contractors of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by the NRPs. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.

Disclaimer of Liability: Notwithstanding the above, the Government shall not be restricted in, nor incur any liability for, the disclosure and use of:

> Data not identified with a suitable notice or legend as set forth in this Article; nor

Information contained in any Data for which disclosure and use is restricted, if such information is or becomes generally known without breach of this agreement, is properly known to the Government or is generated by the Government independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the NRPs has furnished, or is required to furnish to the Government without restriction on disclosure and use.

## ARTICLE IX: FOREIGN ACCESS TO TECHNOLOGY

This Article shall remain in effect during the term of the Agreement and for (*insert number of years*) (  ) years thereafter.

A. DEFINITIONS

1. "Foreign Firm or Institution" means a firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

2. "Know-How" means all information including, but not limited to discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus and machines.

3. "Technology" means discoveries, innovations, Know-How and inventions, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, maskworks, and copyrights developed under this Agreement.

B. GENERAL

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national defense, and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. The controls contemplated in this Article are in addition to, and are not intended to change or supersede, the provisions of the International Traffic in Arms Regulation (22 CFR pt. 121 et seq.), the DoD Industrial Security Regulation (DoD 5220.22-R) and the Department of Commerce Export Regulation (15 CFR pt. 770 et seq.)

C. RESTRICTIONS ON SALE OR TRANSFER OF TECHNOLOGY TO FOREIGN FIRMS OR INSTITUTIONS

1. In order to promote the national security interests of the United States and to effectuate the policies that underlie the regulations cited above, the procedures stated in subparagraphs C.2, C.3, and C.4 below shall apply to any transfer of Technology. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology. Transfers do not include:

(a) sales of products or components, or

(b) licenses of software or documentation related to sales of products or components, or

(c) transfer to foreign subsidiaries of ABC for purposes related to this Agreement, or

(d) transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the conduct of research under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

2. ABC shall provide timely notice to NIH of any proposed transfers from ABC of Technology developed under this Agreement to Foreign Firms or Institutions. If NIH determines that the transfer may have adverse consequences to the national security interests of the United States, ABC, its vendors, and NIH shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to ABC.

3. In any event, ABC shall provide written notice to the NIH Program Manager and OTAO of any proposed transfer to a foreign firm or institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within thirty (30) calendar days of receipt of ABC's written notification, the NIH OTAO shall advise ABC whether it consents to the proposed transfer. In cases where NIH does not concur or sixty (60) calendar days after receipt and NIH provides no decision, ABC may utilize the procedures under Article VI, Disputes. No transfer shall take place until a decision is rendered.

4. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by NIH takes place, ABC shall (a) refund to NIH funds paid for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government ABC shall provide written confirmation of such licenses.

AGREEMENT

D. LOWER TIER AGREEMENTS

ABC shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

## ARTICLE X: TITLE AND DISPOSITION OF PROPERTY

A. DEFINITIONS

In this article "property" means any tangible personal property other than consumable property which is actually consumed during the execution of work under this agreement.

B. TITLE TO PROPERTY

No significant items of property are expected to be acquired under this Agreement. Title to each item of property acquired under this Agreement with an acquisition value of $50,000 or less shall vest in ABC upon acquisition with no further obligation of the Parties unless otherwise determined by the Agreements Officer. Should any item of property with an acquisition value greater than $50,000 be required, ABC shall obtain prior written approval of the Agreements Officer. Title to this property shall also vest in ABC upon acquisition. ABC shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense.

C. DISPOSITION OF PROPERTY

At the completion of the term of this Agreement, items of property with an acquisition value greater than $50,000 shall be disposed of in the following manner:

1. Purchased by ABC at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to NIH; or

2. Transferred to a Government research facility with title and ownership being transferred to the Government; or

3. Donated to a mutually agreed University or technical learning center for research purposes; or

4. Any other NIH-approved disposition procedure.

# Another Example

## ARTICLE X: TITLE AND DISPOSITION OF PROPERTY

A. DEFINITIONS

In this article "property" means any tangible personal property other than consumable property which is actually consumed during the execution of work under this agreement.

B. TITLE TO PROPERTY

ABC will acquire property with an acquisition value greater than $50,000 under this Agreement as set forth in Attachment * to this Agreement which is necessary to further the research and development goals of this Program and is not for the direct benefit of the Government. Title to this property shall vest in ABC upon acquisition. Title to any other items of property acquired under this Agreement with an acquisition value of $50,000 or less shall vest in ABC upon acquisition with no further obligation of the Parties unless otherwise determined by the Agreements Officer. Should any other item of property with an acquisition value greater than $50,000 be required, ABC shall obtain prior written approval of the Agreements Officer. Title to this property shall also vest in ABC upon acquisition. ABC shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense.

C. DISPOSITION OF PROPERTY

At the completion of the term of this Agreement, items of property set forth in Attachment * or any other items of property with an acquisition value greater than $50,000 shall be disposed of in the following manner:

1. Purchased by ABC at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to NIH; or

2. Transferred to a Government research facility with title and ownership being transferred to the Government; or

3. Donated to a mutually agreed University or technical learning center for research purposes; or

4. Any other NIH-approved disposition procedure.

## ANOTHER EXAMPLE

## PROPERTY

In this Article, "property" means any tangible personal property other than property actually consumed during the execution of work under this Agreement.

- (*No*) significant items of property are expected to be acquired under this agreement by the External Partner.
- Title to any item of property valued __insert__ or less that is acquired by the External Partner pursuant to this agreement in performance of the scope of work shall vest in the External Partner upon acquisition with no further obligation of the Parties unless otherwise determined by the Agreement Officer.
- Should any item of property with an acquisition value greater than __insert__ be required, the External Partner shall obtain prior written approval of the Agreement Officer. Title to this property shall vest in (*the External Partner or NIH*) upon acquisition.
- The External Partner shall be responsible for the maintenance, repair, protection, and preservation of all such property (*at its own expense*).
- Property acquired pursuant to this clause shall not be considered as in exchange for services in performance of the scope of work, but shall be considered a Government contribution to the project.

## ARTICLE XI: CIVIL RIGHTS ACT

This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. ABC has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

## ARTICLE XII: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of ABC and the NIH Agreements Officer. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

**NOTE: IN CREATION OF THIS AGREEMENT, THE OTAO MUST REVIEW EACH OF THESE SAMPLE PROVISIONS CONTAINED IN ARTICLE XVI AND INCLUDE**

**ONLY THE ONES APPLICABLE FOR THE INSTANT AGREEMENT. OTHER CLAUSES SHOULD BE ADDED AS NECESSARY.**

## ARTICLE XVI: SPECIAL PROVISIONS

A. RIGHTS AND WELFARE OF HUMAN SUBJECTS

1. The Recipient agrees that the rights and welfare of human subjects involved in research under this OTA shall be protected in accordance with 45 CFR Part 46 and with the Recipient's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Recipient further agrees to provide certification that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects, in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Recipient shall bear full responsibility for the performance of all work and services involving the use of human subjects under this Agreement and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that Recipient retains the right to control and direct the performance of all work under the OTA. Nothing in this OTA shall be deemed to constitute Recipient or any sub consortium, agent or employee of Recipient, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. Recipient agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent consortium without imputing liability on the part of the Government for the acts of the Recipient or its employees.

3. If at any time during the performance of this OTA, the HHS OTAO's determines, in consultation with the OHRP, OPHS, ASH, that the Recipient is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this OTA until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to. complete corrective action within the period designated in the OTAO's written notice of suspension, the HHS OTAO may, in consultation with OHRP, OPHS, ASH, terminate this Agreement in a whole or in part, and the Recipient's name may be removed from the list of those performers with approved Health and Human Services Human Subject Assurances.

B. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

1. The acquisition and supply of all human specimen material (including fetal material) used under this OTA shall be obtained by Recipient in full compliance with applicable Federal, State and Local laws and no undue inducements,

monetary or otherwise, will be offered to any person to influence their donation of human material.

2. The Recipient shall provide written documentation that all human materials obtained because of research involving human subjects conducted under this OTA, by collaborating sites, or by subrecipients identified under this OTA, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Recipient.

3. Provision by the Recipient to the HHS OTAO's of a properly completed "Protection of Human Subjects Assurance Identification/IRS Certification/Declaration of Exemption," Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRS review and approval of the protocol from which the human materials, were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form if it contains the information required by the "Protection of Human Subjects Assurance Identification/IRS Certification/ Declaration of Exemption," Form OMB No. 0990-0263 (formerly Optional Form 310).

C. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart S. The Recipient shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Recipient.

D. NEEDLE EXCHANGE

The Recipient shall not use Agreement funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

E. CARE OF LIVE VERTEBRATE ANIMALS

1. Before undertaking performance of any OTA involving animal related activities, the Recipient shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Recipient shall furnish evidence of the registration to the Agreement Officer.

2. The Recipient shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.

3. The Recipient agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this OTA will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1- 4). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this Agreement, the HHS OTAO's determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Recipient is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this Agreement until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to complete corrective action within the period designated in the OTAO's written notice of suspension, the HHS OTAO's may, in consultation with OLAW, NIH, terminate this Agreement in whole or in part, and the Recipient's name may be removed from the list of those organizations with approved PHS Animal Welfare Assurances.

.

**Note:** The Recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office below or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

F. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: http://grants1.nih.gov/grants/o1aw/references/phspo1.htm. Primate studies will not begin until the CRO's IACUC and the Recipient's Animal Welfare Department provide final approval of the study protocol. All Recipient personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, titled "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/.

G. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U.S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for

the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), https://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Recipient does not have an assurance and will be utilizing a subrecipient to perform the animal work, then the Recipient and subrecipient must have an Inter-Institutional Assurance in place to allow the Recipient to utilize the assurance of the subrecipient to meet the HHS requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by BARDA on behalf of the Recipient.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://awic.nal.usda.gov/final-rules- animal-welfare-9-cfr-parts-1-2-and-3 issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given" the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies http://www.fass.org.

H. APPROVAL OF REQUIRED ASSURANCE BY LAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services shall not be expended by the Recipient for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Recipient under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25–2.28 is submitted by Recipient 30 days prior to commencing research involving live vertebrate animals and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate

animals (i.e. are clearly severable and independent from those activities that do involve Jive vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25- 2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants.nih.gov/grants/olaw/olaw.htm.



I. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this Agreement until the Recipient and any affected subrecipients are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subagreements awards to domestic institutions who possess, use, and/or transfer Select Agents under this OTA, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subagreements awards to foreign institutions who possess, use, and/or transfer Select Agents under this OTA, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Recipient must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR part 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR part 73. When requested by the OTAO, the Recipient shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For security risk assessments, the Recipient must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the OTA.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

J. PRODUCT APPROVAL

The Recipient agrees to comply with cGMP guidelines (21 CFR Parts 210–211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents.

The Recipient agrees to advise the HHS OTAO and OTR promptly of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility during the term or this Agreement. The Recipient also agrees to advise the HHS OTAO's and OTTR immediately if, at any time during the term of this Agreement, the items under this OTA fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

K. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210–211) will be the standard applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of this OTA, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CDER, the Recipient shall have sixty (60) calendar days from the time such material failure is identified to initiate corrective action designed to cure such material failure within three (3) months. If the Recipient fails to initiate such an action within the sixty (60) calendar day period, then the Agreement may be terminated.

L. ANTI-BRIBERY AND ANTI-CORRUPTION

The recipient acknowledges that it has received and read Recipient's "Prevention of Corruption - Third Party Guidelines." Each Party agrees to perform its obligations under this Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Agreement, to terminate this Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article XIV (M.).

M. SALARY RATE LIMITATION *(if adjustable payable milestones are present in this agreement)*

1. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate more than the Federal Executive Schedule Level II in effect on the date an expense is incurred is an unallowable cost under this Agreement.

2. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under the OTAR. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses i.e. indirect costs or facilities and administrative [F&A] costs).

***Note:*** *The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract, order, or OTAR; it merely limits the portion of that salary that may be paid with federal funds.*

3. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year OT, it may be subject to unilateral modification by the OTAO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

4. See the salaries and wages pay tables on the U.S. Office of Personnel Management website for Federal Executive Schedule salary levels that apply to the current and prior periods.

N. MAN-IN-PLANT

With seven (7) days' notice to the Recipient in writing from the OTAO/OTAS, the Government may place a man-in-plant in the Recipient's facility, who shall be subject to the Recipient's policies and procedures regarding security and facility access always while in the Recipient's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him during employment or official duties, while stationed in a Recipient plant.

O. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All

telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services

TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

P. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Agreement.

Q. MATERIALS TRANSFER AGREEMENT

For distribution to third-party parties of any material developed under this Agreement, the Recipient must provide BARDA and AMCG a Materials Transfer Agreement (MTA). Following finalization of the MTA, the Recipient must provide notice of the requests/transfers in the monthly technical report along with copies of the final MTA.

With respect to ATM-AVI, the Government acknowledges that the European component of the clinical trials delivered by the COMBACTE-CARE project agreement are not subject to this restriction and that Recipient may transfer materials necessary to satisfy Recipient's obligations under that agreement in accordance with the requirements of the COMBACTE-CARE project agreement. The Government further acknowledges the right of Recipient to transfer material to Actavis and any successor to Actavis interests without Government notice or approval.

## ANOTHER EXAMPLE

II. GENERAL TERMS AND PROVISIONS

The NRPs agrees to comply with the following:

1. NIH policy consistent with the requirements for Public Access in P.L. 111-8 (described in NOT-OD-09-071) and applicable to “all investigators funded by the NIH”;
2. Department of Health and Human Services Human Subjects regulations applicable to all “research that is conducted or supported by a federal department or agency” (45 CFR 46.101);
3. Requirements for NIH-funded clinical trials to register and report results on ClinicalTrials.gov;
4. NIH Guidelines on Human Stem Cell Research which apply to the expenditure of funds for research using human embryonic stem cells (hESCs) and certain uses of induced pluripotent

stem cells. This also includes restrictions on Human Fetal Tissue Research and Research on Transplantation of Human Fetal Tissue; and,

5. Requirements for ensuring laboratory animal welfare as prescribed in applicable legal authorities (e.g. PHS Act, Animals in Research Act) and incorporated into the PHS Policy on Humane Care and Use of Laboratory Animals.

STATEMENT OF WORK

(Initial Program Plan)

Task l

**REPORT REQUIREMENTS**

*A. QUARTERLY REPORT*

L

On or before ninety (90) calendar days after the effective date of the Agreement and quarterly thereafter throughout the term of the Agreement, the Consortium Management Committee (CMC) shall submit or otherwise provide a quarterly report. Two (2) copies shall be submitted or otherwise provided to the NIH Program Manager, one (1) copy shall be submitted or otherwise provided to the OTAO and one (1) copy shall be submitted or otherwise provided to NIH/(*insert program office*), Attn: Assistant Director for Program Management. The report will have two (2) major sections.

a. Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. The technical status report will include a report on the status of consortium collaborative activities during the reporting period.

b. Business Status Report. (ADJUSTABLE PAYABLE MILESTONES)

The business status report shall provide summarized details of the resource status of this Agreement, including the status of the contributions by the Consortium participants. This report will include a quarterly accounting of current expenditures as outlined in the Annual Program Plan. Any major deviations shall be explained along with discussions of the adjustment actions proposed. The report will also include an accounting of interest earned on Government funds, IF ANY. The Consortium is reminded that interest is not expected to accrue under this Agreement. In the event that interest does accrue on Government funds, the Consortium is required to provide an explanation for the interest accrued in the business report. Depending on the circumstances, the Payable Milestones may require adjustment. In any event, the Government reserves the right to require interest amounts earned in excess of $250 per year to be remitted at periodic intervals to be agreed upon by both Parties. All such interest rebates shall be made payable to the United States Treasury.

Business Status Report. (FIXED PAYABLE MILESTONES)

The business status report shall provide summarized details of the resource status of this Agreement, including the status of the labor contributions by the Consortium participants. This report will include a quarterly accounting of current labor hour expended as outlined in the Annual Program Plan. Any major deviations shall be

explained along with discussions of the adjustment actions proposed.

c. Annual Program Plan Document

The CMC shall submit or otherwise provide to the NIH Program Manager one (1) copy of a report which describes the Annual Program Plan as described in Article m, Section D. This document shall be submitted not later than thirty (30) calendar days following the Annual Site Review as described in Article III, Section x.

d. Special Technical Reports

As agreed to by the Consortium and the NIH Program Manager, the CMC shall submit or otherwise provide to the NIH Program Manager one (1) copy of special reports on significant events such as significant target accomplishments by Consortium Members, significant tests, experiments, or symposia.

E. PAYABLE MILESTONES **REPORTS**

The CMC shall submit or otherwise provide to the NIH Program Manager, documentation describing the extent of accomplishment of Payable Milestones. This information shall be as required by Article V, paragraph B and shall be sufficient for the NIH Program Manager to reasonably verify the accomplishment of the milestone of the event in accordance with the Statement of Work.

F. FINAL REPORT (*Note: The final report is the last payable milestone for the completed agreement.*)

I. The CMC shall submit or otherwise provide a Final Report making full disclosure of all major developments by the Consortium upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement. With the approval of the NIH Program Manager, reprints of published articles may be attached to the Final Report. Two (2) copies shall be submitted or otherwise provided to the NIH Program Manager and one (1) copy shall be submitted or otherwise provided to NIH (*insert program office*), xxxxx

J. The Final Report shall be marked with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations. The Final Report shall be marked on the front page in a conspicuous place with the following marking:

'DISTRIBUTION STATEMENT B. Distribution authorized to U.S. Government agencies only to protect information not owned by the U.S. Government and protected by a contractor's "limited rights" statement, or received with the understanding that it not be routinely transmitted outside the U.S. Government. Other requests for this document shall be referred to NIH/technical Information Officer.

# Another example

## Attachment No. 2 Reporting Requirements

ABC will complete electronically all reports and Deliverables, including monthly status updates, quarterly progress reports, the final project report, Deliverables, and invoice information ABC will use the same website that was used to submit its proposal. Hardcopies of invoices will also be required per the instructions in Section 6.02 Payments, above, until ABC is advised otherwise. A user ID and password is required for access to this site. ABC will specify who should have access to the website. After the Agreement is executed, the Agreement Officer will provide detailed instructions for submitting reports and Deliverables, including the specific web address, user ID, and password.



1. **Monthly Status Update.** The Team Project Manager must provide electronic updates per the instructions identified above, to the Government Technical Manager. Updates are to be available on the website by the close of business on the second working day following the end of the month. The update must include (in bullet format) "Accomplishments during the past month" and "Planned Activities during the next 30-60 days." Monthly updates will not be required for the period that a Quarterly Status and Progress Report is due.
2. **Quarterly Status and Progress Report** ABC must share the same quarterly report with all project sponsors at the same time. The report submitted to NIH report must be identical to the report shared with all project sponsors. There should be no alterations or changes to the report in the sponsor's absence. All sponsors and team members must debate the technical findings at the same time. The Team Project Manager must provide electronic status and progress reports, per the instructions above, that are available on the website, on or before (90) calendar days after the effective date of the Agreement and each quarter thereafter throughout the term of the Agreement. Each report must have four (4) sections:
    (a) *Technical Status Section.* The technical status section will detail technical progress (describe how task(s) were completed, data collected, and results of the research) to date for each active Project area and will report on all problems, technical issues or major developments during the reporting period.
    (b) *Business Status Section.* The business status section will summarize details of the resource status of this Agreement, including the status of the contributions by the Team Participants. This section will include a quarterly accounting of budgeted, actual and cumulative expenditures, including cost share amounts. This section will explain any major deviations and discuss the adjustment actions proposed.
    (c) *Payable Milestone Section.* This section must contain information (as required by Article VI, Section 6.02.2) sufficient for the Technical Manager to verify each milestone of each activity/Deliverable has been accomplished.

(d) *Public Page.* This section will contain information on the technical status of the Project and the milestones completed during the quarter. Information on this page will be information that NIH may release to the public in whole or in part at any time. The information on this page must not contain proprietary data or confidential business information. The Team Project Manager must provide a point of contact for coordination, preparation, and distribution of any press releases.

3. **Draft Final Report.** ABC must share the same draft final report for NIH with all project sponsors at the same time. The report submitted to NIH report must be identical to the report shared with al project sponsors. There should be no alterations or changes to the report in the sponsors absence. All sponsors and team members must debate the technical findings at the same time. The Team Project Manager must submit an electronic Draft Final Report on or before the end of the project performance period. The Technical Manager will work with the Team Project Manager and/or Project co-sponsors to remediate draft final report comments, as required.

4. **Final Project Report** ABC must share the final report for NIH with all project sponsors at the same time. The Team Project Manager must submit an electronic final report within 14 calendar days following the approval by the Technical Manager of the Draft Final Report. The Final Report addresses all comments supplied by the Technical Manager and is the final version. All Final Reports will be publicly available, and, in some cases, a separate public version may be required. All projects require a Final Report regardless of project scope. The instructions are described above. The report must contain a technical and financial section as follows:

   (a) *Impact from the Research Results.* This section defines how this research impacts technology development or consensus standards strengthening or general information for decision makers or a combination of multiple areas if appropriate. Specific information must be provided indicating what net improvement(s) were made because of this work. Specific measures can be included if known with the goal here to convey how this research is bringing a positive change to the current state of practice or art.

   (b) *Final Financial Section.* This section of the report contains a final Project financial report that summarizes the status of Government and Team contributions for the Project and reconciles any prior discrepancies or variances in contributions.

## Another Sample

ATTACHMENT 2: REPORTING REQUIREMENTS

A. TECHNICAL REPORTS

A conference call between the Agreements Officer's Technical Representative and the principal investigator shall occur once every two weeks or as directed by the OTR. During this call, the principal investigator will discuss the activities during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. The principal investigator may choose to include other key personnel on the conference call to give detailed updates on specific projects, or this may be requested by the OTR. On an as needed basis, the OTTR or principal investigator may assign this responsibility to a delegate.



B. PROJECT MEETINGS

The Recipient shall participate in Project Meetings to coordinate the performance of the Agreement as requested by the OTR. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Recipient and its subrecipients. Such meetings may include, but are not imited to, meetings of the Recipient (and Subrecipients invited by the Recipient) to discuss study designs, site visits to the Recipients and subrecipient's facilities, and meetings with the Recipient and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Recipient must provide data, reports, and presentations to groups of outside experts (subject to appropriate agreements to protect confidential or proprietary data) and Government personnel as required by the OTTR in order to facilitate review of Agreement activities.

C. REPORT DELIVERABLES

Unless otherwise specified by the OTAO, delivery of reports to be furnished to the Government under this Agreement (including invoices), shall be delivered electronically along with a concurrent email notification to the OTAO, OTAS, and OTTR summarizing the electronic delivery.

For electronic delivery of final versions of the deliverables listed below, the Recipient shall upload documents into the appropriate folder on https://eroom.bardatools.hhs.gov/eRoom ("eRoom") which is the designated USG file sharing system. The USG shall provide two Recipient representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the USG prior to gaining user access. A notification email should be sent to the OTAO, OTAS, and OTTR upon electronic delivery of any documents.

D. DELIVERABLES

Successful performance of the final agreement shall be deemed to occur upon performance of the work set forth in the Statement of Work dated September 9, 2XX5, set forth in Attachment No. 1 of this agreement and upon delivery and acceptance, as required by the Statement of Work or elsewhere in this Agreement, by the Agreement Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule below:

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 1 | Project Meeting | Every two weeks or as amended by OTAO and OTTR | The Recipient and BARDA will participate in teleconferences every other week to discuss the performance of the Agreement. The Recipient will prepare a proposed agenda and will record, maintain and provide draft meeting minutes to the OTTR for review and concurrence. The Recipient will send a final version of the meeting minutes to the OTTR. The OTTR will distribute the draft and final version to the OTAS and other BARDA staff. (For avoidance of doubt, financial information is not expected at these updates, which will be technically focused. BARDA reserves the right to include financial personnel in these project meetings, if needed. | The Recipient provides agenda to the OTTR, OTAO, and the OTAS within 2 business days of meeting.<br>OTTR (with OTAS concurrence) distributes agenda to BARDA participants prior to meeting.<br>The Recipient provides meeting minutes within 3 business days of the meeting.<br>OTTR reviews and comments on minutes within 10 business days. | 1 electronic and 1 hard copy to OTTR and OTAS.<br>Final will be uploaded to eRoom. |
| | | Every third month (Quarterly) | The Recipient and BARDA will participate in quarterly face-to- face site visits or teleconferences in Washington, D.C. and/or at work sites of the Recipient and its subrecipients to discuss the performance of the Agreement. The meetings will be used to discuss Agreement progress in relation to the Work Breakdown Structure (WBS), Integrated Master Schedule (IMS), and Agreement Performance Reports<br>{APR) as well as study designs, technical, financial, regulatory, and ethical aspects of the program. These meetings may also include site visits to the Recipient and subrecipient's facilities. The Recipient will provide data, reports, and presentations to groups of outside experts and USG personnel. | The Recipient shall provide itinerary and agenda at least 5 business days in advance of site visit.<br>OTTR review and distributes itinerary and agenda within 3 business days of meeting. | |
| | | AZ/BARDA Joint OTAR Oversight | Members of the JOC will meet approximately every six months as detailed | Meeting minutes will be taken by the Recipient and provided to the OTTR, | |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| | | Committee meeting (every 6 months or on an ad hoc basis as needed) | in Article V. | OTAO, and OTAS within 3 business days of the meeting.<br>OTTR will distribute the minutes to the JOC members and return . any BARDA edits or comments to the Recipient within 3 business days of original receipt of the draft minutes. | |
| 2 | Monthly Status Report | The 30th calendar day of each month following the fractional portion of the initial month and first full month of the OTA award. Monthly reports are due each month within 30 days after the last day of that month, except on the month when the Annual Technical Progress Reports are due. The reporting period will reflect the prior month's activities. | The Monthly/Annual Status Report will address the items listed below and cross-referenced to the Work Breakdown Structure (WBS), Scope of Work (SOW), Integrated Master Schedule (IMS), Performance Measurement Baseline Review (PMBR) report, Agreement Performance Reports (APR), and approval strategy.<br>An Executive Summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities. The Executive Summary should be limited to 2-3 pages and highlight critical issues for that reporting period.<br>The report should detail the planned and actual progress of the SOW activities during the period covered, explaining occurrences of any differences between the two, and the corrective steps.<br>The report should list any regulatory submissions relevant to the antibiotic candidates covered under this Agreement that have taken place during the reporting period. | Monthly Reports:<br>The Recipient provides Monthly Status Report deliverables within 30 days after the last day of that month reflecting the prior month's activities.<br>OTTR and OTAS will review Monthly Reports with Recipient and provide feedback. | 1 electronic and 1 hard copy to OTTR and OTAS.<br>Final will be uploaded to eRoom. |
| 3 | Integrated Master Schedule (IMS) | Within 60 days of OTA award and updated monthly | The Recipient will provide an IMS and monthly status updates in the monthly report to reflect changes in schedule, performance, and critical path. The Recipient will include BARDA Portfolio Management Milestones | The Recipient shall provide an IMS within 60 days of OTA award and updated within 30 days after the last day of each month. | 1 Electronic copy [Adobe Acrobat (.PDF) and Microsoft Project Schedule (.mmp) format] to |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| | | | in their IMS and provide monthly updates within their IMS. The IMS will be a standalone schedule containing only those activities that are applicable to the SOW. Individual project schedules for the assets within the portfolio agreement will also be provided on a monthly basis. | IMS shall be in both PDF and Microsoft Project Form.<br>BARDA shall provide the Recipient with a written list of concerns in response to the Recipient's submitted IMS, and the Recipient must address, in writing, all concerns raised by BARDA within 10 business days of Recipient's receipt of this list of concerns. | OTTR and OTAS; upload to eRoom |
| 4 | Financial Status Report | The 30th calendar day of each month following the fractional portion of the initial month and first full month of the OTA award. Financial Status Reports and updated monthly within 30 days after the last day of that month in the Project Status Report. | Recipient will provide a monthly Financial Status Report at an agreed upon WBS level using a format agreed upon with BARDA. | Recipient shall provide a Financial Status Report within 30 days after the last day of that month.<br>Recipient must address in writing all concerns raised by BARDA staff to the satisfaction of BARDA. | 1 electronic and 1 hard copy to OTTR and OTAS; upload to eRoom |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 5 | Risk Management Plan | 90 days following OTA award and updated quarterly (additional submissions as requested by OTAS or OTTR) | The Recipient will provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule and performance objectives. The Risk Management Plan will include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance. | The Recipient will provide a Risk Management Plan 90 days following OTA award and update Quarterly in their Monthly or Annual Project Status Reports.<br>BARDA will provide the Recipient with a written list of concerns (if any exist) in response to the Recipient's submitted Risk Management Plan, and Recipient must address in writing all concerns raised by BARDA within 20 business days of Recipient's receipt of this list of concerns. | 1 electronic copy to OTTR and OTAS; upload to eRoom |
| 6. | Deviation Notification and Mitigation Strategy | As needed | Process for changing IMS activities associated with cost and schedule as baselined at the PMBR. | The Recipient will notify BARDA of significant changes to the IMS. This includes increases in cost above 5% or schedule slippage of more than 30 days, which would require a POP extension. The Recipient will provide a high level management strategy for risk mitigation. | 1 electronic copy to OTTR and OTAS; upload to eRoom |
| 7 | In-Process Review Presentation | Annual or event driven review following completion of a pre-defined stage of product development and prior to initiation of a new stage | The Recipient will provide a presentation to BARDA and other Intergovernmental agency invitees on the Portfolio Progress at an In- Process Review meeting. | The Recipient will provide an update to technical progress made towards Portfolio Progress at an In-Process Review meeting and provide the presentation to BARDA no later than 10 business days prior to the meeting. | 1 electronic and 1 hard copy to OTTR and OTAS; upload to eRoom |

AGREEMENT

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 8 | Incident Report | Within 24 or 48 hrs of activity or incident | The Recipient will communicate and document all critical programmatic concerns, risks, or potential risks with BARDA within 48 hours. Recipient shall communicate via email or telephone. In addition, the Recipient will report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products within 24 hrs of activity or incident. Recipient will communicate via email, oral, or written communication. | Recipient will notify (orally or in writing) BARDA OTTR and OTAS within 48 hrs of Recipient identifying a critical project risk or potential risk and within 24 hrs for Security activities or incident. Recipient will provide additional updates within 48 hrs of additional developments, additional information and/or understanding. The Recipient will submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. If corrective action is recommended, the Recipient must address in writing its consideration of concerns raised by BARDA The Recipient will address BARDA's concerns in writing within 5 business days. | 1 electronic and 1 hard copy to OTTR and OTAS; upload to eRoom |
| 9 | Draft and Final Technical Progress Report | Draft 75 calendar days before and Final shall be submitted on or before the completion date of the POP | A draft of Final Technical Progress Report containing a summation of the work performed and the results obtained for the entire OTA period of performance. The draft report shall be duly marked as "Draft." The Final Technical Progress Report incorporating the feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire Agreement period of performance. This final report shall detail, document and summarize the results of the entire Agreement. This report shall be in sufficient | The Recipient shall provide a draft Technical Progress Report 75 calendar days before the end of the POP and the Final Technical Progress Report shall be submitted on or before the completion date of the POP. Subrecipient-prepared reports will be submitted to the OTTR and OTAS for review and comment no later than 5 business days after receipt by the prime Recipient. OTTR provides edits and additional feedback to draft report within 15 | 1 electronic copy to OTTR and OTAS; upload to eRoom |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| | | | detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as "Final." | calendar days of receipt, which the Recipient will consider incorporating into the Final Technical Progress Report.<br>The Recipient will submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the Agreement.<br>The Recipient will submit one copy of a comprehensive final report to the OTAS and one (1) copy (one electronically on a CD) to the OTTR. | |
| 10 | Study Protocols | At least 10 business days prior to FDA Submission | The Recipient will provide Pre-Clinical/ Non-Clinical/ Clinical Trial Protocols to **BARDA** for evaluation, prior to FDA submission.<br>The OTAS and OTIR reserve the right to request within the period of performance a nonproprietary<br>Study Protocol for distribution within the United States<br>Government (USG). | The Recipient and BARDA will collaboratively develop draft and final protocols for all Pre- Clinical/ Non-Clinical/ Clinical activities within the SOW.<br>The Recipient will submit draft and final protocols to BARDA for review and comment.<br>If the draft protocols are to be submitted to the FDA, BARDA review will take place prior to FDA submission.<br>BARDA will return comments to Recipient on the protocols no later than 10 business days from the date of receipt.<br>The Recipient will address, in writing, all concerns raised by BARDA.<br>The Recipient shall communicate BARDA's concerns and/or recommendations to Actavis prior to FDA submission. | 1 electronic copy to OTIR and OTAS; upload to eRoom |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| | | | | The Recipient and Actavis are not required to make any protocol revisions based on BARDA's concerns and/or recommendations.<br>In the event that BARDA disagrees with the final study protocol design, BARDA will notify the Recipient of nonconcurrence in writing.<br>Final FDA submissions shall be submitted to BARDA concurrently or no later than 5 calendar days after its submission to CDER. | |
| 11. | Study Reports | Within five (5) calendar days of the reports being available to AZ and 15 business days prior to anticipated submission to FDA | The OTAS and OTIR reserve the right to request within the period of performance a nonproprietary Study Report for distribution within the USG.<br>The Recipient will submit an interim study report to BARDA for any severable discrete work segments. If funding for a severable study is scheduled in two separate periods of performance, then an interim study report is due on or before the completion date of the POP. | The Recipient will provide Draft and Final Pre-Clinical/ Non-Clinical Study Reports to BARDA for review and comment within two (2) calendar days of these reports being available to AZ.<br>The Recipient will submit proposed Pre-Clinical/Non- Clinical Study Report to BARDA at least 15 business days prior to anticipated FDA submission.<br>If corrective action is recommended, Recipient will address, in writing or by corrective action, all concerns raised by BARDA.<br>The Recipient will work with Actavis to consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission.<br>Final FDA submissions shall be provided to BARDA concurrently or no later than 2 business days of its submission to CDER. | 1 electronic copy to OTIR and OTAS; upload to eRoom |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 12 | Manufacturing Campaign Reports (For avoidance of doubt, this relates to the clinical supply material during the POP and not once the product is commercially available.) | Within 30 calendar days after receipt of batch records and 15 business days prior to submission to FDA | The OTAS and OTIR reserve the right to request within the POP Manufacturing Campaign Reports for distribution within the USG. | The Recipient will submit Batch Analysis Reports or Manufacturing Campaign Reports to BARDA at least 15 business days prior to anticipated FDA submission.<br>If corrective action is recommended, Recipient will address in writing or by corrective action all concerns raised by BARDA.<br>The Recipient will work with Actavis to consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission.<br>Final FDA submissions shall be submitted to BARDA electronically concurrently or no later than five calendar days after its submission to CDER. | 1 electronic copy to OTIR and OTAS; upload to eRoom |
| 13 | Regulatory Meeting Notification | Within 24 hours of the anticipated scheduling Type A, Bore meetings OR within 48 hours of meeting occurrence for ad hoc meetings | The Recipient will forward the dates and times of any anticipated meeting with the regulatory agency to BARDA and seek to arrange for appropriate BARDA staff to attend the regulatory meetings relevant to BARDA- funded work. BARDA staff shall include up to a maximum of four people. | The Recipient will notify BARDA of an upcoming meeting with the regulatory agency within 48 hours of being informed that a meeting is scheduled. | 1 Electronic and 1 Hard Copy to OTIR and OTAS; upload to eRoom |
| 14 | Regulatory Correspondence and Meeting Minutes | Within three (3) business days of receiving correspondence from Actavis or the Regulatory Agency | The Recipient will forward Recipient and CDER-issued draft minutes and final minutes of any meeting with the Regulatory Agency to BARDA relevant to the portfolio program. All documents shall be duly marked as either “Draft” or “Final.” | The Recipient provides Regulatory correspondence and meeting minutes within three<br>(3) business days of receipt of the meeting or correspondence. | 1 Electronic and 1 Hard Copy to OTIR and OTAS; upload to eRoom |

AGREEMENT

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 15 | Regulatory Submissions | At least 10 calendar days prior to anticipated submission to FDA | The Recipient will provide BARDA the opportunity to review and comment upon regulatory documents before anticipated submission to the Regulatory Agency. Such documents shall include responses/comments/questions that the Regulatory Agency has passed on to the sponsor regarding the compounds in this Agreement as well as the name and address of the IRBs involved in clinical studies. All documents will be duly marked as either "Draft" or "Final."<br><br>(Note: BARDA will have already seen the Study Reports prior to submission.)<br><br>For avoidance of doubt, the Recipient is not required to provide to BARDA routine, general correspondence or information amendments (e.g. routine emails). | The Recipient will coordinate with Actavis to submit draft Regulatory Meeting Briefing Packets to BARDA at least 10 calendar days prior to anticipated submission to the Regulatory Agency. BARDA will provide comments to Recipient within five (5) business days of receiving the briefing. If corrective action is recommended, Recipient will address in writing its considerations of all concerns raised by BARDA. The Recipient will work with Actavis to consider revising documents to address BARDA's concerns and/or Recommendation prior to submission to regulatory authorities.<br>Final Regulatory submissions shall be submitted to BARDA concurrently or no later than 5 business days of its submission to CDER. | 1 electronic copy to OTIR and OTAS; Upload to eRoom |
| 16 | FDA Audits | Within 10 business days of scheduled audit or within 48 hours of an *ad hoc* site visits / audits if the FDA did not provide advance notification | The Recipient will notify the OTTR and OTAS within 24 hours of FDA's arrival to conduct site visits/audits by any regulatory agency. In the event of an FDA inspection which occurs as a result of this Agreement and for this product, or for any other FDA inspection that has the reasonable potential to impact the performance of this Agreement, the Recipient will provide BARDA with an exact copy (nonredacted) of the FDA Form 483, and the Establishment Inspection Report (EIR). Recipient shall provide the OTTR and OTAS copies of the plan for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the | The Recipient will notify the OTTR and OTAS within 10 business days of a scheduled audit or within 24hours of receiving notice of an ad hoc site visit(s)/audit(s) if the FDA did not provide advanced notification.<br>The Recipient will also provide copies of any FDA audit report received from subrecipients that occur as a result of this Agreement or for this product within five business days of receiving correspondence from the FDA and/or third party.<br>Within 10 business days of audit report, the Recipient will provide | 1 Electronic and 1 Hard Copy to OTTR and OTAS; Upload to eRoom |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| | | | audit report within 10 business days, status updates during the plans execution, and a copy of all final responses to the FDA. The Recipient shall also provide redacted copies of any FDA audit report received from subrecipients that occur as a result of this Agreement or for this product within five business days of receiving correspondence from the FDA and/or third party. The Recipient shall make arrangements, where practical, for a BARDA representative(s) to be present during the final debrief by the regulatory Inspector for audits of the Recipient. | OTAS with a plan for addressing areas of nonconformance, if any exist. | |
| 17 | QA Audit Reports | 5 business days of report completion | The Recipient will inform the OTIR and OTAS of upcoming, ongoing, or recent audits/site visits of subrecipients as part of the weekly communications, including goals and agenda. BARDA reserves the right to participate in the audits. Upon completion of the audit/site visit the Recipient shall provide a report capturing the findings, results, and next steps in proceeding with the subrecipient. If action is requested of the subrecipient, details addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. Recipient shall provide responses from the subrecipients to address these concerns and plans for corrective action execution.<br>For avoidance of doubt, as our subrecipients may be involved in other activities for the Recipient, the reportable audit information will only pertain to that which materially affects those programs funded under the portfolio partnership. | The Recipient will inform the OTTR and OTAS of upcoming, ongoing, or recent audits/site visits of subrecipients.<br>The Recipient will notify the OTIR and OTAS within 5 business days of report completion . | 1 electronic copy to OTIR and OTAS; upload to eRoom |

AGREEMENT

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 18 | BARDA Audit | *Ad Hoc* | The Recipient shall accommodate for periodic or *ad hoc* site visits by BARDA. If BARDA, Recipient, or other parties identifies any issues during an audit, Recipient shall capture the Issues, identify potential solutions and provide a report to BARDA. | If BARDA, the Recipient, or other parties identify any issues during an audit, Recipient shall capture the issues, identify potential solutions, and provide a report to BARDA within 10 business days.<br>The OTIR and OTAS will review the deliverable and provide a response to Recipient.<br>Once any corrective action undertaken by Recipient is completed, Recipient will provide a final report to BARDA. | 1 electronic copy to OTTR and OTAS; Upload to eRoom |
| 19 | Technical Documents<br><br>- | Within 10 business days upon request by OTAS/OTIR and 15 business days prior to anticipated submission to FDA | The Recipient will provide the OTIR and OTAS upon request with deliverables from the following contract funded activities: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, S0Ps, Master Production Records, Certificate of Analysis.<br><br>(The OTAS and OTIR reserve the right to request within the period of performance a nonproprietary technical Documents for distribution within the USG.) | The Recipient will provide technical documents within 10 business days upon request by OTAS/OTIR.<br>If additional time is required, Recipient will request additional time from BARDA on a per-deliverable basis.<br>If corrective action is recommended, Recipient will address, in writing or by corrective action, concerns raised by BARDA.<br>The Recipient will submit proposed FDA technical documents to BARDA at least 15 business days prior to anticipated FDA submission.<br>The Recipient will work with Actavis to consider revising technical documents to address BARDA's concerns and recommendation prior to FDA submission. | For final documents,<br>1 electronic copy to OTIR and OTAS; upload to eRoom. |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 20 | Animal Model or Other Technology Transfer Package | Within 10 business days of request by OTAS/OTIR | The Recipient shall provide Animal Model or Other Technology Transfer Package relevant data. | The Recipient will provide Animal Model or other Technology Transfer Package within 10 business days of request by OTAS/OTIR. | 1 electronic copy to OTIR and OTAS; upload to eRoom |
| 21 | Raw Data or Data Analysis | Within 20 business days, or as available, after receipt of request by OTAS/OTIR | The Recipient shall provide Raw Data or Data Analysis for review by BARDA, if requested. (For avoidance of doubt, clinical data will be subject to human subject privacy policies.) | The Recipient will provide raw data or data analysis within 20 business days (or as available) of request by OTAS/OTIR. | 1 electronic copy to OTIR and OTAS; Upload to eRoom. |

ATTACHMENT 3: PORTFOLIO PERFORMANCE METRICS

Portfolio Performance Metrics (PPM) will be collaboratively developed by the Joint OTAR Oversight Committee and prior to the exercise of any options. These metrics should span all aspects of the program and should include metrics for all molecules within the portfolio partnership.

In-Process Review (IPR) meetings will be held in an annual or event driven manner following completion of a pre-defined stage of product development and prior to initiation of a new stage (e.g. Option award). At least 30 days prior to an IPR meeting, the Recipient and OTTR will discuss the progress to date under the portfolio and activities planned for the next stage of development. The Recipient will prepare and present a PowerPoint presentation during the IPR which provides an update on the technical progress made towards achieving the Portfolio Performance Metrics. The Recipient will provide a copy of the final PowerPoint presentation to the OTTR and OTAO 10 business days prior to the meeting.

At the IPR, BARDA will assess the overall portfolio and progress, and decide at its sole discretion if an offer to progress to the next Option will be offered to Recipient.

Below are the Portfolio Performance Metrics for the Base Period at the time of Agreement award. These may be modified by the Joint OTAR Oversight Committee during the base period of the Agreement. The Portfolio Performance Metrics below will be achieved through the performance of the nonseverable activities contained only in the base period. Option exercise is not required for the Recipient to achieve any of the metrics listed below.

## SCHEDULE OF PAYMENTS AND PAYABLE MILESTONES

| TASK | MONTH | PAYABLE MILESTONES | NIH PAYMENT | CONSORTIUM PAYMENT |
|---|---|---|---|---|

AGREEMENT NUMBER:
ATTACHMENT NO. 3

FUNDING SCHEDULE

Q. PROJECTED PROGRAM FUNDING COMMITMENTS

| | NIH Funding | Consortium Contribution |
|---|---|---|
| FY9* | $ | $ |
| FY9* | $ | $ |
| FY9* | $ | $ |
| TOTALS | $ | $ |

R. CONSORTIUM MEMBER CONTRIBUTIONS

| **Member** | **Contribution** |
|---|---|
| Company A | $ |
| Company B | $ |
| Company C | $ |
| Company D | $ |
| TOTALS | $ |

LIST OF GOVERNMENT AND CONSORTIUM REPRESENTATIVES

GOVERNMENT:

*(NAME)*
NIH/OFFICE
3701 N. Fairfax Drive
Arlington, VA 22203-1714
Phone: (703) 696-****
FAX: (703) 696-****
Email: *******@*******

*(NAME)*
NIH/OFFICE
3701 N. Fairfax Drive
Arlington, VA 22203-1714
Phone: (703) 696-****
FAX: (703) 696-****
Email: *******@******

CONSORTIUM:

*(NAME)*
(ORGANIZATION)
address:
phone:
FAX:
Email: *******@******

*(NAME)*
(ORGANIZATION)
address:
phone:
FAX:
Email: *******@******

This page is intentionally left almost blank.

# M. MODEL OT FOR PROTOTYPE PROJECTS

# Other Transaction (OT) Agreement

OTHER TRANSACTIONS FOR PROTOTYPE AGREEMENT

BETWEEN

AMERICAN SUPERCONDUCTOR CORPORATION
64 Jackson Road Devens, MA 01434

AND

THE DEPARTMENT OF HOMELAND SECURITY
Office of Procurement Operations
245 Murray Drive, Bldg. 410
Washington, DC 20528

CONCERNING:

**OTHER TRANSACTION AGREEMENT NO.:** HSHQDC-08-9-00001

**DEFINITIZATION OF LETTER CONTRACT NO.:** HSHQDC-07-C-00050 (the "Letter Contract")

**EFFECTIVE DATE:** Date executed by the Government

**CAGE CODE:** 0D9R0

**DUNS NUMBER:** 18-5904497

**Total Value of the Agreement**

| | |
|---|---|
| Total Estimated Government Cost Sharing Contribution: | $24,908,413 |
| Total Estimated Contractor Cost Sharing Contribution: | $14,177,770 |
| Total Estimate Value of the Cost Sharing Agreement: | $39,086,183 |
| Funds Previously Obligated by Letter Contract: | $3,826,806 |
| Funds Obligated This Action: | $1,936,462 |
| Total Government Funds Obligated to Date: | $5,763,268 |

**PROCUREMENT REQUEST NUMBER:**
RSIN-08-00020

**ACCOUNTING AND APPROPRIATION CODES:**
TBD

This Agreement is entered into between the United States of America, hereinafter called the Government and/or DHS, and American Superconductor Corporation, hereinafter called the "Contractor".

FOR AMERICAN SUPERCONDUCTOR CORPORATION

David Henry, Senior V.P. & CFO
Date

FOR THE UNITED STATES OF AMERICA:

Wanda J. Arnwood, OT Contracting Officer
Date 1/22/08

| ARTICLES | | PAGE |
|---|---|---|
| ARTICLE I | Scope of the Agreement | 1 |
| ARTICLE II | Term | 1 |
| ARTICLE III | Statement of Work | 2 |
| ARTICLE IV | Payable Event Schedule and Deliverables | 8 |
| ARTICLE V | Agreement Administration | 11 |
| ARTICLE VI | Obligation and Payment | 11 |
| ARTICLE VII | Disputes | 13 |
| ARTICLE VIII | Intellectual Property | 14 |
| ARTICLE IX | Civil Rights Act | 19 |
| ARTICLE X | Property | 19 |
| ARTICLE XI | Liability | 19 |
| ARTICLE XII | General Terms and Conditions | 20 |
| ARTICLE XIII | Options | 21 |

ATTACHMENTS

ATTACHMENT 1 Limited Rights Proprietary Information

## ARTICLE I: SCOPE OF THE AGREEMENT

The Nation's critical electric power infrastructure needs to be capable of withstanding both severe natural disasters and terrorist attacks to avoid widespread system blackouts. Of principal concern for protection are large, densely populated urban areas that are traditionally host to critical centers of finance, trade and government, where significant disruptions to the electric power grid can severely impact the regional and national economy and security. Manhattan is a prime example of one of the world's most dense load areas and is home to the U.S.'s most critical financial center.

Under this Agreement, Contractor in collaboration with Consolidated Edison (Con Edison) and Southwire Company will develop, design and deploy the world's first high temperature superconductor ("HTS") electric cable system, "Secure Super Grids™" , in New York City with a built-in fault current limiting capability demonstrating a significantly enhanced level of electric power security, that can be widely applied to the NYC Manhattan grid network and grid networks in major cities in the United States and the world.

In addition to the critical security feature of the "Secure Super Grids™", this technology will be widely used to rebuild the nation's failing electric power grid infrastructure particularly in our cities and metropolitan areas where the combination of increased electricity demand, existing high system fault current levels and local resistance issues can only be solved with new superconductor technology being developed under this program.

M

This Agreement is an 'other transaction' pursuant to Section 831 of the Homeland Security Act of 2002, Public Law 107-296. The Federal Acquisition Regulation (FAR) does not apply to this Agreement. This Agreement is not intended to be, nor shall it be construed as, by implication or otherwise, a partnership, a corporation, or other business organization.

## ARTICLE II: TERM

A. The Term of this Agreement

The period of performance of this cost reimbursement, cost share Agreement shall include the work performed during the period from May 17, 2007 through September 30, 2010.

B. Termination Provisions

Subject to a reasonable determination that this Agreement will not produce beneficial results commensurate with the expenditure of resources, either Party may terminate this Agreement by written notice to the other Party and by mutually agreeing to the outstanding issues that develop during the course of performance. In the event of a termination of the Agreement, the Government and the Contractor will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination. Failure of the Parties to agree to a reasonable adjustment will be

resolved pursuant to Article VII, Disputes. In the event of termination by either party, the Government shall reimburse Contractor for all allowable costs incurred through the date of the termination of the Agreement. It is agreed that the provisions set forth in Article VII, Disputes, Article VIII, Intellectual Property, Article XI, Liability, and Article XII, General terms and Provisions, shall survive the termination of this Agreement.

C. Extending the Term

The Parties may extend by mutual written agreement the term of this Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the OT Contracting Officer and the Contractor.

## ARTICLE III: STATEMENT OF WORK

Under the terms of this Agreement, the Contractor and its subcontractors (the "Team") propose to demonstrate an HTS cable system installed as a substation-to-substation tie within Con Edison's existing and severely congested distribution network. Moreover, Contractor proposes to develop and demonstrate an HTS cable system that seamlessly and cost effectively incorporates fault current limiting capabilities within the HTS cable system itself. The proposed program will also incorporate a parallel development of a stand-alone fault current limiter. The Contractor shall execute the project pursuant to Article III – Statement of Work (SOW) with milestones set forth in Article IV – Payable Event Schedule and Deliverables (the "Project").

The Team proposes to demonstrate a superconductor cable system that has the technical capability for installation as a substation-to-substation tie within Con Edison's existing and severely congested distribution network. Moreover, since the proposed insertion of a superconductor cable in a power network has the potential to increase the 13kV fault current beyond the interrupting capability of existing substation equipment, the Team proposes the development of a breakthrough HTS cable design that seamlessly and cost effectively incorporates the required fault current limiting attributes within the HTS cable itself. The proposed August 2008 demonstration will mitigate the overall Project risks by specifically testing the fault current limiting capabilities of the Superconducting Cable with the Integrated FCL. The Project will also incorporate a parallel development of the stand-alone FCL which could be used directly in the proposed substation demonstration of the Superconductor Cable, should the results of the integrated fault current limiting superconductor cable require additional time for development, or not fully meet the required performance requirements in this first prototype implementation. If the integrated fault current limiting superconductor cable meets the technical and schedule requirements for the proposed substation demonstration, then the stand alone fault current limiter demonstration will be evaluated technically for potential installation elsewhere on the Con Edison system.

**Background and Technical Performance Requirements**

The Project Team will develop and build a significant demonstration of this highly innovative technology with the support of DHS. Specifically, the Team intends to build a fault current limiting cable of a meaningful length and capacity to clearly demonstrate both the current carrying capability as well as the fault limiting characteristics. This demonstration is proposed to be designed, built and successfully demonstrated by August 31, 2008 assuming an uninterrupted flow of funding. DHS will directly fund Oak Ridge National Laboratories for the testing necessary for a successful demonstration. A successful demonstration would verify the deployment ability of this technology in a critical electrical infrastructure such as a substation-to-substation tie as part of Con Edison's proposed substation by 2010.

The development methodology will permit this technology to advance from engineering concept to a meaningful demonstration by August 2008. The methodology is based on a staged, milestone driven program that uses an incremental validation technique to ensure that any technical obstacles encountered will be small, rapidly identified and corrected to minimize any program impact. This approach is a proven technique and provides the greatest amount of risk mitigation possible. The Project is divided into two distinct phases.



Phase 1 consists of a technology demonstration of a Superconductor Cable with Integrated FCL capability in a laboratory demonstration along with the parallel development of the stand-alone FCL.

The objective of the Phase 1 effort is to assess two approaches to limiting fault currents and select the most appropriate approach for integration into the Con Edison network.

Phase 2 entails the fabrication, engineering integration and installation of this technology into Con Edison's proposed substation, which is planned to be in service in 2010.

The objective of the Phase 2 effort is to demonstrate the technology and to gather operational data on the operation and performance of the cable system.

The details of each of the phases are as follows:

Phase 1: Development of Superconductor Cable with Integrated FCL and Development of Stand Alone FCL

Phase 1 has two distinct program elements, Phases 1A and 1B which include:

Phase 1A: Superconductor Cable with Integrated FCL

Phase IA, Step 1 - Development and Preliminary Design

System Optimization
The first step will be to optimize the design of the overall circuit containing both superconductor and conventional elements. The optimization point will be key parameters such as the temperature of the HTS cable and the overall current capacity of the cable and will allow a specification for the components to be generated.

HTS Cable Design
Once the specification for the cable is determined then the cable design must be completed. This design will be performed in conjunction with Southwire Corporation and will be based upon their highly successful demonstration of a 13.8 kV superconductor cable in the AEP power grid in Columbus OH. This cable design will result in a wire specification that has been developed based upon an optimized system and cable design to provide maximum current carrying capacity and inherent fault current limiting capabilities.

Wire Development
Once the wire is specified then the architecture of the wire needs to be determined and demonstrated. AMSC is in a strong position for this effort because of its extensive experience with the development, manufacture and sale of HTS wire with tailored thermal, mechanical, and electrical properties.

This top down system level approach allows for some iteration up and down this chain as the program moves forward and the requirements and limitations of the three processes become apparent. During this process the cost implications of each specification can be evaluated and optimized to achieve the lowest system cost. Testing this type of device requires a sophisticated setup of a cryogenic system and terminations, predicated on design and procurement. Design and procurement will be conducted during this phase to account for the long lead times for these materials. Furthermore, many of these systems will be designed with the intent to use them during Phase 2 of this project in which a Superconductor Cable will be installed in the Con Edison electric power grid. In addition to the new HTS cable in Phase 2, the only other costs that would need to be incurred during Phase 2 are associated with the cryogenic system and the performance of the necessary installation work at the site. It is this type of spiral development that will minimize costs and shorten project lifecycles.

Phase IA, Step 2 Tests and Optimization

Once a design is determined a prototype HTS cable will be fabricated of suitable length to evaluate the key manufacturing parameters including current carrying capacity, and current limiting capability. This prototype is expected to be ten feet long. An appropriate control system with the required auxiliary system components will be designed, fabricated and supplied for testing. Testing will be performed in a laboratory (currently anticipated to be at Oak Ridge National Laboratory) to demonstrate the performance of the design and identify any areas where further optimization is required.

The following parameters of the cable will be demonstrated:

| | |
|---|---|
| Maximum Operating Current: | 4,000 amps |
| Maximum Fault Current: | 40,000 amps |
| Fault current reduction: | TBD based on the length of the test cable |

The primary purpose of this test cable is to demonstrate the manufacturability of the cable design which will be demonstrated by the maximum operating current of the cable. If there is damage or degradation of the HTS wire during the manufacturing process the cable will not meet the full current value.

Phase IA, Step 3 Fabricate and Test Full Cable Design
In the final step of this effort, a cable system that is sufficiently long will be fabricated to demonstrate all of the attributes required by urban utilities, high current capacity (approximately 4000 amps), voltage withstand (13.8 kV) and current limiting. This test would be performed at Oak Ridge National Laboratories directly funded by DHS.

The following parameters of the cable will be demonstrated:

| | |
|---|---|
| Operating Voltage: | 13.8 KV |
| Maximum Operating Current: | 4,000 amps |
| Maximum Fault Current: | 40,000 amps |
| Fault current reduction: | TBD based on the length of the test cable |
| BIL Test: | Per IEC Standard for 13.8 kV |
| Voltage Withstand: | Per IEC Standard for 13.8 kV |

The exact reduction of the fault current in this short test cable will be determined prior to testing and reviewed by the project team and agreed upon with DHS.



Phase 1B: Stand-Alone FCL

In parallel with the development efforts for an integrated fault current limiting cable, the team proposes the concurrent development of a stand-alone FCL which may or may not include superconductor technology. If the Phase 1A demonstration results do not allow for an installation of Phase 1A technology by February 2010 then this stand-alone-device can potentially be installed in conjunction with the already demonstrated superconductor cable design (for the AEP project in Columbus, Ohio) in the 2010 timeframe.

Con Edison has been developing commercial FCL concepts for the past several years and has been technically evaluating potential companies and technologies that may satisfy the technical requirements. If superconductor cables are to be used in future substations some form of fault current limiting technology (either integrated or stand alone) must be included. By incorporating this element in the Project the Team is ensured that a superconductor cable will be available for substation installation in 2010. It is the

Team's intention to use the integrated superconductor fault current limiting cable in 2010 unless the testing in 2008 indicates that it is technically or economically infeasible to do so.

This effort will include the evaluation and preliminary comparisons between multiple stand alone fault current limiter designs and development of a selected stand alone FCL device to operate at an appropriate current level and at 13.8kV.

It is also important to note that the development of the stand alone FCL device is not only a risk reducing alternative but may be the preferred technical solution in certain applications. It will also have some potential value in substations where an interconnecting cable is simply not needed or practical. Therefore, even if this technology were not selected for the 2010 demonstration it could have applicability elsewhere in Con Edison's network, and in many other applications including mitigation of cryogenic recovery times for existing superconducting cable designs, which are not integrally fault current limiting. In addition, the planned parallel effort provides flexible alternatives to assure a successful demonstration, and the planned integration and sharing of modeling and performance information may provide a basis for future redesign of existing superconductor cable/fault current limiter systems to mitigate recovery times and reduce the size of future superconductor cables. This would allow the cables to fit within existing ducts, eliminating excavation and interference costs, and greatly improve the economics of superconductor cable installations over conventional cable alternatives.

There may also be some benefits in providing more precise and validated modeling of superconducting cable performance because of the separated copper bypass path rather than a copper fault "ride through" path directly within the superconducting cable. Test data, performance data and model validations may provide additional insights into operation of future superconducting cables in transmission applications with multiple conventional cable paths around them, and may give a more precise model of how the quenching of a superconducting cable would affect loop flows and might possibly be optimized to mitigate them.

Multiple standalone fault current limiter designs will be evaluated with separate sequential design milestones for concepts including footprint requirements to meet required ratings, device modeling, detailed design, integrated modeling, laboratory or factory testing, rating certification and demonstration used to assure the ultimate success of the final design chosen based on early milestone results.

Phase 1 efforts will also include all the engineering, design, and analysis required to confirm the technical applicability of the Phase 1 integrated fault current limiting superconductor cable for installation in the area of the substation. This includes all detailed installation engineering and design, relay protection requirements and required system planning studies and analysis.

The standalone FCL devices will only be tested at the Oak Ridge National Laboratory if the primary cable design proves inadequate. If it is to be tested it will be required to meet

the same requirements as the integrated superconductor fault current limiting cable system, namely,

| | |
|---|---|
| Operating Voltage: | 13.8 KV |
| Maximum Operating Current: | 4,000 amps |
| Maximum Fault Current: | 40,000 amps |
| Fault current reduction: | TBD (approximately 25%) |
| BIL Test: | Per IEC Standard for 13.8 kV |
| Voltage Withstand: | Per IEC Standard for 13.8 kV |

The exact reduction of the fault current in this device will be determined prior to testing and reviewed by the project team and agreed upon with DHS.

Phase 2: Installation at Proposed Substation

The scope of Phase 2 will include the fabrication of an approximately 1,000 foot (300m) long integrated superconductor fault current limiting cable system, including cryogenics, terminations, all associated engineering and design and installation of this system at the proposed substation. The Team would then operate and maintain the system and equipment for a period of one year after commissioning of the cable system. In the event the results of the testing of the integrated system in 2008 are not acceptable, an alternative approach of installing a superconductor cable of similar design to the AEP-DOE project in conjunction with the FCL device developed in the project Phase 1B would be evaluated and pursued.



The specific responsibilities for this segment are as follows:

The responsibilities of the Project Team include but are not limited to the fabrication delivery and installation of equipment and development of:

- Integrity/construction test criteria;
- Functional testing acceptance criteria;
- Training needs analysis;
- System descriptions and design basis documentation;
- Acceptance testing protocol;
- Testing and acceptance criteria;
- Integration engineering and design;
- Operation and maintenance procedures;
- Alarm response procedures;
- New construction standards and operating procedures jointly with Con Edison related to any of the new technologies being deployed
- Installation, operation and testing of the system and equipment in accordance with Con Edison's standard construction and operating procedures.

The anticipated system performance for this cable is as follows:

| | |
|---|---|
| Operating Voltage: | 13.8 KV |
| Maximum Operating Current: | 4,000 amps |
| Maximum Fault Current: | 40,000 amps |
| Fault current reduction: | TBD based on the length of the cable but approximately 25% |
| BIL Test: | Per IEC Standard for 13.8 kV |
| Voltage Withstand: | Per IEC Standard for 13.8 kV |

The exact reduction of the fault current in this cable will be determined prior to testing and reviewed by the project team and agreed upon with DHS.

## ARTICLE IV: PAYABLE EVENT SCHEDULE AND DELIVERABLES

A. Payment Schedule

The Contractor shall perform the work required by Article III. The Contractor shall be paid for each Payable Milestone accomplished and delivered in accordance with the Schedule of Payments and Payable Milestones set forth below. Both the Schedule of Payments and the Funding Schedule set forth below may be revised or modified in accordance with subparagraph C of this article.

B. Schedule of Payments and Payable Milestones

| Task Description | Value | Date | Gov't Cost Share | Contractor Cost Share |
|---|---|---|---|---|
| Payable Milestones Under Letter Contract – 5/17/2007 – 1/22/2008 | | | | |
| | | | | |
| **Work Package #0: May 17, 2007 – January 22, 2008** | | | | |
| Written System Level Specifications | $355,870 | 7/29/07 | $232,654.82 | $123,215.18 |
| Network Wire and Cable Analysis | $433,800 | 9/27/07 | $283,602.61 | $150,197.39 |
| HTS Wire Development | $779,584 | 10/19/07 | $509,663.57 | $269,920.43 |
| HTS Wire Testing | $296,141 | 7/28/07 | $193,606.18 | $102,534.82 |
| Cable Development | $512,094 | 11/8/07 | $334,788.37 | $177,305.63 |
| Stand Alone FCL Initial Proposal and Evaluation | $1,025,580 | 11/12/07 | $670,486.78 | $355,093.22 |
| Site Planning and Cryogenics | $335,667 | 11/8/07 | $219,446.84 | $116,220.16 |
| Test Planning | $166,425 | 11/5/07 | $108,802.59 | $57,622.41 |
| Initial Program Administration, Wire and Materials | $1,753,341 | 11/14/07 | $1,146,270.36 | $607,070.64 |
| Program Review #1 | $195,000 | 1/15/08 | $127,483.88 | $67,516.12 |
| ***Total Value of the Letter Contract*** | *$5,853,502* | | $3,826,806.00 | $2,026,696.00 |
| | | | | |
| Payable Milestones Under OT Agreement – Effective Date of OT Award | | | | |
| | | | | |
| **Work Package #1:** | | | | |
| Program Review #2 | $195,000 | 2/15/08 | $123,700.92 | $71,299.08 |
| Program Review #3 | $195,000 | 3/15/08 | $123,700.92 | $71,299.08 |
| Program Review #4 | $195,000 | 4/15/08 | $123,700.92 | $71,299.08 |
| Program Review #5 | $195,000 | 5/15/08 | $123,700.92 | $71,299.08 |
| Program Review #6 | $195,000 | 6/15/08 | $123,700.92 | $71,299.08 |
| Program Review #7 | $195,000 | 7/15/08 | $123,700.92 | $71,299.08 |

| Task Description | Value | Date | Gov't Cost Share | Contractor Cost Share |
|---|---|---|---|---|
| Program Review #8 | $195,000 | 8/15/08 | $123,700.92 | $71,299.08 |
| Program Review #9 | $195,000 | 9/15/08 | $123,700.92 | $71,299.08 |
| Program Review #10 | $195,000 | 10/15/08 | $123,700.92 | $71,299.08 |
| All 50 meter HTS wires shipped to Southwire | $658,791 | 5/2/08 | $417,913.11 | $240,877.89 |
| All 300 meter HTS wires shipped to Southwire | $1,399,442 | 6/26/09 | $887,755.23 | $511,686.77 |
| *Subtotal* | *$3,813,233* | | $2,418,976.65 | $1,394,256.35 |
| **Work Package #2: HTS Wire Development** | | | | |
| 50 meter HTS Wire design completed | $150,036 | 2/1/08 | $95,177.39 | $54,858.61 |
| 50 meter HTS Wire engineering support to manufacturing and testing | $438,245 | 1/31/08 | $278,006.73 | $160,238.27 |
| 300 meter HTS Wire design completed | $96,450 | 9/18/08 | $61,184.38 | $35,265.62 |
| 300 meter HTS Wire engineering support to manufacturing | $459,547 | 12/19/08 | $291,519.94 | $168,027.06 |
| *Subtotal* | *$1,144,278* | | $725,888.44 | $418,389.56 |
| | | | | |
| **Work Package #3: HTS Wire Testing** | | | | |
| Completion of 3 meter and 50 meter wire characterization testing | $464,214 | 3/21/08 | $294,480.52 | $169,733.48 |
| *Subtotal* | *$464,214* | | $294,480.52 | $169,733.48 |
| | | | | |
| **Work Package #4: Cable Development** | | | | |
| Final 3 meter Cable Fabrication and Test | $305,421 | 4/25/08 | $193,748.00 | $111,673.00 |
| 50 meter cable design completed and materials purchased | $771,955 | 2/15/08 | $489,700.24 | $282,2 |
| 50 meter cable fabricated | $353,350 | 4/15/08 | $224,152.42 | $129,1 |
| 50 meter HTS cable installed at test site | $235,163 | 8/8/08 | $149,178.87 | $85,9 |
| 50 meter HTS cable demonstration testing completed | $80,840 | 8/29/08 | $51,281.96 | $29,5 |
| 50 meter HTS cable engineering testing completed | $138,765 | 1/9/09 | $88,027.48 | $50,7 |
| *Subtotal* | *$1,885,494* | | $1,196,088.98 | $689,4 |
| **Work Package #5: Site Planning and Cryogenics** | | | | |
| Refrigeration system Concept design completed | $60,000 | 12/28/08 | $38,061.82 | $21,9 |
| Wiring Design Package Complete | $200,000 | 2/8/08 | $126,872.74 | $73,1 |
| Transmission Design Package Complete | $125,000 | 3/21/08 | $79,295.46 | $45,7 |
| Physical Design Package- York Substation to Con Ed for review | $200,000 | 3/28/08 | $126,872.74 | $73,1 |
| Physical Design Package- York Substation Complete | $75,000 | 5/28/08 | $47,577.28 | $27,4 |
| Altran Misc Design Effort Complete | $200,000 | 5/30/08 | $126,872.74 | $73,127.26 |
| Physical Design Package-E75th Substation for ConEd Review | $400,000 | 6/27/08 | $253,745.49 | $146,254.51 |
| Physical Design Package-E75th Substation Complete | $301,161 | 8/22/08 | $191,045.61 | $110,115.39 |
| *Subtotal* | *$1,561,161* | | $990,343.89 | $570,817.11 |
| **Work Package #6: Stand-alone Fault Current Limiter** | | | | |
| Phase I Review | $100,000 | 2/15/08 | $63,436.37 | $36,563.63 |
| Award of Phase II | $225,000 | 3/15/08 | $142,731.84 | $82,268.16 |
| Single Phase System Manufacture Complete | $675,000 | 6/608 | $428,195.51 | $246,804.49 |
| Completion of Phase II Demonstration | $300,000 | 8/29/08 | $190,309.11 | $109,690.89 |
| Phase III Review | $100,000 | 9/1/08 | $63,436.37 | $36,563.63 |
| Award of Phase III | $100,000 | 9/12/08 | $63,436.37 | $36,563.63 |
| Phase III System Design Complete | $350,000 | 1/31/09 | $222,027.30 | $127,972.70 |
| Phase III System Manufacture Complete | $950,000 | 3/30/10 | $602,645.53 | $347,354.47 |
| Completion of Phase III | $311,512 | 7/30/10 | $197,611.91 | $113,900.09 |
| *Subtotal* | *$3,111,512* | | $1,973,830.31 | $1,137,681.69 |
| **Work Package #7: 50 meter Cable Testing** | | | | |
| 50 meter Demonstration Test Plan and Materials | $1,3,75,163 | 3/21/08 | $872,353.51 | $502,809.49 |
| 50 meter Demonstration Tests completed | $702,152 | 9/1/09 | $445,419.75 | $256,732.25 |
| *Subtotal* | *$2,077,315* | | $1,317,773.26 | $759,541.74 |
| **Work Package #8: 300 meter Cable System** | | | | |
| 300 meter cable long-lead materials ordered | $500,000 | 9/26/08 | $317,181.86 | $182,818.14 |
| 300 meter HTS cable fabricated | $2,027,542 | 3/6/09 | $1,286,199.08 | $741,342.92 |
| 300 meter cable and terminations installed | $253,443 | 12/18/09 | $160,775.04 | $92,667.96 |
| 300 meter cable commissioning tests completed | $133,462 | 1/29/10 | $84,663.45 | $48,798.55 |
| Electrical System Design Complete | $353,369 | 5/23/08 | $224,164.47 | $129,204.53 |
| Electrical Components Received | $750,000 | 7/17/09 | $475,772.79 | $274,227.21 |
| Refrigeration System Design Complete | $500,000 | 1/20/08 | $317,181.86 | $182,818.14 |

M

| Task Description | Value | Date | Gov't Cost Share | Contractor Cost Share |
|---|---|---|---|---|
| Refrigeration Main Components Received/ Fabricated | $800,000 | 1/23/09 | $507,490.97 | $292,509.03 |
| Refrigeration system fabricated | $1,100,000 | 6/12/09 | $697,800.09 | $402,199.91 |
| Refrigeration system Factory Test Complete | $200,000 | 8/21/09 | $126,872.74 | $73,127.26 |
| Refrigeration System Installation Complete | $240,989 | 12/18/09 | $152,874.68 | $88,114.32 |
| *Subtotal* | *$6,858,805* | | $4,350,977.02 | $2,507,827.98 |
| **Work Package #9: Integration and Installation** | | | | |
| Trenching- York Substation | $236,128 | 3/27/09 | $149,791.04 | $86,336.96 |
| Trenching-75th Street | $904,389 | 3/27/09 | $573,711.57 | $330,677.43 |
| Trenching- 75th Street Substation | $942,369 | 3/27/09 | $597,804.70 | $344,564.30 |
| Concrete Work | $328,862 | 7/17/09 | $208,618.12 | $120,243.88 |
| Steel Work | $178,730 | 9/18/09 | $113,379.83 | $65,350.17 |
| Cryogenic Piping | $356,300 | 11/13/09 | $226,023.79 | $130,276.21 |
| Equipment Installation | $812,500 | 12/18/09 | $515,420.52 | $297,079.48 |
| HTS Cable Installation | $1,781,261 | 11/30/09 | $1,129,967.35 | $651,293.65 |
| Electrical Wiring and Connections | $5,876,130 | 12/18/09 | $3,727,603.66 | $2,148,526.34 |
| Testing and Commissioning | $900,000 | 2/26/10 | $570,927.34 | $329,072.66 |
| *Subtotal* | *$12,316,669* | | $7,813,247.91 | $4,503,421.09 |
| | | | | |
| ***Total Estimated Value of the OT Agreement*** | **$33,232,681** | | **$21,081,607** | **$12,151,074** |
| ***Total Value of the Letter Contract*** | **$5,853,502** | | **$3,826,806** | **$2,026,696** |
| ***Total Value of the OT Agreement & Letter Contract*** | ***$39,086,183*** | | **$24,908,413** | **$14,177,770** |

C. Modifications

1. At any time during the term of the Agreement, progress or results may indicate that a change in the Statement of Work and/or the Payable Milestones would be beneficial or required to achieve the program objectives. Recommendations for modifications, including justifications to support any changes to the Statement of Work and/or the Payable Milestones, will be documented in a letter and submitted by the Contractor to the Government Program Manager with a copy to the OT Contracting Officer. This letter will detail the technical, chronological, and financial impact of the proposed modification to the research program. Any resultant modification is subject to mutual agreement of the parties. The Government is not obligated to pay for nor is Contractor obligated to perform under the additional or revised Payable Milestones until the Payable Milestones Schedule is formally revised by the OT Contracting Officer and made part of this Agreement. If the revised Payable Milestones Schedule is not formally revised by the OT Contracting Officer and made part of this Agreement, then the Contractor may terminate this Agreement pursuant to Article IIB.

2. The Government Program Manager shall be responsible for the review and verification of milestone completion, including acceptance of all Data Deliverables due and any recommendations to revise or otherwise modify the Agreement Statement of Work, Schedule of Payments and Payable Milestones, or other proposed changes to the terms and conditions of this Agreement.

3. For minor or administrative Agreement modifications (e.g., changes in the paying office or appropriation data, changes to Government or Contractor personnel identified in the Agreement, etc.), Government shall make these types of changes unilaterally.

4. The OT Contracting Officer will be responsible for effecting all modifications to this Agreement.

## ARTICLE V: AGREEMENT ADMINISTRATION

Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

Government: Wanda J. Armwood, OT Contracting Officer, Tel: (202) 254-6678; E-Mail Address: Wanda.Armwood@dhs.gov

Contractor: John W. Powell, Managing Director, Legal, Tel: (978) 842-3539; E-Mail Address: jpowell@amsc.com

Contractor: Michael P. Richardson, Manager of Strategic Planning and Corporate Development, Tel: (978) 842-3351; E-Mail Address: mrichardson@amsc.com

Technical matters under this Agreement shall be referred to the following representatives:

Government: Patrick Murphy, Program Manager, Tel: (202) 254-6656; E-Mail Address: Patrick.M.Murphy@dhs.gov

Contractor: James Maguire, Vice President Superconductor Projects, 978-842-3036; E-Mail Address: jmaguire@amsc.com

The Government and the Contractor may change its representatives named in this Article by written notification to the other party. The Government will effect the change as stated in subparagraph C.4 of Article IV above.

## ARTICLE VI: OBLIGATION AND PAYMENT

A. Obligation

The Government's liability to make payments to the Contractor is limited to only those funds obligated under this Agreement or by amendment to the Agreement. Government may obligate funds to the Agreement incrementally. No legal liability on the part of the Government for any payment may arise for performance under this Agreement unless obligated to this Agreement or until funds are made available to the Contracting Officer for performance and until the Contractor receives notice of availability, to be confirmed in writing by the Contracting Officer.

B. Payments

1. The Contractor shall invoice the Government for each completed milestone per the Article IV B. The following information shall be included on each milestone invoice:

Agreement Number
Invoice Number
A description of services performed

Quantity of service received or performed
The time of period covered by the invoice
Terms of Payment
Payment Office
Amount claimed

2. The Contractor shall document each Payable Milestone by submitting the deliverables or performing the demonstration in accordance with the Payable Milestone Schedule and Deliverables in Article IV B. The Contractor shall submit an electronic invoice to the ST.Invoicing email address below, one (1) copy to the Program Manager identified in Article V and one (1) copy to the OT Contracting Officer for payment approval.

DHS
Science & Technology
Attn: Invoicing/PPB/Deborah DeVault
Washington, DC 20528
E-mail address: ST.Invoicing@dhs.gov

After written verification and acceptance of the deliverable by the Government Program Manger and approval of the OT Contracting Officer, the invoice will be forwarded to the payment office within five (5) calendar days of receipt of the invoice. Payments will be made by the Dallas Finance Center within fifteen (15) calendar days. Subject to change only through written Agreement modification, payment shall be made via electronic funds transfer to the Contractor's address set forth below:

Bank Account of Payee:

| | |
|---|---|
| **Bank Name:** | Bank of America |
| **Bank Address:** | One Federal Street<br>Boston, MA 02110 |
| **ABA Number:** | 011-000-138 |
| **Depositor Account Number:** | 005719-6818 |
| **Depositor Account Title:** | American Superconductor Corporation |

3. Financial Records and Reports: The Contractor's relevant financial records associated with this Agreement are not subject to examination or audit by the Government, except as noted below, since the confirmed accomplishment of the appropriate milestone completes the obligation of both parties.

4. Comptroller General Access to Records: To the extent that the total Government payments under this Agreement exceed $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such party or entity, that has not entered into

any other Agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a Government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement.

## ARTICLE VII: DISPUTES

A. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

B. Dispute Resolution Procedures

1. Any disagreement, claim or dispute between the Government and the Contractor concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may only be raised under this Article.

2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) through the contracting Points of Contact by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under subparagraph B.3 of this Article constitute the basis for relief under this Article unless the Government in the interests of justice waives this requirement.



3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the OT Contracting Officer) in writing of the relevant facts, identify unresolved issues, and specify the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by a Government Designee, and a designated Representative of the Contractor ("Contractor Representative"). The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Government Designee and the Contractor Representative shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, the parties may raise any dispute to a higher level of official of the parties. These officials will review the dispute jointly. Following the review, these officials will resolve, if possible, the issue(s) in writing. Such resolution shall not be subject to further administrative review and, to the extent permitted by law, shall be final and binding.

5. Should the parties still not be able to resolve the dispute after all the foregoing steps have been taken, the parties are free to pursue any legal action necessary.

6. Pending the resolution of any such dispute, work under this Agreement and payments by the Government, will continue as elsewhere provided herein unless the Agreement is terminated by one of the parties pursuant to Article II B.

## ARTICLE VIII: INTELLECTUAL PROPERTY

A. Definitions

As used in this Article, the following terms shall have the following meanings and such meanings shall be applicable to both the singular and plural forms of the terms. All other terms of this Agreement shall be ascribed their plain, commonly accepted definitions.

1. "Created" in relation to any copyrightable work ("Work") means when the Work is fixed in any tangible medium of expression for the first time, as provided for at 17 U.S.C. § 101. "Background Works" are Works Created outside of this Agreement and "Foreground Works" are Works Created under this Agreement and the Letter Contract.

2. "Government" or "U.S. Government means, for this Article only, the U.S. Department of Homeland Security.

3. "Government Purpose" means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Subject Inventions, Technical Data, Computer Software, or Foreground Works for commercial purposes or authorize others to do so.

4. "Government Purpose Rights" means the rights to—

> (i) Use, modify, reproduce, release, perform, display, or disclose Technical Data, Computer Software and Foreground Works within the Government without restriction; and
>
> (ii) Release or disclose Technical Data, Computer Software and Foreground Works outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose the Technical Data, Computer Software and Foreground Works for United States Government Purposes only.

5. "Invention" means any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

6. "Limited Rights" means the rights to use, modify, reproduce, release, perform, display, or disclose, , in whole or in part, within the Government Background Works and Proprietary Information, but only in connection with the Project. The Government may not, without the written permission of the Contractor , release or disclose the Proprietary Information and Background Works outside the Government, use the Proprietary Information and Background Works for manufacture, or authorize the Proprietary Information and Background Works to be used by another party, except that the Government may reproduce, release or disclose such Proprietary Information and Background Works or authorize the use or reproduction of the Proprietary Information and Background Works by persons outside the Government if reproduction, release, disclosure, or use is—

a) Necessary for emergency repair and overhaul; and

c) Subject to a prohibition on the further reproduction, release, disclosure, or use of the Proprietary Information under a use and non-disclosure agreement provided by Contractor; and

d) The Contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use and is not able to assist the Government in performing such emergency repair and overhaul.

7. "Made" in relation to any Invention means the conception or first actual reduction to practice of such Invention.

8. "Practical application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

9. "Proprietary Information" means Technical Data, computer software and software documentation, including but not limited to that listed in Attachment I ("Limited Rights Proprietary Information"), owned by Contractor which was developed or Created outside of this Agreement and which embodies trade secrets or which:

a) is not generally known, or is not available from other sources without obligations restricting its disclosure;

b) has not been made available by the owners to others without obligation restricting its disclosure;

c) is not described in an issued patent or a published copyrighted work or is not otherwise available to the public without obligation restricting its disclosure; or

d) can be withheld from disclosure under the Freedom of Information Act, 5 U.S.C. § 552 *et seq.* and is identified as such by labels or markings designating the information as proprietary.

10. "Special Purpose License" means a license to the Government conveying a nonexclusive, nontransferable, irrevocable, worldwide, royalty-free license to practice and have practiced any Subject Invention for or on behalf of the Government for research or Government Purposes only.

11. "Subject invention" means any Invention of any party Made by its employees under this Agreement and the Letter Contract.

12. "Technical Data" means recorded information of a scientific or technical nature, regardless of form or the media on which it may be recorded, developed under this Agreement. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

13. "Computer Software" as used in this clause, means computer programs, computer data bases, and documentation thereof, developed under this Agreement and the Letter Contract.

14. "Government Purpose Rights Data" as used in this clause, Technical Data developed under this Agreement and the Letter Contract.

B. Patents

1. The Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this Agreement or any subcontract at any tier. In furtherance of this authorization and consent, the Contractor agrees to:

> a) Report to the OT Contracting Officer, promptly and in reasonable written detail, each notice or claim of patent infringement based on the performance of this contract of which the Contractor has knowledge;
>
> (b) In the event of any claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this Agreement or out of the use of any supplies furnished or work or services performed under this Agreement, furnish to the Government, when requested by the OT Contracting Officer, all evidence and information in possession of the Contractor pertaining to such suit or claim. (Such evidence and information shall be furnished at the expense of the Government except where the Contractor has agreed to indemnify the Government.); and
>
> (c) Include, and require inclusion of, this clause in all subcontracts at any tier for supplies or services (including construction and architect-engineer subcontracts and those for material, supplies, models, samples, or design or testing services) expected to exceed $1,000,000.00.

2. Allocation of Principal Rights. Each party shall separately own any Subject Inventions made solely by its employees under this Agreement. The parties shall jointly own Subject Inventions Made jointly by the Government and any Contractor employees under this Agreement and the Letter Contract. The Contractor hereby grants the Government a Special Purpose License to each Subject Invention.

3. Action to Protect the Government's Interest.

a. The Contractor agrees to execute or to have executed and promptly deliver to Government all instruments necessary to establish or confirm the rights the Government has throughout the world in those Subject Inventions.
b. The Contractor shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement No.: HSHQDC-08-9-00001. The Government has certain rights in the invention."

4. Reporting on Utilization of Subject Inventions. Upon request by the Government, the Contractor shall submit a final report on the utilization of Subject Inventions or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees. The report shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor subcontractor(s), and such other data and information as the Government may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the Government. The Government shall not disclose such information to persons outside the Government without permission of the Contractor.



5. Non-exclusive Licenses to Others. In addition to the Special Purpose License, the Contractor, its assignees or exclusive licensees agree to grant a non-exclusive license(s) to a responsible applicant(s), upon terms that are reasonable under the circumstances, if:

a. the Contractor or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention within 5 years of the termination or expiration of this Agreement;

b. Such action is necessary to alleviate health or safety needs that are not reasonably satisfied by the Contractor, assignee, or their licensees; or

c. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the Contractor, assignee, or exclusive licensees.

If the Contractor, assignee, or exclusive licensee refuses to grant such a non-exclusive license, Government has the right to seek resolution through the disputes process set forth in Article VII.

C. Copyrights

1. Copyright Ownership. The Contractor shall own the copyright in all Foreground and Background Works which are copyrightable under Title 17, United States Code. The Contractor shall have the option to register the copyright at the Contractor's expense.

2. Rights to Government. The Contractor hereby grants to the Government, Government Purpose Rights in all Foreground Works. The Government shall not release or disclose the Foreground Works to any person unless: (a) prior to such release or disclosure the recipient signs a use and non-disclosure agreement provided by Contractor; or (b) the recipient is a Government contractor receiving access to the Foreground Works for the performance of a Government Contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government Furnished Information Marked with Restrictive Legends, or a comparable Government contract clause. The Contractor hereby grants to the Government Limited Rights in any Background Works used in connection with the Project.

3. Disclosure. The Contractor shall furnish to the Government, at no cost to the Government and upon written request by the Government, three (3) copies of each Foreground Work if the Work is required to be delivered to the Government under this Agreement.

D. Technical Data, Computer Software and Proprietary Information

1. Outside Proprietary Information means any Proprietary Information, which is not listed in Attachment I, and which has not been developed under this Agreement or the Letter Contract. Outside Proprietary Information shall be expressly provided under a Non-Disclosure Agreement mutually agreed to by the parties. Unless otherwise expressly provided in the Non-Disclosure Agreement, the Government shall not use or disclose such Proprietary Information without the prior written permission of the Contractor except under a written agreement of confidentiality to employees and contractors of the receiving party who have a need for the information in connection with their duties under this Agreement. The Government shall not be liable for release of unmarked information.

2. Proprietary Information Rights. The Contractor hereby grants the Government, Government Purpose Rights in any Government Purpose Rights Data and Computer Software. The Government shall not release or disclose the such Government Purpose Rights Data and Computer Software to any person unless: (a) prior to such release or disclosure the recipient signs a use and non-disclosure agreement provided by Contractor; or (b) the recipient is a Government contractor receiving access to the Government Purpose Rights Data and Computer Software for the performance of a Government Contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government Furnished Information Marked with Restrictive Legends, or a comparable Government contract clause. For the Proprietary Information listed in Attachment I, Limited Rights Proprietary Information, the Contractor hereby grants the Government Limited Rights in the Proprietary Information. Proprietary Information, Government Purpose Rights Data and Computer Software shall be exempt from the Freedom of Information Act, 5 U.S.C. § 552 et seq.

3. Consultation Before Disclosure. The parties agree to confer and consult with each other prior to publication or other public disclosure of the results of work under this Agreement to ensure that no Proprietary Information, Works, Technical Data, Computer

Software and/or military critical technology or other controlled information is released. Prior to submitting a manuscript for publication or before any other public disclosure, each party will offer the other party ample opportunity to review such proposed publication or disclosure, to submit objections, and to file applications for patents in a timely manner.

E. Lower Tier Agreements

1. The Contractor shall include this Article VIII, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier.

## ARTICLE IX: CIVIL RIGHTS ACT

This Agreement is subject to the requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in employment.

## ARTICLE X: PROPERTY

The Government shall have no right, title and/or interest in or to any and all equipment procured and/or developed and manufactured by Contractor or its subcontractors under this Agreement.



## ARTICLE XI: LIABILITY

A. Property.

All property is to be furnished "as is." Except as otherwise provided in this Agreement or the attached Statement of Work, no party to this Agreement shall be liable to any other party for any property of that other party consumed, damaged or destroyed in the performance of this Agreement, unless and to the extent it is due to the negligence or willful misconduct of the party or an employee or agent of the party. Contractor's liability under this provision is subject to Article XI C.

B. Contractor Employees.

Subject to Article XI C, the Contractor agrees to indemnify and hold harmless and defend the Government, its employees and agents, against any liability or loss for any claim made by an employee or agent of the Contractor, or persons claiming through them, for death, injury, loss or damage to their person or property arising in connection with this Agreement, except to the extent that such death, injury, loss or damage arises from the negligence of the Government or its employees.

C. No Warranty.

Except as specifically stated in Article IX, the parties make no express or implied warranty as to any matter whatsoever, including the conditions of the research or any invention or other intellectual property, or product, whether tangible or intangible, made, or developed under this agreement, or the merchantability, or fitness for a particular

purpose of the research or any invention or other intellectual property, or product. The parties further make no warranty that the use of any invention or other intellectual property or product contributed, made or developed under this agreement will not infringe any other united states or foreign patent or other intellectual property right. In no event will any party be liable to any other party for punitive, exemplary, or consequential damages. In addition, in no event shall either party's aggregate liability to the other party arising out of or related to the performance or nonperformance of this agreement (including any liability arising under any indemnification obligation contained in this agreement), exceed the total funding received by Contractor under this Agreement.

D. Other Liability.

The Government shall not be liable to any party to this Agreement, whether directly or by way of contribution or indemnity, for any claim made by any person or other entity for personal injury or death or for property damage or loss, arising in any way from this Agreement, including, but not limited to, the later use, sale or other disposition of research and technical developments, whether by resulting products or otherwise, whether made or developed under this *Agreement* or contributed by either party pursuant to this Agreement, except as provided under the Federal Tort Claims Act (28 U.S.C. § 2671 *et seq*) or other Federal law where sovereign immunity has been waived.

## ARTICLE XII: GENERAL TERMS AND PROVISIONS

A. Relationship of the Parties.

The parties to this Agreement and their employees are independent contractors and are not agents of each other, joint ventures, partners or joint parties to a formal business organization of any kind. Neither party is authorized or empowered to act on behalf of the other with regard to any contract, warranty nor representation as to any matter, and neither party will be bound by the acts or conduct of the other.

B. Publicity/Use of Name Endorsement.

Any public announcement of this Agreement shall be coordinated between the Contractor, the Government and the public affairs office supporting the Government. By entering into this Agreement, the Government does not directly or indirectly endorse any product or service provided, or to be provided, by Contractor, its successors, assignees, or licensees. The Contractor shall not in any way imply that this Agreement is an endorsement of any such product or service.

C. No Benefits.

No member of, or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, nor to any benefit that may arise there from; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

D. Governing Law.

The laws applicable to the Government shall govern the construction, validity, performance and effect of this Agreement for all purposes.

E. Waiver of Rights.

Any waiver shall be in writing and provided to all other parties. Failure to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any party hereto.

F. Severability.

The illegality or invalidity of any provision of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement.

G. Assignment.

Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by any party without the prior written consent of the Government. Notwithstanding the foregoing, Contractor, without such consent, shall be permitted to assign this Agreement and all its associated rights and obligations to an U. S. entity that acquires (whether through acquisition, merger, consolidation, reorganization or otherwise) all or substantially all of the business and assets of such Party to which this Agreement pertains.



H. Entire Agreement.

This Agreement constitutes the entire Agreement between the parties concerning the subject matter hereof and supersedes the Letter Contract. This Agreement takes precedence over any terms in the Letter Contract that may conflict with any terms stated herein. This Agreement may not be amended or modified without a written agreement signed by a duly authorized representative of both of the parties.

Allowable costs under this agreement shall include such costs, incurred by the Contractor in connection with the work performed during the period from and including May 17, 2007 to the effective date of the agreement, as would have been allowable pursuant to the terms of this agreement, if the agreement had been in effect during said period; provided, however, that such costs shall not in the aggregate exceed $5,853,502, which amount is included in the total estimated cost of Letter Contract HSHQDC-07-C-00050.

**TOTAL PROJECT COST SUMMARY**

| | |
|---|---|
| DIRECT LABOR | $1,784,610 |
| INDIRECT COST | $13,404,680 |
| TRAVEL | $199,212 |
| SUBCONTRACTORS | $20,120,143 |

| | |
|---|---|
| CONSULTANTS | $0 |
| MATERIALS | $3,567,498 |
| OTHER DIRECT COSTS | $10,000 |
| TOTAL COST | $39,086,143 |

**COST SHARE**

| | |
|---|---|
| AMSC | $ 6,677,770 |
| CON EDISON | $ 7,500,000 |
| GOVERNMENT | $24,908,413 |

**PROJECT FUNDING PROFILE**

| Government Fiscal Year | Total Program | Government Share |
|---|---|---|
| GFY07 | $ 1,940,465 | $ 1,268,605 |
| GFY08 | $ 12,782,165 | $ 8,581,750 |
| GFY09 | $ 13,308,116 | $ 8,175,193 |
| GFY10 | $ 11,055,397 | $ 6,882,865 |
| GFY11 | $ - | $ - |
| Total GFY | $39,086,143 | $24,908,413 |

## ARTICLE XIII: OPTIONS

The Government reserves the right to modify this agreement to include terms and conditions for additional work or to exercise any option for future phases. The cost, technical content and duration of these additional periods and/or options shall be subject to negotiation between the parties. The parameters associated with any additional work or options shall be negotiated and agreed to prior to completion of the Agreement.

## ATTACHMENT I

## LIMITED RIGHTS PROPRIETARY INFORMATION/GOVERNMENT PURPOSE RIGHTS DATA AND SOFTWARE

| *Technical Data/Computer Software To Be Furnished with Restrictions* | *Basis for Assertion* | *Asserted Rights Category* | *Person Asserting Restrictions* | *Expiration Date* |
|---|---|---|---|---|
| 1. Pre-existing integrated HTS/FCL cable data | Developed at private expense outside of Agreement | Limited Rights Proprietary Information | American Superconductor | N/A |
| 2. Pre-existing HTS/FCL cable wire data | Developed at private expense outside of Agreement | Limited Rights Proprietary Information | American Superconductor | N/A |
| 3. Pre-existing stand-alone fault current limiter data | Developed at private expense outside of Agreement | Limited Rights Proprietary Information | American Superconductor | N/A |
| 4. Integrated HTS/FCL cable data developed on the Letter Contract or this Agreement | Developed under the Letter Contract or this Agreement | Government Purpose Rights | American Superconductor | N/A |
| 5. HTS/FCL cable wire data developed on the Letter Contract or this Agreement | Developed in part or whole under the Letter Contract or this Agreement | Government Purpose Rights | American Superconductor | N/A |
| 6. Pre-existing cryogenics and refrigeration system data | Developed at private expense outside of Agreement | Limited Rights Proprietary Information | Linde/BOC | N/A |
| 7. Stand-alone fault current limiter data developed on the Letter Contract or this Agreement | Developed in part or whole under the Letter Contract or this Agreement | Government Purpose Rights | American Superconductor or its Stand-alone FCL Subcontractors | N/A |
| 8. Pre-existing Stand-alone fault current limiter data | Developed at private expense outside of Agreement | Limited Rights Proprietary Information | Stand-alone FCL Subcontractors | N/A |
| 9. Pre-existing HTS cable, cable termination and/or raw materials there-of data | Developed at private expense | Limited Rights Proprietary Information | Southwire Company | N/A |
| 10. Pre-existing HTS cable, cable termination and/or raw materials there-of data | Developed at private expense | Limited Rights Proprietary Information | Southwire Company | N/A |
| | | | | |

M

| | | | | |
|---|---|---|---|---|
| 11. Integrated HTS/FCL cable, cable termination and/or raw materials there-of data developed on the Letter Contract and/or the agreement | Developed in part or whole under the Letter Contract or this Agreement | Government Purpose Rights | Southwire Company | N/A |
| 12. Cryogenics and refrigeration system data developed on the Letter Contract and/or the agreement | Developed in part or whole under the Letter Contract or this Agreement | Government Purpose Rights | Linde/BOC | N/A |
| 13. Utility grid system and modeling data | Developed at private expense | Limited Rights Proprietary Information | Consolidated Edison of NY | N/A |
| 14. All other technical data and computer software developed by American Superconductor or its Subcontractors under the Letter Contract or this Agreement | Developed in part or whole under the Letter Contract or this Agreement | Government Purpose Rights | American Superconductor or its Subcontractors, as applicable | N/A |

AMSC and its subcontractor(s) reserve the right to supplement the above list of data and software items upon mutual agreement of the Government.

AMSC proprietary data regarding HTS wire, other than the items listed above, will not be delivered under this Agreement.

# N. SAMPLE BROAD AGENCY ANNOUNCEMENT

**ONR BAA Announcement # 05-021**

# BROAD AGENCY ANNOUNCEMENT (BAA)

**INTRODUCTION:**

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2). A formal Request for Proposals (RFP), solicitation, and/or additional information regarding this announcement will not be issued.

The Office of Naval Research (ONR) will not issue paper copies of this announcement. The ONR reserves the right to select for award all, some or none of the proposals in response to this announcement. The ONR reserves the right to fund all, some or none of the proposals received under this BAA. ONR provides no funding for direct reimbursement of proposal development costs. Technical and cost proposals (or any other material) submitted in response to this BAA will not be returned. It is the policy of ONR to treat all proposals as sensitive competitive information and to disclose their contents only for the purposes of evaluation.

N

## I. GENERAL INFORMATION

**1. Agency Name -**

Office of Naval Research,
875 N. Randolph Street Suite 1425
Arlington, VA 22203-1995

**2. Research Opportunity Title -**

**Personnel Transfer At-Sea Prototype Demonstrator**

**3. Program Name – Seabasing Innovative Naval Prototype (INP): Personnel Transfer At-Sea Demonstrator**

**4. Research Opportunity Number -**

**ONR BAA – 05-021**

**5. Response Date -**

Full Proposals are due by no later than 2:00 p.m. (Eastern Daylight Time) on 30 September 2005.

**NOTE: Although full proposals are due on 30 September 2005, this BAA will remain open until 4 April 2008 since contractors will be required to submit a second, more detailed Phase II cost proposal as a deliverable of Phase I. However, only contractors who were awarded a Phase I contract will be considered for Phase II.**

**6. Research Opportunity Description -**

**Background:**

The Office of Naval Research, beginning in FY06, is embarking on an effort to develop "Game Changing" Innovative Naval Prototypes (INPs) for Seabasing. The total INP Seabasing effort is currently programmed to run from FY06 through the end of FY11 with a total of $295M programmed. Other Seabsing INP BAAs to be released include the Sea Base Connector Transformable-Craft (T-CRAFT) Prototype Demonstrator, the Sea Base Transformational Package and Ordnance Rapid Transfer System (TransPORTS) Prototype Demonstrator, and the Sea Base Intermediate Transfer Station (ITS) Prototype Demonstrator.

This BAA addresses only a portion of the total Seabasing INP program and is specifically focused on the Personnel Transfer At-Sea Prototype Demonstrator. Of the $295M programmed for the Seabasing INPs, it is estimated that this total effort would cost less than $60M.

Under this BAA, the Office of Naval Research (ONR 33) is soliciting proposals for a prototype demonstrator of an at-sea personnel transfer system capable of transferring a large number of troops, between two ships, in a safe and rapid manner through Sea States 4 to 5. Transfer will take place both underway (speeds ~10-20 knots) and at zero speed (anchored, moored, etc.). The prototype design should lend itself to both new construction ship designs and retro-fit of existing ships. Ship sizes used for demonstration purposes would range between an USS SWIFT (HSV-2) sized ship up to a LMSR (T-AKR 300 or 310 class) sized vessel.

**Program Plan:**

The Office of Naval Research (ONR 33) anticipates a two phase program.

The first phase of the program, which is envisioned to be 12 months in duration, would consist of multiple awards for preliminary designs which describe the prototype and the technologies to be included in the prototype to meet the desired capabilities. Each Phase I award is estimated to be valued at between $1M and $3M.

The government requires detailed Phase I and Phase II cost proposals under this solicitation. However, the cost proposal for Phase II will be required as one of the deliverables of Phase II. Using this detailed proposal and the other Phase I deliverables, the government may then down select for a single Phase II award.

Phase II, envisioned to be 36 months in duration, will consist of several tasks, corresponding to major milestones. The first task would be to perform the necessary simulations and model tests to develop a detailed design of the prototype system. The second task would be to construct and test a land-based (or pier side) prototype. Upon successful completion of the land based demonstration, the third task would be the design, construction, and demonstration of the at-sea prototype. It is envisioned that phase II would be incrementally funded, broken down by the major tasks. It is estimated that the total Phase II award would be less than $50M.

**Desired Capabilities of the Personnel Transfer At-Sea Demonstrator:**

The Office of Naval Research has identified a list of capabilities, desired thresholds/objectives, and other relevant information for the Personnel Transfer At-Sea Demonstrator provided below. It can not be over-stressed that the safety of personnel and equipment (including the ships) is paramount to this effort.


Capability List:

1. Large ship (i.e., T-AKR 300, T-AKR 310 classes) to Large ship transfer of personnel and their gear underway (10-20 knots) and at zero speed (anchored, moored, rafted, etc).
2. Small ship (i.e., HSV-2) to/from Large ship (i.e., T-AKR 300, T-AKR 310 classes) transfer of personnel and their gear underway (10-20 knots) and at zero speed (anchored, moored, rafted, etc.).
3. System fully operable to connect, disconnect and transfer personnel through a temperature range of $15^{o}$F to $115^{o}$F.
4. System must be capable of being integrated into new ship concepts as well as being back-fittable to existing ships.
5. System must self-deploy and self-retract.
6. System must be designed for day and night operations.
7. System must take into account human factor issues to accommodate troops ranging between the 5 and 95 percentile for size and weight of men/women.

8. System must prevent the possibility of personnel or their equipment (pack, rifle, etc.) from falling overboard during the staging, transfer, and assembly processes.
9. System should have a rapid failsafe break away capability.

Thresholds/Objectives:

| **Notional Requirements** | **Threshold** | **Objectives** |
|---|---|---|
| System fully operable through | Sea State 4 | Sea State 5 |
| Underway transfer ship speed | >10 knots (best heading) | >20 knots (all headings) |
| Zero speed headings | Best heading | Best heading |
| Personnel transfer rates | 300/hour | 500/hour |
| System connection time | 30 min | 15 min |
| System quick disconnect time | 10 min | 5 min |

Other relevant information:

1. If the system requires active ship control, fendering, and/or mooring systems, these systems should be automated and integrated with the transfer system to the maximum extent possible.
2. It is envisioned that ship separation would be as little as a few feet for anchored/moored applications and as much as 150 feet, depending upon individual system design and ship speeds.

**7. Points of Contact -**

Questions of a technical nature shall be directed to the cognizant Technical Point of Contact, as specified below:

Science and Technology Points of Contact:

Ms. Kelly Cooper
Office of Naval Research, ONR 334
875 N. Randolph Street Suite 1425
Arlington, VA 22203-1995
Telephone Number: (703) 696-0869
Email Address: cooperkb@onr.navy.mil

Questions of a business nature shall be directed to the cognizant Business Point of Contact, as specified below:

Business Point of Contact:

Brenda Burke
Senior Contract Specialist
875 N. Randolph Street Suite 1425
Arlington, VA 22203-1995
Telephone Number: (703) 588-2440
Email Address: brenda_burke@onr.navy.mil

**8. Instrument Types -**

It is anticipated that ONR will award one or more procurement contracts for this effort.

**9. Catalog of Federal Domestic Assistance (CFDA) Numbers – N/A.**

**10. Catalog of Federal Domestic Assistance (CFDA) Titles – N/A.**

**11. Additional Information – N/A**

## II. AWARD INFORMATION

The Navy anticipates awarding one or more contracts to be incrementally funded over a period of five years. Phase I awards are anticipated to be between $1M and $3M per awardee. If awarded, the single Phase II award is estimated to be less than $50M. The total estimated budget for the program is less than $60M million dollars.

## III. ELIGIBILITY INFORMATION

The Government encourages teaming arrangements between and among the following groups: domestic and foreign companies, universities and institutions, and U.S. government laboratories; however, awards will be limited to teams which have the capability to manufacture and test the prototype demonstrator within the United States.



## IV. APPLICATION AND SUBMISSION INFORMATION

**1. Application and Submission Process -**

**Full Proposals** - The due date for receipt of Full Proposals is 2:00 p.m. (EDT) on 30 September 2005. It is anticipated that any final selections would be made by 31 December 2005. As soon as the final proposal evaluation process is completed, the Offeror will be notified via email or letter of its selection or non-selection for an award. Proposals exceeding the page limit may not be evaluated.

This Broad Agency Announcement constitutes all the information to be provided regarding this solicitation. No Pre-Proposal Industry Days are anticipated prior to the proposal submission date.

**2. Content and Format of White Papers/Full Proposals -**

The Proposals submitted under this BAA are expected to be unclassified. The Proposal submissions will be protected from unauthorized disclosure in accordance with FAR 15.207, applicable law, and DoD/DoN regulations. Offerors are expected to appropriately mark each page of their submission that contains proprietary information.

**Full Proposal Format – Volume 1 - Technical and Volume 2 - Cost Proposal**

• Paper Size – 8.5 x 11 inch paper, also will allow up to 11X17 inch paper for Schedule and/or Design Concept foldouts
• Margins – 1" inch
• Spacing – single or double-spaced
• Font – Times New Roman, 12 point
• Number of Pages – Volume 1 is limited to no more than 50 pages. Volume 2 does not have a page limitation. Double sided printing is encouraged. The Cover Page, Table of Contents, Statement of Work and Resumes are excluded from the page limitations. Full Proposals exceeding the page limit may not be evaluated.
• Copies – one (1) original, two (2) copies, and five (5) electronic copies on a CD-ROM, (in .PDF format).

**Full Proposal Content**

**Volume 1: Technical Proposal**

**Cover Page:**

This should include the words "Technical Proposal" and the following:

1) BAA number;
2) Title of Proposal;
3) Identity of Prime Offeror and complete list of subcontractors, if applicable;
4) Technical contact (name, address, phone/fax, electronic mail address)
5) Administrative/business contact (name, address, phone/fax, electronic mail address) and;
6) Duration of effort (differentiate basic effort and options)

**Table of Contents:** (not included in page count)

**Statement of Work:** A Statement of Work (SOW) clearly detailing the scope and objectives of the program and the technical approach to be taken for both phases, broken out by phase and tasks. It is anticipated that the proposed SOW will be incorporated as an attachment to the resultant award instrument. To this end, such proposals must include a severable self-standing SOW without any proprietary restrictions, which can be attached

to the contract or agreement award. Include a detailed listing of the technical tasks/subtasks organized by year.

**Prototype Concept Description:** A description of the effort that articulates an understanding of the capabilities desired and how the offeror's proposed technologies will be integrated into a single prototype demonstrator to achieve ONR's objectives. Include a description of risk reduction technology development or demonstrations, if any, required prior to detail design of the at-sea prototype.

**Project Schedule and Milestones:** The proposal should include a detailed listing of the technical tasks/subtasks in Work Breakdown Structure format and also organized by year. The proposal should also include a schedule of events and milestones for the proposed program keyed to the work breakdown structure and program phases. Deliverables and program review dates should be included.

**Assertion of Data Rights:** Include here a summary of any proprietary rights to pre-existing results, prototypes, or systems supporting and/or necessary for the use of the research, results, and/or prototype. Any data rights asserted in other parts of the proposal that would impact the rights in this section must be cross-referenced. If there are proprietary rights, the Offeror must explain how these affect its ability to deliver research data, subsystems and toolkits for integration. Additionally, Offerors must explain how the program goals are achievable in light of these proprietary limitations. If there are no claims of proprietary rights in pre-existing data, this section shall consist of a statement to that effect.

**Deliverables:** A detailed description of the results and products to be delivered for each phase of the program.

**Management Approach:** A discussion of the overall approach to the management of this effort, including brief discussions of the total organization, use of personnel; project/function/subcontractor relationships; government research interfaces; and planning, scheduling and control practice. Identify which personnel and subcontractors (if any) will be involved in each program phase. Include a description of the facilities that are required for the proposed effort with a description of any Government Furnished Equipment/Hardware/Software/ Information required, by version and/or configuration.

**Experience:** A description of the experience and qualifications of the offeror, subcontractors, and key personnel relevant to the proposed effort. Specific examples of work accomplished similar in complexity, magnitude and technical content to that proposed should be provided. Brief resumes (Not Included in Page Limitations) of key prime and subcontractor personnel may be included.

**VOLUME 2: Cost Proposal**

The Cost Proposal shall consist of a cover page and two parts. Part 1 will provide a detailed cost breakdown of all costs, by cost category, by Gov't fiscal year and Part 2 will provide a cost breakdown by task/sub-task, corresponding to the task numbers in the proposed Statement of Work. Each program phase should be priced separately.

The government requires the submission of both the Phase I and Phase II cost proposals for overall Seabasing INP budget development/scheduling by the proposal due date of 30 September 2005. In addition, a more detailed cost proposal for Phase II will be required as one of the deliverables of Phase I.

A separate cost item, outside of the Phase I and Phase II efforts, to address prototype disposal should be included in the response to this solicitation.

**Cover Page:** The use of the SF 1411 is optional. The words "Cost Proposal" should appear on the cover page in addition to the following information:

- BAA number
- Title of Proposal
- Identity of prime Offeror and complete list of subcontractors, if applicable
- Technical contact (name, address, phone/fax, electronic mail address)
- Administrative/business contact (name, address, phone/fax, electronic mail address) and
- Duration of effort (separately identify basic effort and any proposed options)

**Part 1:** Detailed breakdown of all costs, by cost category, by Gov't fiscal year:

- Direct Labor – Individual labor category or person, with associated labor hours and unburdened direct labor rates
- Indirect Costs – Fringe Benefits, Overhead, G&A, COM, etc. (Must show base amount and rate)
- Travel – Number of trips, destination, duration, etc.
- Subcontract – A cost proposal as detailed as the Offeror's cost proposal will be required to be submitted by the subcontractor. The subcontractor's cost proposal can be provided in a sealed envelope with the Offeror's cost proposal or will be requested from the subcontractor at a later date
- Consultant – Provide consultant agreement or other document which verifies the proposed loaded daily/hourly rate
- Materials should be specifically itemized with costs or estimated costs. An explanation of any estimating factors, including their derivation and application, shall be provided. Include a brief description of the Offeror's procurement method to be used (Competition, engineering estimate, market survey, etc.)

- Other Directs Costs, particularly any proposed items of equipment or facilities. Equipment and facilities generally must be furnished by the contractor/recipient. (Justifications must be provided when Government funding for such items is sought). Include a brief description of the Offeror's procurement method to be used (Competition, engineering estimate, market survey, etc.)
- Fee/Profit including fee percentage.

**Part 2 :** Cost breakdown by task/sub-task using the same task numbers in the Statement of Work.

**3. Significant Dates and Times**-

| **Anticipated Schedule of Events *** | | |
|---|---|---|
| **Event** | **Date (MM/DD/YEAR)** | **Time (EDT)** |
| Full Proposals Due Date | 09/30/05 | 2 P.M. |
| Notification of Selection for Award | 12/31/05 | _____ |
| Contract Award | 03/31/06 | _____ |

***These dates are estimates as of the date of this announcement.**

**4. Submission of Late Proposals –**

Any proposal, modification, or revision, that is received at the designated Government office after the exact time specified for receipt of proposals is "late" and will not be considered unless it is received before award is made, the contracting officer determines that accepting the late proposal would not unduly delay the acquisition and

(a) If it was transmitted through an electronic commerce method authorized by the announcement, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(b) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of proposals and was under the Government's control prior to the time set for receipt of proposals; or

(c) It was the only proposal received.

However, a late modification of an otherwise timely and successful proposal, that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

N

Acceptable evidence to establish the time or receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the Government office designated for receipt of proposals by the exact time specified in the announcement, and urgent Government requirements preclude amendment of the announcement closing date, the time specified for receipt of proposals will be deemed to be extend to the same time of day specified in the announcement on the first work day on which normal Government processes resume.

The contracting officer must promptly notify any offeror if its proposal, modifications, or revision was received late and must inform the offeror whether its proposal will be considered.

**5. Address for the Submission of Full Proposals –**

Office of Naval Research,
Attn: Brenda Burke, Code 0254
875 N. Randolph Street, Suite 1425
Arlington, VA 22203-1995
Telephone Number: (703) 588-2440

**NOTE: PROPOSALS SENT BY FAX OR E-MAIL WILL NOT BE CONSIDERED.**

## V. EVALUATION INFORMATION

**1. Evaluation Criteria –**

The following evaluation criteria apply to the Full Proposals. Proposals will be selected through a technical/scientific decision process. Criteria A-C are listed in descending order of priority. Any sub criteria listed under A-C are of equal importance to each other.

**A. Overall scientific and technical merits of the proposal.**
1. The soundness of technical concept.
2. The offeror's awareness of the state-of-the-art and understanding of scope of the problem and the technical effort needed to address it.
3. Game changing capability.

**B.** Capabilities, facilities, related experience, and past performance of the Offeror and the Offeror's team.

**C. Schedule and Cost Realism**

The objective of this criterion is to establish that the proposed schedule and costs are reasonable and realistic for the technical and management approach offered, as well as to

determine the proposer's practical understanding of the effort. This will be principally measured by cost per labor-hour and number of labor-hours proposed. Cost reduction approaches that will be received favorably include innovative management concepts that maximize direct funding for technology and limit diversion of funds into overhead.

Socio-Economic Merits - For proposed awards made as contracts, the socio-economic merits of each proposal will be evaluated based on the extent of the Offeror's commitment in providing meaningful subcontracting opportunities (to the maximum extent practicable) for small businesses, HUBZone small businesses, small disadvantaged businesses, woman-owned small businesses, veteran-owned small businesses, service disabled veteran small businesses, historically black colleges and universities, and minority institutions.

**2. Evaluation Panel -**

Government technical experts from the Office of Naval Research and other Federal entities will perform the evaluation of proposals. The Government may use selected non-government personnel or support contractor personnel to assist in the evaluation and administrative functions of any White Papers and proposals ensuing from this solicitation. Such non-government personnel will be bound by appropriate non-disclosure agreements to protect proprietary and source-selection information.

## VI. AWARD ADMINISTRATION INFORMATION

**1. Administrative Requirements –**

- CCR - Successful Offerors not already registered in the Central Contractor Registry (CCR) will be required to register in CCR prior to award of any grant, contract, cooperative agreement, or other transaction agreement. Information on CCR registration is available at http://www.onr.navy.mil/02/ccr.htm.

- Certifications – Proposals should be accompanied by a completed certification package which can be accessed on the ONR Home Page at Contracts & Grants. For grant proposals and proposals for cooperative agreements or other transaction agreements (other than for prototypes), the certification package is entitled, "Certifications for Grants and Agreements. " For contract proposals and for other transaction proposals involving prototypes (Section 845 agreements), the certification package is entitled, "Representations and Certifications for Contracts. "

- Online Representations and Certifications Application (ORCA) – In addition to the submission of ONR specific Representations and Certifications, successful offerors not already registered in ORCA will be required to register prior to award of any contract. Information on ORCA registration is available at http://www.orca.bpn.gov.

- Subcontracting Plans - Successful contract proposals that exceed $500,000, submitted by all but small business concerns, will be required to submit a Small Business Subcontracting Plan in accordance with FAR 52.219-9, prior to award.

**2. Reporting -**

Specific deliverables should be proposed by the offeror and will be finalized with the technical program officer and the contract specialist. Reports and hardware deliverables that the Navy anticipates for the proposed program are as follows:

- Monthly technical and financial status reports.
- Detailed schedule for the total program.
- Quarterly progress review presentation material and record of meeting.
- Preliminary concept design report and drawings
- Phase II cost proposal
- Simulation plan
- Simulation results report
- Model testing plan
- Detailed design report and drawings
- Model testing results report
- Final design report and drawings
- Land based Prototype construction plan and drawings
- Land based test plan
- Land based test results
- At-Sea Prototype design
- At-Sea Prototype construction plan
- At-Sea Prototype and ship interface design and drawings
- As-built drawings
- At-sea test plan
- At-sea test results report
- Prototype demonstration

## VII. OTHER INFORMATION

**1. Government Property/Government Furnished Equipment (GFE) and Facilities**

Each proposer must provide a very specific description of any equipment/hardware that it needs to acquire to perform the work. This description should indicate whether or not each particular piece of equipment/hardware will be included as part of a deliverable item under the resulting award. Also, this description should identify the component, nomenclature, and configuration of the equipment/hardware that it proposes to purchase for this effort. It is the Government's desire to have the contractors purchase the equipment/hardware for deliverable items under their contract. The purchase on a direct reimbursement basis of special test equipment or other equipment that is not included in a

deliverable item will be evaluated for allowability on a case-by-case basis. Maximum use of Government integration, test, and experiment facilities is encouraged in each of the Offeror's proposals.

Government research facilities and operational military units are available and should be considered as potential government furnished equipment/facilities. These facilities and resources are of high value and some are in constant demand by multiple programs. It is unlikely that all facilities would be used for this topic. The use of these facilities and resources will be negotiated as the program unfolds. Offerors should explain which of these facilities they recommend.

**2. BAA Questions and Answers**

During the solicitation period, potential responders will be able to ask questions pertaining to this BAA via the following website:
http://www.onr.navy.mil/02/baa/05_021/

All questions received and their respective answers will be posted so that all potential bidders can benefit from the information posted.

This page is intentionally left almost blank.

# O. MODEL OTFR AGREEMENT

**FIXED PAYABLE MILESTONE MODEL OT**

AGREEMENT

BETWEEN

(INSERT CONSORTIUM NAME AND ADDRESS)

**AND**

NIH

CONCERNING

(INSERT RESEARCH AND DEVELOPMENT EFFORT)

Agreement No.:

ARPA Order No.: .

Total Amount of the Agreement $(1NCT.UDES CONSORTIUM AND GOVERNMENT FUNDING)

Total Estimated Government Funding of the Agreement $

Funds Obligated: $

Authority: *(Cite appropriate OT authority)*

Line of Appropriation:

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by NIH, and the (INSERT CONSORTIUM NAME) pursuant to and under U.S. Federal law.

| FOR (INSERT CONSORTIUM NAME) | FOR THE UNITED STATES OF AMERICA, NIH |
|---|---|
| _____ | _____ |
| (Signature) | (Signature) |
| _____ | _____ |
| (Name, Title) (Date) | (Name, Title) (Date) |

O

**TABLE OF CONTENTS**


| **ARTICLES** | | **PAGE** |
|---|---|---|
| ARTICLE I | Scope of the Agreement | |
| ARTICLE II | Term | |
| ARTICLE III | Management of the Project | |
| ARTICLE IV | Agreement Administration | |
| ARTICLE V | Obligation and Payment | |
| ARTICLE VI | Disputes | |
| ARTICLE VII | Patent Rights | |
| ARTICLE VIII | Data Rights | |
| ARTICLE IX | Foreign Access to Technology | |
| ARTICLE X | Title and Disposition of Property | |
| ARTICLE XI | Civil Rights Act | |
| ARTICLE XII | Execution | |
| Article XIII | Special Provisions | |
| ARTICLE XIV | Transfers&Assignments | |

ATTACHMENTS

| | |
|---|---|
| ATTACHMENT 1 | Statement of Work |
| ATTACHMENT 2 | Report Requirements |
| ATTACHMENT 3 | Schedule of Payments and Payable Milestones |
| ATTACHMENT 4 | Funding Schedule |
| ATTACHMENT 5 | List of Government and (INSERT COMPANY NAME) Representatives |

ARTICLE I: SCOPE OF THE AGREEMENT

A. Vision and Background

1. (THIS PARAGRAPH(S) DESCRIBES THE VISION OF THE PROGRAM AND SHOULD ANSWER THE FOLLOWING QUESTIONS: WHAT IS THE AGREEMENT ALL ABOUT? WHAT IS THE CURRENT TECHNOLOGICAL SITUATION? WHAT MAKES THIS PROGRAM A"CRITICAL TECHNOLOGY" EFFORT? WHY IS THE CURRENT TECHNOLOGY NOT SUFFICIENT? WHY IS IT NECESSARY FOR THE GOVERNMENT TO SUPPORT INDUSTRY IN ADDRESSING THIS SITUATION? WHAT ARE THE ISSUES OF PARTICULAR IMPORTANCE TO THE ISSUING AGENCY? WHAT ARE THE DUAL-USE (MILITARY AND COMMERCIAL) APPLICATIONS? WHAT IS THE MARKET POTENTIAL? WHAT ARE THE COMMERCIALIZATION GOALS? IF THE PROGRAM IS SUCCESSFUL, THEN WHAT? WHERE DO WE GO FROM HERE? IF THIS COLLABORATION IS SUCCESSFUL, WHAT WILL WE HAVE ACCOMPLISHED?)

B. Definitions

**Agreement:** The body of this Agreement and Attachments 1 - **X,** which are expressly incorporated in and made a part of the Agreement.

Article 1 B Definitions

**Agreement:** The body of this Agreement and Attachments 1 – (**correct number),** which are expressly incorporated in and made a part of the Agreement.

**Computer Software:**

Means:

Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Does not include computer databases or computer software documentation.

Consortium **is** when a team is formed to under Articles of Collaboration to perform the responsibilities of an agreement.

**Data:** Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, and trade secrets made in the performance of work under this Agreement within the Field. The term does not include financial, administrative, cost, pricing or management information.

**Foreign Firm or Institution:** A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any _agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals. Specifically excluded from the definition of Foreign Firm or Institution are the entities listed on Attachment 4 along with their non-US affiliates.

**Government:** The United States of America, as represented by xxxx

**Government Purpose Rights:** The rights to use, duplicate, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

**Invention:** Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

**Know-How:** Information, practical knowledge, techniques, and skill development by Recipient in the performance of work under this Agreement necessary for the Practical Application of a Subject Invention with the Field.

**Limited Rights:** Th rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. DHHS will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Non-Traditional Research Participate(S) (NRP) is or are

**Other Transaction (OT)** means: A legally binding, non-acquisition instrument (generally called "an agreement") used in instances where the principal purpose is facilitating NIH's mission.

**Other Transaction Agreement Officer (OTAO):** Is the responsible government official authorized to bind the government by signing this Agreement and bilateral modifications.

**Other Transaction Agreement Specialist (OTAS):** Is a supporting official that executes agreement modifications on behalf of the Other Transaction Agreement Officer.

**Other Transaction Agreement Technical Representative (OTTR):** Is the primary government official for all technical matters on the Agreement.

**Practical Application:** With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public.

**Program:** Research and development being conducted by the Parties pursuant to this Agreement.

**Property:** Any tangible personal property other than property consumed during the execution of work under this Agreement.

**Recipient/Awardee/contractor/Consortium** is the entity awarded this agreement.

**SubRecipient/subAwardee/subcontractor** are entities that a sub contractual relationship with Recipient/ Awardee/Contractor

**Subject Invention:** Any Invention conceived in the performance of work under this Agreement (as defined below) within the Field for which Recipient pursues a patent.

**Technology:** Discoveries, innovations, Know-How and Subject Inventions, whether patentable or not, conceived in the performance of work under this Agreement, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights developed under this Agreement.

C. Efforts Required by This Agreement

1. Company ABC (ABC) shall perform a research and development program (Program) designed to develop (INSERT RESEARCH AND DEVELOPMENT EFFORT). The research shall be carried out in accordance with the Statement of Work incorporated in this Agreement as Attachment 1. ABC shall submit or otherwise provide all documentation required by Attachment 2, Report Requirements.

2. ABC shall be paid for each Payable Milestone accomplished in accordance with the Schedule of Payments and Payable Milestones set forth in Attachment 3 and the procedures of Article V. The parties recognize that the nature of the Payable Milestones is fixed and subject to revision only in accordance with Article III, Paragraph D Modifications. While fixed, the parties recognize that the Payable Milestones are constructed using the concept of "Substantial Compliance" where variable outcomes possible and acceptable.

3. The Government and ABC (Parties) estimate that the Statement of Work of this Agreement can only be accomplished with an ABC aggregate resource contribution of $ (INSERT DOLLAR AMOUNT) from the effective date of this Agreement through (INSERT NUMBER OF MONTHS) ( ) months thereafter. ABC intends and, by entering into this Agreement, undertakes to cause these funds to be provided. ABC contributions will be provided as detailed in the Funding Schedule set forth in Attachment 4.

D. Goals / Objectives

1. The goal of this Agreement is (INSERT GOAL(S) OF AGREEMENT).

2. The Government will have continuous involvement with ABC. The Government will also obtain access to research results and certain rights in data and patents pursuant to Articles VII and VIII. NIH and ABC are bound to each other by a duty of good faith and best research effort in achieving the goals of the Program.

3. 3. This Agreement is an "other transaction" pursuant to *(THE OTAO MUST PICK THE CORRECT AUTHORITY)*

Section 402(b)(7) or 402(b)(12) of the Public Health Service (PHS) Act

Section 480(e)(3)(C) of the PHS, 42 U.S.C. 287a(e)(3)(C

42 U.S.C. 284n(b),

The National Heart, Blood Vessel, Lung, and Blood Act of 1972, Pub. L. No. 92-423, 86 Stat. 679 (1972),

or, H.R.6, The 21st Century Cures Act (Cures Act),

4. The Parties agree that the principal purpose of this Agreement is for the Government to support and stimulate ABC to provide its best efforts in advanced research and technology development and not for the acquisition of property or services for the direct benefit or use of the Government. The Federal Acquisition Regulation (FAR) and Department of Defense FAR Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not a procurement contract or grant agreement for purposes of FAR Subpart 31.205-18.

ARTICLE II: TERM

A. The Term of this Agreement

The Program commences upon the date of the last signature hereon and continues for (INSERT NUMBER OF MONTHS) ( ) months. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified herein, shall be given effect, notwithstanding this Article.

B. Termination Provisions

Subject to a reasonable determination that the program will not produce beneficial results commensurate with the expenditure of resources, either Party may terminate this Agreement by written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. The Government and ABC will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VI, Disputes. The Government has no obligation to reimburse ABC beyond the last completed and paid milestone if ABC decides to terminate.

C. Extending the Term

The Parties may extend by mutual written agreement the term of this Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the OTAO and the ABC Administrator.

ARTICLE III: MANAGEMENT OF THE PROJECT (NOTE: THIS ARTICLE MAY BE SUBSTANTIALLY REVISED DEPENDING ON THE FACTS OF EACH AGREEMENT.)

A. Management and Program Structure

ABC shall be responsible for the overall technical and program management of the Program, and technical planning and execution shall remain with ABC. The NIH Program Manager shall provide recommendations t Program developments and technical collaboration and be responsible for the review and verification of the Payable Milestones.

B. Program Management Planning Process

Program planning will consist of an Annual Program Plan with inputs and review from ABC and NIH management, containing the detailed schedule of research activities and payable milestones. The Annual Program Plan will consolidate quarterly adjustments in the research schedule, including revisions/modification to payable milestones.

1. Initial Program Plan: ABC will follow the initial program plan that is contained in the Statement of Work (Attachment 1), and the Schedule of Payments and Payable Milestones (Attachment 3).

2. Overall Program Plan Annual Review

(a) ABC, with NIH Program Manager review, will prepare an overall Annual Program Plan in the first quarter of each Agreement year. (For this purpose, each consecutive twelve (12) month period from (and including) the month of execution of this Agreement during which this Agreement shall remain in effect shall be considered an "Agreement Year".) The Annual Program Plan will be presented and reviewed at an annual site review which will be attended by ABC Management, the NIH Program Manager, Senior NIH management as appropriate, and other NIH program managers and personnel as appropriate. ABC, with NIH participation and review, will prepare a final Annual Program Plan.

(b) The Annual Program Plan provides a detailed schedule of research activities, commits ABC to use its best efforts to meet specific performance objectives, includes forecasted expenditures and describes the Payable Milestones. The Annual Program Plan will consolidate all prior adjustments in the research schedule, including revisions/modifications to payable milestones. Recommendations for changes, revisions or modifications to the Agreement which result from the Annual Review shall be made in accordance with the provisions of Article III, Section C.

C. Modifications

1. As a result of quarterly meetings, annual reviews, or at any time during the term of the Agreement, research progress or results may indicate that a change in the Statement of Work and/or the Payable Milestones, would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the Statement of Work and/or the Payable Milestones, will be documented in a letter and submitted by ABC to the NIH Program Manager with a copy to the NIH Agreements Officer. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the research program. ABC shall approve any Agreement modification. The Government is not obligated to pay for additional or revised Payable Milestones until the Payable Milestones Schedule (Attachment 3) is formally revised by the NIH OTAOand made part of this Agreement.

2. The NIH Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement Statement of Work, Schedule of Payments or Payable Milestones, or other proposed changes to the terms and conditions of this Agreement.

3. For minor or administrative Agreement modifications (e.g. changes in the paying office or appropriation data, changes to Government or ABC personnel identified in the Agreement, etc.) no signature is required by ABC.

ARTICLE IV. **ARTICLEV: AGREEMENTADMINISTRATION**

**A. Administrative and contractual matters under this Agreement will be referred to the following representatives of the Parties:**

Government Points of Contact

Other Transactions Agreement Specialist (OTAS}

Name

Telephone: xxx-xxx-xxxx

email

Other Transactional Agreement Officer (OTAO)

Name

Telephone: xxx-xxx-xxxx

email

Recipient Points of Contact Heidi Name

Telephone: xxx-xxx-xxxx

email

**B. Technical matters under this Agreement will be referred to the following representatives:**

Government Points of Contact

Other Transactional Authority Technical Representative (OTTR)

Name

Telephone: xxx-xxx-xxxx

email

Alternate OTTR

Name

Telephone: xxx-xxx-xxxx

email

O

Recipient Points of Contact

Recipient Program Manager:

(XXX}

juliet.mcguillan@astrazeneca.com

Alternate:

ARTICLE V: OBLIGATION AND PAYMENT

A. Obligation

1. The Government's liability to make payments to ABC is limited to only those funds obligated under the Agreement or by modification to the Agreement. NIH may obligate funds to the Agreement incrementally.

2. If modification becomes necessary in performance of this Agreement, pursuant to Article III, paragraph B, the NIH OTAOand ABC Administrator shall execute a revised Schedule of Payable Milestones consistent with the then current Program Plan.

B. Payments

1. ABC has an established and agrees to maintain an established accounting system which complies with Generally Accepted Accounting Principles and the requirements of this Agreement. An acceptable accounting system is one in which all cash receipts and disbursements are controlled and documented properly.

2. ABC shall document the accomplishments of each Payable Milestone by submitting or otherwise providing the Payable Milestones Report required by Attachment 2, Part D. ABC shall submit an original and one (1) copy of all invoices to the OTAOfor payment approval. After written verification of the accomplishment of the Payable Milestone by the NIH Program Manager, and approval by the Agreements Officer, the invoices will be forwarded to the payment office within fifteen (15) calendar days of receipt of the invoices at NIH. Payment approval for the final Payable Milestone will be made after a determination by NIH that agreement results equals value of the accumulated government funds and ABC contributions. Payments will be made by xxxxx within fifteen (15) calendar days of NIH's transmittal. Subject to change only through written Agreement modification, payment shall be made to the address of the ABC Administrator set forth below.

3. Address of Payee: (INSERT NAME AND ADDRESS OF PAYEE)

4. Limitation of Funds: In no case shall the Government's financial liability exceed the amount obligated under this Agreement.

5. Financial Records and Reports: ABC shall maintain adequate records to account for all funding under this Agreement and shall maintain adequate records to account for ABC funding provided under this Agreement. Upon completion or termination of this Agreement, whichever occurs earlier, the ABC Administrator shall furnish to the OTAO a copy of the Final Report required

by Attachment 2, Part E. ABC's relevant financial records are subject to examination or audit on behalf of NIH by the Government for a period not to exceed three (3) years after expiration of the term of this Agreement. The OTAO or designee shall have direct access to sufficient records and information of ABC, to ensure full accountability for all funding under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party.

(a) The Comptroller General, at its discretion, shall have access to and the right to examine records of any party to the agreement or any entity that participates in the performance of this agreement that directly pertain to, and involve transactions relating to, the agreement.

(b) Excepted from this requirement is any party to this agreement or any entity that participates in the performance of the agreement, or any subordinate element of such party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a government entity in the year prior to the date of the agreement.

(c) This clause shall not be construed to require any party or entity, or any subordinate element of such party or entity, that participates in the performance of the agreement, to create or maintain any record that is not otherwise maintained in the ordinary course of business or pursuant to a provision of law.

(d) The Comptroller General shall have access to these records until three years after the date the final payment is made by the United States.

(e) All the terms of the clause shall be included in all subagreements to the agreement.

ARTICLE VI: DISPUTES

A. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

B. Dispute Resolution Procedures

1. Any disagreement, claim or dispute between NIH and ABC concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resc the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made unde subparagraph B.3 of this article constitute the basis for relief under this article unless the Director of NIH in th interests of justice waives this requirement.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the NIH OTAOor Consortium Administrator, as the case may be) in writing of the relevant facts, identify unresolved issues, and specify the

clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the NIH's Special Assistant for Acquisition and senior executive (no lower than (INSERT A LEVEL OF EXECUTIVE FAR ENOUGH REMOVED FROM THE PROGRAM TO MAINTAIN A GREATER LEVEL OF IMPARTIALITY) level) appointed by ABC. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Deputy Director for Management and the senior executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, upon written request to the Director of NIH, made within thirty (30) calendar days of the expiration of the time for a decision under subparagraph B.3 above, the dispute shall be further reviewed. The Director of NIH may elect to conduct this review personally or through a designee or jointly with a senior executive (no lower than (INSERT A LEVEL OF EXECUTIVE FAR ENOUGH REMOVED FROM THE PROGRAM TO MAINTAIN A GREATER LEVEL OF IMPARTIALITY) level) appointed by ABC. Following the review, the Director of NIH or designee will resolve the issue(s)and notify the Parties in writing. Such resolution is not subject to further administrative review and, to the extent permitted by law, shall be final and binding.

(5. Subject only to this article and 41 U.S.C. § 321-322, if not satisfied with the results of completing the above process, either Party may within thirty (30) calendar days of receipt of the notice in subparagraph B.4 above pursue any right and remedy in a court of competent jurisdiction. NOTE: THIS PARAGRAPH SHOULD NOT BE INCLUDED IN THIS AGREEMENT UNLESS THIS ISSUE IS RAISED BY THE COMPANY)

C. Limitation of Damages

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of NIH funding disbursed as of the time the dispute arises. In no event shall NIH be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, or other indirect damages. (ABC disclaims any liability for consequential, indirect, or special damages, except when such damages are caused by willful misconduct of ABC personnel. In no event shall ABC's liability under this Agreement exceed the funding it has received up to the time of incurring such liability. NOTE: THIS PART OF THE PARAGRAPH SHOULD NOT BE INCLUDED IN THIS AGREEMENT UNLESS THE ISSUE IS RAISED BY ABC.)

ARTICLE VII: PATENT RIGHTS (NOTE: IN THE EVENT MARCH-IN RIGHTS ARE THE ONLY RIGHTS REASONABLY WARRANTED, THIS ARTICLE SHALL BE REPLACED WITH A CONCISELY WRITTEN ARTICLE DEFINING AND DESCRIBING MARCH-IN RIGHTS AND ANY OTHER APPROPRIATE TERMS .)

A. Definitions

1. "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

2. "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

3. “Practical application” means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

4. “Subject invention” means any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

B. Allocation of Principal Rights

Unless ABC shall have notified NIH (in accordance with subparagraph C.2 below) that ABC does not intend to retain title, ABC shall retain the entire right, title, and interest throughout the world to each subject invention consistent with the provisions of this Article and 35 U.S.C. § 202. With respect to any subject invention in which ABC retains title, NIH shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the subject invention throughout the world.

C. Invention Disclosure, Election of Title, and Filing of Patent Application

1. ABC shall disclose each subject invention to NIH within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to NIH shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. ABC shall also submit to NIH an annual listing of subject inventions.

2. If ABC determines that it does not intend to retain title to any such invention, ABC shall notify NIH, in writing, within eight (8) months of disclosure to NIH. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by NIH to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

3. ABC shall file its initial patent application on a subject invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. ABC may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

4. Requests for extension of the time for disclosure election, and filing under Article VII, paragraph C, may, at the discretion of NIH, and after considering the position of ABC, be granted.

D. Conditions When the Government May Obtain Title

Upon NIH's written request, ABC shall convey title to any subject invention to NIH under any of the following conditions:

1. If ABC fails to disclose or elects not to retain title to the subject invention within the times specified in paragraph C of this Article; provided, that NIH may only request title within sixty (60) calendar days after learning of the failure of ABC to disclose or elect within the specified times.

2. In those countries in which ABC fails to file patent applications within the times specified in paragraph C of this Article; provided, that if ABC has filed a patent application in a country after the times specified in paragraph C of this Article, but prior to its receipt of the written request by NIH, ABC shall continue to retain title in that country; or

3. In any country in which ABC decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a subject invention.

E. Minimum Rights to ABC and Protection of ABC's Right to File

1. ABC shall retain a nonexclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title, except if ABC fails to disclose the invention within the times specified in paragraph C of this Article. The ABC license extends to the domestic (including Canada) subsidiaries and affiliates, if any, within the corporate structure of which ABC is a party and includes the right to grant licenses of the same scope to the extent that ABC was legally obligated to do so at the time the Agreement was awarded. The license is transferable only with the approval of NIH, except when transferred to the successor of that part of the business to which the invention pertains. NIH approval for license transfer shall not be unreasonably withheld.

2. The ABC domestic license may be revoked or modified by NIH to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which ABC has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of NIH to the extent ABC, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

3. Before revocation or modification of the license, NIH shall furnish ABC a written notice of its intention to revoke or modify the license, and ABC shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

F. Action to Protect the Government's Interest

1. ABC agrees to execute or to have executed and promptly deliver to NIH all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which ABC elects to retain title, and (ii) convey title to NIH when requested under paragraph D of this Article and to enable the Government to obtain patent protection throughout the world in that subject invention.

2. ABC agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by ABC each subject invention made under this Agreement in order that ABC can comply with the disclosure provisions of paragraph C of this Article. ABC shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U. S. or foreign statutory bars.

3. ABC shall notify NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

4. ABC shall include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made with Government support under Agreement No. MDA972-9*-3-00** awarded by NIH. The Government has certain rights in the invention."

G. Lower Tier Agreements

ABC shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

H. Reporting on Utilization of Subject Inventions

ABC agrees to submit, during the term of the Agreement, an annual report on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by ABC or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by ABC, and such other data and information as the agency may reasonably specify. ABC also agrees to provide additional reports as may be requested by NIH in connection with any march-in proceedings undertaken by NIH in accordance with paragraph J of this Article. Consistent with 35 U.S.C. § 202(c)(5), NIH agrees it shall not disclose such information to persons outside the Government without permission of ABC.

I. Preference for American Industry

Notwithstanding any other provision of this clause, ABC agrees that it shall not grant to any person the exclusive right to use or sell any subject invention in the United States or Canada unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements fo such an agreement may be waived by NIH upon a showing by ABC that reasonable but unsuccessful efforts h been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

J. March-in Rights

ABC agrees that, with respect to any subject invention in which it has retained title, NIH has the right to require ABC, an assignee, or exclusive licensee of a subject invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if ABC, assignee, or exclusive licensee refuses such a request, NIH has the right to grant such a license itself if NIH determines that:

1. Such action is necessary because ABC or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the subject invention;

2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by ABC, assignee, or their licensees;

3. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by ABC, assignee, or licensees; or

4. Such action is necessary because the agreement required by paragraph (I) of this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such Agreement.

ARTICLE VIII: DATA RIGHTS (NOTE: THIS ARTICLE MAY BE SUBSTANTIALLY REVISED DEPENDING ON THE FACTS OF EACH AGREEMENT.)

A. Definitions

1. "Government Purpose Rights", as used in this article, means rights to use, duplicate, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

2. "Unlimited Rights", as used in this article, means rights to use, duplicate, release, or disclose, Data in whole or in part, in any manner and for any purposes whatsoever, and to have or permit others to do so.

3. "Data", as used in this article, means recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, trade secrets, and mask works. The term does not include financial, administrative, cost, pricing or management information and does not include subject inventions included under Article VII.

B. Allocation of Principal Rights

1. This Agreement shall be performed with mixed Government and ABC funding. The Parties agree that in consideration for Government funding, ABC intends to reduce to practical application items, components and processes developed under this Agreement.

2. ABC agrees to retain and maintain in good condition until (INSERT NUMBER OF YEAR) ( ) years after completion or termination of this Agreement, all Data necessary to achieve practical application. In the event of exercise of the Government's March-in Rights as set forth under Article VII or subparagraph B.3 of this article, ABC agrees, upon written request from the Government, to deliver at no additional cost to the Government, all Data necessary to achieve practical application within sixty (60) calendar

days from the date of the written request. The Government shall retain Unlimited Rights, as defined in paragraph A above, to this delivered Data.

3. ABC agrees that, with respect to Data necessary to achieve practical application, NIH has the right to require ABC to deliver all such Data to NIH in accordance with its reasonable directions if NIH determines that:

(a) Such action is necessary because ABC or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the technology developed during the performance of this Agreement;

(b) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by ABC, assignee, or their licensees; or

(c) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by ABC, assignee, or licensees.

4. With respect to Data delivered pursuant to Attachment 2 (and listed below), the Government shall receive Government Purpose Rights, as defined in paragraph A above. With respect to all Data delivered, in the event of the Government's exercise of its right under subparagraph B.2 of this article, the Government shall receive Unlimited Rights.

C. Marking of Data

Pursuant to paragraph B above, any Data delivered under this Agreement shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in Agreement XXXX between the Government and ABC.

D. Lower Tier Agreements

ABC shall include this Article, suitably modified to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

ARTICLE IX: FOREIGN ACCESS TO TECHNOLOGY

This Article shall remain in effect during the term of the Agreement and for (INSERT NUMBER OF YEARS ) years thereafter.

A. Definition

1. "Foreign Firm or Institution" means a firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business

organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

2. "Know-How" means all information including, but not limited to discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus and machines.

3. "Technology" means discoveries, innovations, Know-How and inventions, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, maskworks, and copyrights developed under this Agreement.

B. General

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national defense, and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. The controls contemplated in this Article are in addition to, and are not intended to change or supersede, the provisions of the International Traffic in Arms Regulation (22 CFR pt. 121 et seq.), the DoD Industrial Security Regulation (DoD 5220.22-R) and the Department of Commerce Export Regulation (15 CFR pt. 770 et seq.)

C. Restrictions on Sale or Transfer of Technology to Foreign Firms or Institutions

1. In order to promote the national security interests of the United States and to effectuate the policies that underlie the regulations cited above, the procedures stated in subparagraphs C.2, C.3, and C.4 below shall apply to any transfer of Technology. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology. Transfers do not include:

(a) sales of products or components, or

(b) licenses of software or documentation related to sales of products or components, or

(c) transfer to foreign subsidiaries of ABC for purposes related to this Agreement, or

(d) transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the conduct of research under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

2. ABC shall provide timely notice to NIH of any proposed transfers from ABC of Technology developed under this Agreement to Foreign Firms or Institutions. If NIH determines that the transfer may have adverse consequences to the national security interests of the United States, ABC, its vendors, and NIH shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to ABC.

3. In any event, ABC shall provide written notice to the NIH Program Manager and OTAO of any proposed transfer to a foreign firm or institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general

terms of the transfer. Within thirty (30) calendar days of receipt of ABC's written notification, the NIH OTAO shall advise ABC whether it consents to the proposed transfer. In cases where NIH does not concur or sixty (60) calendar days after receipt and NIH provides no decision, ABC may utilize the procedures under Article VI, Disputes. No transfer shall take place until a decision is rendered.

4. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by NIH takes place, ABC shall (a) refund to NIH funds paid for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government ABC shall provide written confirmation of such licenses.

D. Lower Tier Agreements

ABC shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

ARTICLE X: TITLE AND DISPOSITION OF PROPERTY

A. Definitions

In this article "property" means any tangible personal property other than consumable property which is actually consumed during the execution of work under this agreement.

B. Title to Property

No significant items of property are expected to be acquired under this Agreement. Title to each item of property acquired under this Agreement with an acquisition value of $50,000 or less shall vest in ABC upon acquisition with no further obligation of the Parties unless otherwise determined by the Agreements Officer. Should any item of property with an acquisition value greater than $50,000 be required, ABC shall obtain prior written approval of the Agreements Officer. Title to this property shall also vest in ABC upon acquisition. ABC shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense.

C. Disposition of Property

At the completion of the term of this Agreement, items of property with an acquisition value greater than $50, shall be disposed of in the following manner:

1. Purchased by ABC at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to NIH; or
2. Transferred to a Government research facility with title and ownership being transferred to the Government; or
3. Donated to a mutually agreed University or technical learning center for research purposes; or
4. Any other NIH-approved disposition procedure.

OR

ARTICLE X: TITLE AND DISPOSITION OF PROPERTY

A. Definitions

In this article "property" means any tangible personal property other than consumable property which is actually consumed during the execution of work under this agreement.

B. Title to Property

ABC will acquire property with an acquisition value greater than $50,000 under this Agreement as set forth in Attachment * to this Agreement which is necessary to further the research and development goals of this Program and is not for the direct benefit of the Government. Title to this property shall vest in ABC upon acquisition. Title to any other items of property acquired under this Agreement with an acquisition value of $50,000 or less shall vest in ABC upon acquisition with no further obligation of the Parties unless otherwise determined by the Agreements Officer. Should any other item of property with an acquisition value greater than $50,000 be required, ABC shall obtain prior written approval of the Agreements Officer. Title to this property shall also vest in ABC upon acquisition. ABC shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense.

C. Disposition of Property

At the completion of the term of this Agreement, items of property set forth in Attachment * or any other items of property with an acquisition value greater than $50,000 shall be disposed of in the following manner:

1. Purchased by ABC at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to NIH; or
2. Transferred to a Government research facility with title and ownership being transferred to the Government; or
3. Donated to a mutually agreed University or technical learning center for research purposes; or
4. Any other NIH-approved disposition procedure.

ARTICLE XI: CIVIL RIGHTS ACT

This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. ABC has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

ARTICLE XII: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of ABC and the NIH Agreements Officer. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

**ARTICLE XI: SPECIAL CLAUSES**

**A. Protection of Human Subjects**

1. The Recipient agrees that the rights and welfare of human subjects involved in research under this OTA shall be protected in accordance with 45 CFR Part 46 and with the Recipient 's current Assurance of Compliance on file with the Office for Human Research Protections {OHRP), Office of Public Health and Science (OPHS}. The Recipient further agrees to provide certification that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects, in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Recipient shall bear full responsibility for the performance of all work and services involving the use of human subjects under this Agreement and 'shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that Recipient retains the right to control and direct the performance of all work under the OTA. Nothing in this OTA shall be deemed to constitute Recipient or any sub consortium, agent or employee of Recipient, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government.

Recipient agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent consortium without imputing liability on the part of the Government for the acts of the Recipient or its_ employees.

3. If at any time during the performance of this OTA, the HHS OTAO's determines,

in consultation with the OHRP, OPHS, ASH, that the Recipient is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this OTA until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to. complete corrective action within the period of time designated in the OTAO's written notice of suspension, the HHS OTAO may, in consultation with OHRP, OPHS, ASH, terminate this Agreement in a whole or in part, and the Recipient's name may be removed from the list of those performers with approved Health and Human Services Human Subject Assurances.

**B. Human Materials (Assurance of OHRP Compliance)**

1. The acquisition and supply of all human specimen material (including fetal material) used under this OTA shall be obtained by Recipient in full compliance with applicable Federal, State and Local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

2. The Recipient shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this OTA, by collaborating sites, or by subrecipients identified under this OTA, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Recipient.

3. Provision by the Recipient to the HHS OTAO's of a properly completed "Protection of Human Subjects Assurance Identification/IRS Certification/Declaration of Exemption", Form 0MB No. 0990-0263 (formerly Optional Form 310), certifying IRS review and approval of the protocol from which the human materials, were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRS Certification/ Declaration of Exemption", Form OMS No. 0990-0263(formerly Optional Form 310).

**C. Research Involving Human Fetal Tissue**

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart S. The Recipient shall make available, for audit by the Secretary, HHS, the physician statements and informed

consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Recipient.

**D. Needle Exchange**

The Recipient shall not use Agreement funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

**E. Care of Live Vertebrate Animals**

1. Before undertaking performance of any OTA involving animal related activities, the Recipient shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Recipient shall furnish evidence of the registration to the Agreement Officer.

2. The Recipient shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.

3. The Recipient agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this OTA will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture **(see** 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1- 4). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this Agreement, the HHS OTAO's determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Recipient is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this Agreement until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the HHS OTAO's may, in consultation with OLAW, NIH, terminate this Agreement in whole or in part, and the Recipient's name may be removed from the list of those organizations with approved PHS Animal Welfare Assurances.

**Note:** The Recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office below or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

**F. Animal Welfare**

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: http://grants1.nih.gov/grants/o1aw/references/phspo1.htm. Primate studies will not begin until the CRO's IACUC and the Recipient's Animal Welfare Department provide final approval of the study protocol.

**G. Protection of Personnel Who Work with Nonhuman Primates**

All Recipient personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled,

"Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http:ljwwwl.od.nih.gov/oma/manualchapters/intramural/3044-2/.

**H. Information on Compliance with Animal Care Requirements**

Registration with the U.S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http:ljwww.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http:ljgrants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http:ljgrants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Recipient does not have an assurance and will be utilizing a subrecipient to perform the animal work, then the Recipient and subrecipient must have an Inter-Institutional Assurance in place to allow the Recipient to utilize the assurance of the subrecipient to meet the HHS requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by NIH on behalf of the Recipient.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals http:ljwww.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http:ljawic.nal.usda.gov/final-rules- animal-welfare-9-cfr-parts-1-2-and-3 issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http:ljwww.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given" the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies http://www.fass.org.

**I. Approval of Required Assurance by Law**

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (NIH) shall not be expended by the Recipient for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Recipient under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 is submitted by Recipient 30 days prior to commencing research involving live vertebrate animals and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7

U.S.C. 2136 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve Jive vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25.

2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants.nih.gov/grants/olaw/olaw.htm.

Registration with the Select Agent Program for Work Involving the Possession, Use, and/or Transfer of Select Biological Agents or Toxins

- Work involving select biological agents or toxins shall not be conducted under this Agreement until the Recipient and any affected subrecipients are granted a certificate of registration or are authorized to work with the applicable select agents.

- For prime or subagreements awards to domestic institutions who possess, use, and/or transfer Select Agents under this OTA, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

- For prime or subagreements awards to foreign institutions who possess, use, and/or transfer Select Agents under this OTA, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for

- U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Recipient must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the OTAO, the Recipient shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Recipient must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the OTA.

- Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

**J. Product Approval**

The Recipient agrees to comply with the guidelines in 21 CFR Parts 210-211, 600 for manufacturing, processing and packing of drugs, chemicals, biological, and reagents.

The Recipient agrees to advise the HHS OTAO and OTTR promptly of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility during the term or this Agreement. The Recipient also agrees to advise the HHS OTAO's and OTTR immediately if at any time

during the term of this Agreement, the items under this OTA fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

**K. Manufacturing Standards**

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of this OTA, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CDER, the Recipient shall have sixty (60) calendar days from the time such material failure is identified to initiate corrective action designed to cure such material failure within three (3) months. If the Recipient fails to initiate such an action within the sixty (60) calendar day period, then the Agreement may be terminated.

**L. Anti-Bribery and Anti-Corruption**

ABC acknowledges that it has received and read Recipient's 'Prevention of Corruption - Third Party Guidelines'. Each Party agrees to perform its obligations under this Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein.

**M. Salary Rate Limitation**

1. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in

effect on the date an expense is incurred is an unallowable cost under this Agreement and shall be addressed in accordance with Article VII.C.

2. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under the OTAR. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

**Note:** The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract, order, or OTAR; it merely limits the portion of that salary that may be paid with Federal funds.

3. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year OTAR, it may be subject to unilateral modification by the OTAO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

4. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

## N. Man-In-Plant

With seven (7) days advance notice to the Recipient in writing from the OTAO/OTAS, the Government may place a man-in-plant in the Recipient's facility, who shall be subject to the Recipient's policies and procedures regarding security and facility access at all times while in the Recipient's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Recipient plant.

## O. Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All

telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General

Department of Health and Human Services TIPS HOTLINE

P.O. Box 23489
Washington, D.C. 20026

**P. Prohibition on Contractor Involvement with Terrorist Activities**

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Agreement.

**Q, Materials Transfer Agreement**

For distribution to third-party parties of any material developed under this Agreement, the Recipient must provide NIH Materials Transfer Agreement (MTA). Following finalization of the MTA, the Recipient must provide notice of the requests/transfers in the monthly technical report along with copies of the final MTA.

**R. Inspection and Acceptance**

1. The OTAO or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this Agreement.

O

2. For the purpose of this Section, the designated OTTR is the authorized representative of OTAO. The OTTR will assist in resolving technical issues that arise during performance. The OTTR; however, is not authorized to change any OTA terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

3. Inspection and acceptance will be performed at:

xxxxxx

**ARTICLE XII: TRANSFERS & ASSIGNMENTS**

All transfers and/or assignment will be conducted in a manner that is consistent with the Assignment of Claims Act (31 U.S. Code § 3727) and the Prohibition on transfer of contract and certain allowable assignments (41 U.S.C.A. § 6305).

ATIACHMENTN0.1.PAGE 1

STATEMENT OF WORK

(Initial Program Plan)

Taskl

**REPORT**
REQUIREMENTS

**A.** QUARTERLY REPORT

On or before ninety (90) calendar days after the effective date of the Agreement and quarterly thereafter throughout the term of the Agreement, the Consortium Management Committee (CMC) shall submit or otherwise provide a quarterly report. Two (2) copies shall be submitted or otherwise provided to the NIH Program Manager, one (1) copy shall be submitted or otherwise provided to the NIH Agreements Officer and one (1) copy shall be submitted or otherwise provided to NIH/(INSERT PROGRAM OFFICE), Attn: Assistant Director for Program Management. The report will have two (2) major sections.

1. Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. The technical status report will include a report on the status of consortium collaborative activities during the reporting period.

2 Business Status Report. The business status report shall provide summarized details of the resource status of this Agreement, including the status of the labor contributions by the Consortium participants. This report will include a quarterly accounting of current labor hour expended as outlined in the Annual Program Plan. Any major deviations shall be explained along with discussions of the adjustment actions proposed.

**B. ANNUALPROGRAMPLANDOCUMENT**

The CMC shall submit or otherwise provide to the NIH Program Manager one (1) copy of a report which describes the Annual Program Plan as described in Article m, Section D. This document shall be submitted not later than thirty (30) calendar days following the Annual Site Review as described in Article m, Section D.

**C.** SPECIAL TECHNICAL **REPORTS**

As agreed to by the Consortium and the NIH Program Manager, the CMC shall submit or otherwise provide to the NIH Program Manager one (1) copy of special reports on significant events such as significant target accomplishments by Consortium Members, significant tests, experiments, or symposia.

**D.** PAYABLE MILESTONES **REPORTS**

The CMC shall submit or otherwise provide to the NIH Program Manager, documentation describing the extent of accomplishment of Payable Milestones. This information shall be as required by Article V, paragraph B and shall be sufficient for the Program Manager to reasonably verify the accomplishment of the milestone of the event in accordance with the Statement of Work.

**E.** FINAL REPORT (NOTE: The Final Report is the last Payable Milestone for the completed Agreement)

1. The CMC shall submit or otherwise provide a Final Report making full disclosure of all major developments by the Consortium upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement. With the approval of the NIH Program Manager, reprints of published articles may be attached to the Final Report. Two (2) copies shall be submitted or otherwise provided to the NIH Program Manager and one (1) copy shall be submitted or otherwise provided to NIH (INSERT PROGRAM OFFICE), Attn:

2. The Final Report shall be marked with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations. The Final Report shall be marked on the front page in a conspicuous place with the following marking:

3. 'DISTRIBUTION STATEMENT B. Distribution authorized to U.S. Government agencies only to protect information not owned by the U.S. Government and protected by a contractor's "limited rights" statement, or received with the understanding that it not be routinely transmitted outside the U.S. Government. Other requests for this document shall be referred to NIH/technical Information Officer."

# SCHEDULEOFPAYMENTSANDPAYABLEMILESTONES

| TASK MONTH | PAYABLE MILESTONES | NIH PAYMENT | CONSORTIUM PAYMENT |
|---|---|---|---|

# FUNDING SCHEDULE

**Q.** PROJECTED PROGRAM FUNDING COMMITMENTS

| | NIH Funding | Consortium Contribution |
|---|---|---|
| FY9* | $ | $ |
| FY9* | $ | $ |
| FY9* | $ | $ |
| TOTALS | $_____ | $ |

**R.** CONSORTIUM MEMBER CONTRIBUTIONS

| *Member* | *Contribution* |
|---|---|
| Company A | $ |
| CompanyB | $ |
| CompanyC | $ |
| CompanyD | $ |
| TOTALS | $ |

# LIST OF GOVERNMENT AND CONSORTIUM REPRESENTATIVES

GOVERNMENT:

{NAME)

**NIH/OFFICE**

phone: ****

FAX: ***

Email: *******

*<NAME}.*

NIH

phone: ****

FAX: ****

Email: ******

CONSORTIUM:

*<NAME}*

{ORGANIZATION}

(ADDRESS)

phone:

FAX:

Email:

*<NAME}*

{ORGANIZATION}

(ADDRESS)

phone:

FAX:

O

This page is intentionally left almost blank.

# P. SAMPLE PROGRAM SOLICITATION

# Counter-Man-Portable Air Defense System (C-MANPADS) Development and Demonstration

## Solicitation XXXX DRAFT 2

June 18, 2004

### Points of Contact

Agreements Officer

Mr. Mickey Jones
DHS(S&T)
7th and D Streets, SW
Washington, DC 20407
Phone: (202)692-4214
Email: mickey.jones@dhs.gov

Program Manager

Mr. Jim Tuttle
DHS(S&T)
1401 Wilson Blvd, Suite 1200
Arlington, VA 22209
Phone: (703) 235-0272
Email: james.tuttle@dhs.gov

# TABLE OF CONTENTS

1 Program Description ..... 1
1.1 Objectives ..... 1
1.2 Schedule Overview ..... 1
1.3 Other Transactions ..... 1
1.4 Funding ..... 1
2 Technical Scope ..... 2
2.1 Phase II ..... 2
2.2 Phase III (Optional) ..... 2
2.3 Program Plan ..... 2
2.4 Technical Development Activities ..... 3
2.5 Notional Program Schedule ..... 3
2.6 Top Level Performance Objectives ..... 4
3 Program Activities ..... 9
3.1 Phase I Objectives & Deliverables ..... 9
3.2 Phase II Objectives & Deliverables ..... 9
3.3 Phase II Program Reviews ..... 19
4 Phase II Payment Milestones ..... 21
4.1 Payment Milestone A – Phase II Kick-Off Meeting ..... 21
5 Phase II Proposal Preparation Instructions ..... 22
5.1 Phase II Oral Presentation ..... 22
5.2 Draft Agreement Modifications and Phase II Attachments ..... 22
5.3 Phase II Cost Proposal ..... 24
5.4 Proposal Procedures ..... 24
5.5 Proposal Submission Summary ..... 25
6 Evaluation Criteria and Extension ..... 28
6.1 Introduction ..... 28
6.2 Evaluation Criteria ..... 28
6.3 Basis for Award ..... 30
7 Model Agreement ..... 31
7.1 “Other Transactions for Prototypes” Questionnaire ..... 32

# 1 Program Description

## *1.1 Objectives*

The major objective of the DHS Counter-MANPADS Phase II Program is to continue with development, to demonstrate and test C-MANPADS devices on commercial aircraft, and complete engineering, manufacturing, installation, and operations and support planning documents. The prototypes will undergo testing to validate the individual design approaches. Program participants shall continue to implement a streamlined approach to program management that includes team member cooperation, small staffs, abbreviated oversight, face-to-face communications, real-time decision making and problem solving, and short, direct lines of authority.

The Government reserves the right to add a Phase III to the C-MANPADS SD&D effort to procure some additional advanced prototypes and conduct applicable Operational Test & Evaluation (OT&E) activities, including collection of actual reliability and maintainability costs. The Phase III program results will assist DHS in formulating its recommendation for potential full production options.

## *1.2 Schedule Overview*

The effort under this solicitation encompasses Phase II. The SPO's intent is to select and fund one or more proposals resulting from this solicitation and fund those through Phase II. Phase II will be a prototype development, testing, and evaluation phase, ending on 31 January 2006, and resulting in the demonstration and flight testing of prototype systems.

This solicitation provides a notional program execution schedule for Phase II in Section 2.5.

## *1.3 Other Transactions*

DHS(S&T) intends to modify the existing Agreements awarded as Other Transactions for Prototype (OT for Prototype) under Section 831(a)(2) of P.L. 107-296.

## *1.4 Funding*

The government intends to make two or more awards for Phase II for no more than $ 45 M each. Long Lead Items acquired during Phase I were paid for using Phase II funds.

As a part of the Phase II effort contractors will provide Long Lead Item Lists for prospective Phase III efforts. The timing of this requirement will be determined during Phase II.

# 2 Technical Scope

## *2.1 Phase II*

Phase II of the program will develop, integrate, test, and obtain FAA certification of prototypes. Some activities necessary to achieve the Phase II objectives include:

- Finalizing the designs and software development
- Completion of the test articles and integration onto at least one airframe type (assume a generic wide body aircraft)
- Hardware-in-the-loop testing and reliability & maintainability testing
- Finalizing operations and supportability plans and activities
- Modeling and assessing reliability, failure rates, and supportability
- Analyzing recurring operating support costs
- Finalizing the maintenance approach
- Finalizing training requirements and developing training materials
- Finalizing systems engineering
- Operational testing will include flight testing and an option for live-fire testing to validate performance assumptions
- An FAA certification will also be obtained during this phase
- At the end of Phase II, a full report of findings will be published to support a production decision

## *2.2 Phase III (Optional)*

The government is evaluating the feasibility of a Phase III effort for the C-MANPADS program. Phase III of the program will further develop, integrate, test, and certify additional advanced prototypes as OT&E units. As a part of Phase III, C-MANPADS systems completing Phase II testing and evaluation will be modified as a spiral development effort. Following a series of testing and certification events, a number of upgraded units will be installed on commercial aircraft for an extensive operational testing and evaluation period. A final determination of the scope required for this effort will be determined during Phase II.

## *2.3 Program Plan*

Offerors shall provide a Program Plan that meets the Phase II program objectives as a part of their proposal. The government intends to discuss and approve the Program Plan as an element of the OTA negotiation process, and the Program Plan will be included as Appendices of the OTA. The Program Plan shall consist of the following documents:

- Phase II Task Description Document (TDD)
- Phase II Integrated Master Schedule (IMS)
- Phase II Management Plan
- Phase II Payment Milestone Schedule
- Phase II Systems Engineering Management Plan

Descriptions of each document are included in Section 3.2.

## *2.4 Technical Development Activities*

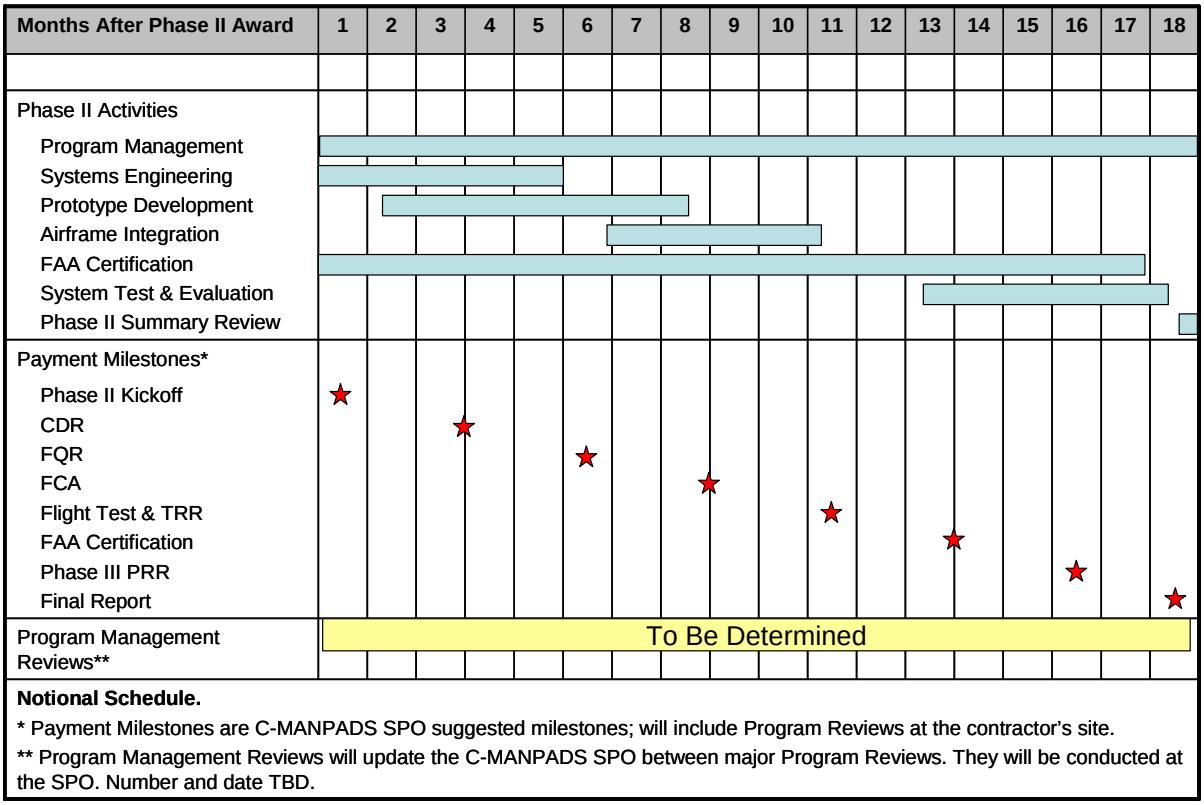
As a minimum, the C-MANPADS SD&D Program will include the development activities listed below in Phase II. The list below is provided for guidance, it is not considered complete, nor intended to indicate the complete scope of the effort. As a part of the Program Plan, offerors will provide a complete work definition and Work Breakdown Structure (WBS) in the Task Description Document (TDD).

| **Phase II – Prototype Development and Testing** |
|---|
| Prototype Development |
| Detailed Design |
| Critical Design Review |
| Software Development |
| Prototype Fabrication |
| Airframe Integration |
| Detail Integration Design |
| Detail Integration Plan |
| Integration Activities |
| FAA Certification |
| System Test & Evaluation |
| Test Planning |
| Critical Item Testing |
| Test Readiness Review |
| Hardware-in-the-Loop Testing |
| Reliability & Maintainability Testing |
| Operational/Flight/Live Fire Testing |
| Test Analysis |
| Finalize Operations & Supportability Activities |
| Model Reliability & Failure Rates |
| Assess Reliability & Supportability |
| Analyze Operating Support Costs |
| Maintenance Approach |
| Handling & Special Test Equipment |
| Training Requirements and Development |
| Operations & Support Plan |
| Systems Engineering |
| Technical Performance Measurement |
| Configuration Management |
| Manufacturability Planning |
| Safety Analysis and Engineering |
| Drawing Package |
| Program Management |
| Periodic Reviews and Reporting |
| Phase II Summary Review |

## *2.5 Notional Program Schedule*

The effort performed following awards under this solicitation will be divided into at least six payment milestones spread over the eighteen-month period. The following chart depicts a notional tasking schedule. The contractor shall provide a detailed plan/schedule; however, the Phase II end-date is approximately 31 January 2006. The offeror's schedule shall ensure that for each major milestone review, deliverables stipulated in Section 3.2 are provided to the C-MANPADS Special Program Office (SPO) with sufficient time (but no less than two weeks) for the SPO to review and return comments to the contractor. Section 3.2 describes Phase II objectives and deliverables in further detail. Upon completion of this phase and after consultation

with a government review team, DHS(S&T) may choose to negotiate with the Phase II contractors for additional phases to this program.




## *2.6 Top Level Performance Objectives*

The following are top-level performance parameters for the proposed missile defense system. These parameters are the second iteration of a set of top-level system requirements. As a part of the proposal process, the offeror will provide system-specific top-level performance parameters including threshold and objective values as documented in the SRD and TPM delivered during the Phase I Preliminary Design Review. Top Level Performance Objectives are defined in terms of threshold and objective performance, cost, and schedule parameters. Each parameter shall have a threshold value and an objective value. For performance, 'threshold' shall mean minimum acceptable value that is necessary to satisfy the need. For schedule and cost, 'threshold' shall mean the maximum allowable value. For each parameter, if no objective value is specified, the threshold value shall also serve as the objective value.

### *2.6.1 System Performance Parameters*

#### 2.6.1.1 Threat

The system shall be capable of protecting commercial airliners during flight against the range of MANPADS represented by first generation through third generation systems.

### 2.6.1.2 Probability of Success

The installed and integrated system shall have a probability of success of 90% or greater against a multiple launch MANPADS attack, where success is measured by the system ability to cause optical break-lock and effective miss-distance greater than the lethal envelopes of first-through-third generation MANPADS. The system should have a probability of success of 80% for two simultaneous (time of impact) threat engagements. A uniform probability of launch over the threat engagement envelope and a maximum atmospheric ozone concentration of 120 parts per billion should be assumed in performing predictive missile warning performance computations.

### 2.6.1.3 False Notification

A False Notification is Emergency Ground Notification (from aircraft to ground) without the presence of a threat. The system False Notification rate shall be less than one in 1,000,000 flights (threshold), where one flight is defined as one takeoff and landing, with an objective value of zero. False Cues and False Notifications should not impede countering simultaneous threat missile launches at a target aircraft.

### 2.6.1.4 Coverage

The system shall be capable of effective operation against a MANPADS attack within the threat envelope, with 360-degree coverage in azimuth and elevation angles commensurate with typical commercial flight profiles and MANPADS profiles.

### 2.6.1.5 Aircraft

The system shall be capable of being installed on commercial aircraft the size of a Boeing 737 or larger. This includes the following aircraft.

- A300
- A310
- A318
- A319
- A320
- A340
- A321
- A330
- B717
- B727
- B737
- B747
- B757
- B767
- B777
- DC-9
- DC-10
- MD-10
- MD-11
- MD-80
- MD-90

### 2.6.1.6 Weight

The total system shall have an installed weight of no more than 800 pounds (threshold), less than 500 pounds (objective).

### 2.6.1.7 Prime power

The system shall draw unconditioned power from existing aircraft power sources.

### 2.6.1.8 Drag

Additional drag caused by an aircraft based system shall not exceed 1% at a representative aircraft cruise altitude, speed, and weight.

#### 2.6.1.9 Common Aircraft Interface

A common means of attaching countermeasures equipment to the aircraft is desired. The method and equipment used for aircraft modification and complete system installation shall be capable of accomplishment by third parties under appropriate commercial licensing agreement.

#### 2.6.1.10 Protection of Sensitive Technology

The offerer shall provide a security management plan to provide a comprehensive protection of system integrity, performance, and critical technologies; including anti-tamper designs.

The system shall prevent or delay exploitation of C-MANPADS critical technology in order to deter technology transfer, alteration of system capability, or the development of countermeasures to US systems.

#### 2.6.1.11 Emergency Ground Notification

The system shall be capable of transmitting Emergency Ground Notification (EGN) of a detected missile launch event to Air Traffic Control (ATC) through the aircraft transponder. Actual transmission of the notification shall be based on the highest possible system confidence of an actual missile event in order to minimize false notifications as discussed in paragraph 2.6.1.3 (above). System shall have provisions to record the report, including date and time, using on-board recording and will provide an interface to the on-board flight data recorder.

#### 2.6.1.12 Flight Deck Interface

The system shall provide the following capability at the flight deck:

- Notification of a detected missile launch. The characteristics of this notification (color, sound, etc.) shall be in accordance with FAA requirements
- Capability to turn off EGN at the flight deck
- Capability to turn off the system at the flight deck
- System status

### *2.6.2 Operations and Supportability Parameters*

#### 2.6.2.1 Availability

The system shall be operationally available without imposing any delays to take-off or landing preparations.

#### 2.6.2.2 Reliability

System reliability shall be greater than 3000 (threshold) or 4500 (objective) flight hours in the commercial aircraft-operating environment.

#### 2.6.2.3 Maintainability

System components shall be removable and replaceable by existing airline maintenance personnel using standard tools and support equipment. The system should not require special test equipment at the flight line level for installation, alignment, removal, or maintenance.

Unscheduled flight-line maintenance time to repair (MTTR) shall be 60 minutes or less (threshold), 30 minutes or less (objective). Scheduled maintenance should occur during prescribed inspection/maintenance intervals.

#### 2.6.2.4 Interference

The system shall not cause any electrical, safety, or operational interference with aircraft systems or surrounding flight operations.

#### 2.6.2.5 Safety

The system shall comply with the applicable FAA, FDA, OSHA, FCC safety requirements to include, but not limited to, safety of flight, safety to personnel on the ground or in the surrounding area, or safety to onboard or nearby equipment or structures. The system shall also comply with FAA airworthiness requirements.

#### 2.6.2.6 Environmental

The system shall pose no environmental hazards.

### *2.6.3 Cost Parameters*

#### 2.6.3.1 Operations and Support Cost

The system shall have an operational (and associated maintenance) cost of less than $300 (constant GFY03$) per take-off and landing. Operational cost includes the use of any expendables, escort aircraft, maintenances costs, and repair costs.

#### 2.6.3.2 Unit Costs

The system shall have a unit cost of no more than $ 1 M (constant GFY03$)(threshold), no more than $500 K (constant GFY03$) (objective), for the 1000th unit delivered and installed

#### 2.6.3.3 Installation

The system shall take no more than 10 days to completely install and check-out the equipment/software on a non-retrofitted aircraft (installation of Group A and Group B equipment). For a retrofitted aircraft, the B-kit equipment shall take no more than 4 days to install and check-out.

#### 2.6.3.4 Life Cycle Costs

One of the highest priority goals of the C-MANPADS program is to minimize the total life cycle cost of the developed system. See Section 3.2.15 for additional information.

# 3 Program Activities

## *3.1 Phase I Objectives & Deliverables*

The technical preliminary design package, along with other Phase I deliverables, shall be updated to reflect the Phase II solicitation requirements and shall be maintained under configuration control throughout Phase II. The required Phase I deliverables included the following.

- System Requirements Document
- Preliminary Design Document
- Long Lead Items List
- Modeling and Analysis Report
- Concept of Operations Document
- System Effectiveness Document
- Aircraft and Avionics Integration Plan
- Technical Performance Measures
- Master Test and Evaluation Plan
- Maintenance Approach Document
- Reliability Analysis and Plan
- Operations and Support Plan
- Manufacturing Rate Assessment
- System Total Ownership Cost (TOC) and Life Cycle Cost (LCC) Document
- Security Management Plan
- Safety Certification Plan

## *3.2 Phase II Objectives & Deliverables*

This section describes the Phase II objectives. Phase II of the C-MANPADS program will continue evaluating C-MANPADS concepts through system development, demonstration, and testing and evaluation activities.

Deliverables will document all findings, while a series of technical interchange meetings (TIM) will be held to verify analyses, approaches, and findings; section 3.3 describes the TIMs in more detail. The Government (including supporting SETA contractors) shall be provided full and complete access to the analytic data and tools used to support contractor findings.

The result of the Phase I effort was a preliminary design of the system, said design being described in the Preliminary Design Review (PDR) and Preliminary Design Document (PDD). Documents delivered at the end of Phase I shall be maintained and updated during Phase II. Phase II deliverables include the following activities, documents and reviews:

### *3.2.1 System Requirements Document*

The Systems Requirements Document shall cover the baseline systems requirements allocated to major configuration items and a test and verification strategy. It shall provide a description of the proposed system, including a description of the key system components, its recommended concept of operation, and key mechanical and electro-optic parameters. It shall set the functional

and system requirements for counter-MANPADS system(s) that will achieve and extend, where practicable, the top level performance objectives set forth in Section 2 above.

### *3.2.2 Concept of Operations Document*

The Concept of Operations Document shall define and describe the following.

- The designed operating scenarios
- The operating sequence of events
- The functions performed by the system, aircraft, aircraft crew, ground personnel, airport operations, and ground equipment

### *3.2.3 Technical Performance Measures*

The contractor shall develop Technical Performance Measures (TPM) to monitor design and development progress maturity. The baseline list of TPM was approved at Phase I PDR. TPM progress shall be presented at design reviews during Phase II.

### *3.2.4 Phase III Long Lead Items List*

During Phase II, the government will request information relating to an optional Phase III. The contractor shall identify long-lead items for procurement such that delivery optimizes Phase III execution timelines. The contractor shall develop its schedule for delivering the Long Lead Items List to the SPO, including sources, costs, and justifications for each item, and allowing sufficient time for the SPO to assess the list and release justifiable funding to facilitate the timely acquisition of those items.

### *3.2.5 Modeling and Simulation*

#### 3.2.5.1 Modeling and Simulation Requirements and Objectives

Modeling and Simulation (M&S) shall be conducted to refine results and assist in system analysis and testing in the following areas:

- Supplement and/or add fidelity to the system effectiveness predictions made during Phase I (the SPO and Contractor will coordinate on specific scenarios that may be run after reviewing the Phase I modeling efforts)
- Result will assist in the development of test plans and assist with the interpretation of test results
- Predict the drag penalty, including viscous effects, associated with installing the proposed IRCM HW on on a minimum of three representative commercial aircraft models as identified in Phase I of the program
- Demonstrate that the IRCM HW installation concept is structurally sound on a minimum of three representative commercial aircraft models as identified in Phase I of the program
- Develop the thermal control and packaging scheme for the IRCM system
- Guide other modifications/enhancements to the Phase I IRCM design concept as required to ensure the resulting IRCM design will satisfy the Contractor's system requirements

#### 3.2.5.2 Modeling and Analysis Report

The Phase II Modeling and Analysis Report shall be updated at each major design review to document progress against the objective areas listed in paragraph **Error! Reference source not found.**. The Modeling and Analysis Report shall detail, for each objective area, the modeling approaches used, listing all relevant assumptions, present modeling results, and explain any departures from modeling approaches, and tools utilized to conduct the analysis.

### *3.2.6 Aircraft and Avionics Integration*

#### 3.2.6.1 Aircraft and Avionics Integration Requirements and Objectives

An initial draft of the Aircraft and Avionics Integration Design document was completed in Phase I for the aircraft on which the development and demonstration units will be tested. During Phase II the contractor shall refine this design and produce a final integration design document for the associated aircraft.

During Phase II, the SPO and contractor shall concur on additional aircraft types for which Aircraft and Avionics Integration Design will be conducted to support Phase III equipment production and installation efforts. This effort will be defined approximately six months into Phase II.

The intellectual property associated with the aircraft interface will be provided to the government as negotiated in the Other Transaction Agreement Modification.

#### 3.2.6.2 Aircraft and Avionics Integration Design Document

This document will serve as the primary basis by which the Counter-MANPADS SPO will monitor and evaluate the installation/integration of C-MANPADS into commercial aircraft. The document shall demonstrate a common, non-proprietary means of attaching and integrating the countermeasures equipment on representative aircraft. The Aircraft and Avionics Integration Design Document shall explicitly detail aircraft electrical and mechanical interface techniques, including power required, digital and discrete interfaces, weight of countermeasure system and proposed attachment methods and locations on representative aircraft types. The Aircraft and Avionics Integration Plan shall also identify installation issues associated with variations in representative aircraft (e.g. avionics data format(s), equipment accessibility, available space, etc.) and demonstrate how the design accommodates those issues.

#### 3.2.6.3 Additional Commercial Aircraft Analysis

During Phase II, the SPO and the contractors will coordinate and agree upon other analysis activity for determining adaptability of their proposed system for application on additional commercial aircraft types such as regional jet aircraft from the following list: BAE-146, CRJ-700, ERJ-135, ERJ-145, CRJ-I00, CRJ-900, EMB-145, ERJ-140, CRJ-200, DO328Jet, EMB-170

### *3.2.7 Test and Evaluation*

#### 3.2.7.1 Test and Evaluation Requirements and Objectives

The C-MANPADS SPO shall monitor and evaluate contractor testing during all phases of the program. The SPO shall review and approve all test plans and evaluations of the C-MANPADS systems. Contractors shall host and conduct test readiness reviews prior to the start of each significant test or testing phase. Development testing shall be conducted to validate that the system, components, hardware and software performs according to their requirements and design specifications. Testing shall demonstrate the system's ability to function in the commercial airline environment and achieve FAA STC certification for each aircraft type with the system installed. The C-MANPADS SPO is particularly interested in the ability of the system to demonstrate viability and minimize the impact to airline maintenance and safety. Effectiveness testing for the C-MANPADS system will consist of on and off aircraft testing. Each contractor shall demonstrate the installed system's susceptibility to false alarms in appropriate approach, departure, and urban environments. The system's ability to detect and defeat the threat shall be tested by a combination of computer simulations, hardware-in-the-loop (HITL) tests, and range testing (where feasible).

Phase II testing is planned to culminate in the live fire of instrumented threat missiles at a surrogate target incorporating the C-MANPADS system. The SPO will serve as overall test conductor and organizer for this test. Each contractor shall provide support for their system during this test. System support provided by contractors shall include installation, maintenance, data collection from and removal of their C-MANPADS system at the end of the testing. Contractors should be prepared to support additional direct support tasks for their C-MANPADS system as required during testing.

The Government anticipates that the live fire target will be configured with airplane representative IR sources to test the effectiveness of the C-MANPADS system. Live fire testing is inherently expensive and every effort made to ensure collection of the maximum amount of data on each event. Within the limits of the test, missile firings will replicate scenarios modeled in Phase I/II to verify the results of the modeling. The Government is planning a series of missile types with single and multiple missile scenarios to exercise the C-MANPADS systems.

#### 3.2.7.2 Master Test and Evaluation Plan

During Phase I, each contractor submitted a Master Test and Evaluation Plan (MTEP) to the SPO for comment and approval. This document serves as a high-level comprehensive overview of all testing conducted to demonstrate the effectiveness and suitability of its system. The contractor shall maintain and update the MTEP as changes to the program or systems occur.

The MTEP shall cover planned Phase I and Phase II testing and will include software, hardware-in-the-loop, STC, maintainability, reliability and operational/flight/live fire testing and associated plans, schedules, test readiness reviews with exit criteria, test analyses with statistical confidence levels, required T&E facility resources and costs. TPMs shall be addressed as appropriate. The contractor shall describe, for each test event: the type of data to be recorded, the method to extract and record the data, the process for analysis of the data, and means by which the data and subsequent analysis will be archived.

The contractor is responsible for all T&E costs incurred through performance of its T&E Plan with the exception of costs associated with range use and threat presentation during live fire testing conducted by the SPO. All contractor T&E costs should be included in the MTEP to the third level of detail.

### *3.2.8 Maintenance Approach Document*

The contractor shall maintain and update the Maintenance Approach Document. The Maintenance Approach Document shall address the following areas:

- Describe the skill levels, numbers of maintainers, tools, scheduled maintenance, unscheduled maintenance, maintenance training, and any other factors that may be necessary to support the deployed systems (including depot maintenance and transshipment of parts, if required)
- Identify the process used for integrating required maintenance tasks into a carrier scheduled maintenance program using the component manufacturers requirements. For those areas where the component/airframe interface is not addressed, develop appropriate maintenance tasks/intervals using the MSG-3 process and then integrate into the maintenance schedule
- Define all handling and special test equipment, keeping in mind that a goal is to avoid requirements for special test equipment at the flight line level for installation, alignment, removal, or maintenance
- Describe the flight-line maintenance concept, requirements, and procedures (including provisions for comprehensive fault detection and fault isolation (i.e., BIT procedures), human factors and limitations, and software update procedures)
- Describe component (overhaul or depot) maintenance concepts, requirements, and procedures for both domestic and international locations (if applicable)
- Analysis of and recommend changes to the infrastructure necessary to provide required system support with minimal impact to airline operational reliability and costs
- Define the operational interface between the system and current maintenance communication and reporting functions on the aircraft
- Define safety procedures and considerations (e.g., personnel cautions and warnings, eye safety requirements, laser emissions, expendable handling, and physical safety mechanisms)
- Define the maintenance training program including the initial and recurring requirements for maintenance personnel
- Assess and quantify the predicted maintainability levels in terms of airline costs for depot and line maintenance

### *3.2.9 Reliability Analysis Plan and Report*

The contractor shall provide a detailed strategy and plan for achieving the required system reliability. The strategy and planned actions shall be comprehensive and include the reliability predictions and failure rate analysis for existing/legacy components (hardware and software) and prototype/developmental components (hardware and software) in the C-MANPADS baseline, the Phase II system, and the proposed Phase III system. Traceability for different configurations shall be clearly identified and supported by reliability data cited in the analysis (e.g. reliability test reports, reliability predictions). Failure rate data sources shall be identified and justified. Analysis and predictions shall be performed to baseline the system's reliability levels within

typical environmental stress factors of commercial aviation. The Reliability Analysis and Plan shall include the following.

- A reliability growth program plan that shall update the system reliability baseline, and identify components that will be improved or re-designed though a test-analyze-and-fix or test-analyze-and-redesign process. Component reliability budgets will be established and well documented. The plan shall track reliability growth of the system and compare the tracked growth with the predicted growth given on a planned growth curve. Interim and final reliability requirements shall be established and progress will be monitored against interim (planned) milestones and the expected number of failures identified to meet final reliability requirements.
- Updated reliability model and assumptions affecting reliability, maintainability, and supportability requirements for mean time between failure (MTBF), mean time to repair (MTTR), and aircraft availability $A_o$
- Maintainability assessment with tests required during T&E (e.g., how testing will be used to determine BIT effectiveness, suitability of technical documentation, use of standard airline tools and practices and sparing levels/objectives and repair level analysis)
- Failure mode effects and criticality (FMECA) analysis and evaluations, including safety assessment and hazard analysis. FMECA analysis shall, as a minimum, include failure mode description, failure cause, operating mode, local effect, end effect, failure rate, criticality, BIT fault detection and fault isolation.
- Failure reporting and corrective action system (FRACAS) analysis shall be thoroughly documented, characterized and analyzed to determine root cause and corrective action; corrective action must be verifiable via a robust test environment before approval
- Assess and quantify the predicted reliability levels in terms of failure rates and airline costs; include a quantitative impact on countermeasure system effectiveness from failure rates
- Document reliability analysis and predictions and, as a minimum, cross-referenced results for the following data used in performing reliability predictions: failure rate data and sources, parts descriptions, reliability assumptions, failure distributions, environmental stress screening, step stress data, regression testing, accelerated testing, service use profiles, constraints, etc.
- Compatibility with airline maintenance models, operational reliability requirements and economic drivers
- A complete listing of all reliability tests and results conducted to achieve reliability predictions during test and evaluation

### *3.2.10 Operations and Support Plan*

During Phase II, the contractor shall maintain and update the Operations and Support Plan (OSP). The OSP shall cover all aspects of supporting the system by the airlines and assess operational impacts to them. The OSP shall address the following areas:

- Plans for support of the system, how the support system interfaces with the existing material and maintenance support of aircraft systems currently operating on commercial aircraft
- Describe the approach for providing support to a wide range of aircraft operators who have current support systems that differ in many respects
- Describe provisions for easy upgrade of the protection system

- Define ground, flight, and cabin crew training requirements, including crew training manual revisions, simulator modifications, and additional crew training time, if any
- Discuss overall security measures engineered to protect military critical technologies (details of these measures will be reflected in the system Program Protection Plan)
- Define supply chain management and infrastructure support and locations for timely turn-around for spares between all required suppliers and airline maintenance locations, including maintenance replacement rates for spares and repair parts at depot and line maintenance activities
- Development of training documents and plans to train air crew, maintenance technicians, and other airport personnel (may be included in the O&S Plan or developed as a separate training document)
- Define de-modification and disposal provisions including environmental, safety, security and health aspects of system disposal
- Define packaging, special storage and handling procedures, and transportation requirements

### *3.2.11 Manufacturing Rate Assessment*

During Phase II, the Government will continue to evaluate and update options to purchase developed systems at varying delivery rates. Contractors shall assist in this assessment by analyzing current production capacity (in excess of that currently employed for military purposes), and making recommendations regarding capital investment that could increase capacity to meet the Governments requirements.

Contractors shall evaluate and document the capacity of their current production facilities, equipment, and personnel to deliver systems, associated spares, and test assets at a rate consistent with the current version of the DHS Cost Ground Rules and Assumptions document. If current production capacity will not satisfy this requirement, the contractor shall assess capital investment, training, test facilities, supplier relationships/capacities and other factors requiring improvement to achieve the required production and installation capacity.

### *3.2.12 Safety Certification Plan*

The Safety Certification Plan shall demonstrate that the system installation has no adverse impact on aircraft safety and the safety of surrounding ground and flight operations. The Safety Certification plan shall identify and address system functional hazards, failure modes and analyses, environmental hazards and any special procedures or training required to achieve an acceptable level of safety as defined by industry and government standards. The Safety Certification Plan shall address these issues as they relate to the system, ground personnel, and ground and flight operations.

### *3.2.13 Supplemental Type Certificate*

The contractor shall obtain a Federal Aviation Administration (FAA) Supplemental Type Certificate (STC) approval for the installation of the system on a transport category aircraft during Phase II. While the contractor is responsible for obtaining the STC from the FAA, the government expects that the SPO will be informed of all interaction between the contractor and the FAA regarding the STC. At a minimum, the contractor shall provide the following documentation to the SPO in support of the FAA STC.

- The FAA-Approved Project Specific Certification Plan (PSCP) should outline plans for obtaining the STC and addresses how the contractor will show compliance with the applicable airworthiness requirements in Federal Aviation Regulations (FAR). The PSCP should define the schedule for major milestones and events, ground and flight testing, and the documentation necessary to obtain the STC. The contractor shall update the PSCP as necessary throughout the STC program.
- Component Qualification Test Plans and Reports
- Aircraft Installation Test Plans and Reports
- Engineering Analyses and Substantiations
- Engineering Drawings (as requested by the SPO)
- Instructions for Continued Airworthiness
- Applicable Manual Supplements (e.g., Airplane Flight Manual, Operating Manual)

### *3.2.14 Anti-Tamper Annex for the Program Protection Plan*

Military systems that may form a basis for this system shall be treated as significant military equipment for export licensing purposes and may contain critical program information (CPI). Additionally, they will be operated, maintained, and supported in the commercial world. Taking full account of these considerations, the contractor shall develop:

- An assessment of the risks to national security resulting from compromise of the system based on identification of the critical technology being protected
  - According to the DoD 5000 series the AT annex shall use a "defense-in-depth" approach based on the risk assessment that include, but is not limited to the following:
    - A description of the planned AT strategy that includes a testing and qualification proposal.
    - The effect compromise would have on the acquisition program if AT is not implemented
    - The prevention of unauthorized or inadvertent disclosure or loss that includes addressing the trade-offs in supportability vs. anti-tamper.
    - How long AT is intended to delay hostile exploitation or reverse-engineering efforts.
    - The estimated time and cost required for system or component redesign if compromise occurs
    - The program's AT point of contact
- Verification and testing of AT implantation shall be conducted by an independent organization

### *3.2.15 System TOC and LCC Document*

One of the highest priority goals of the C-MANPADS program is to minimize the total life Cycle cost of the developed system. The C-MANPADS SPO has issued a set of common ground rules and assumptions to be used in determining the TOC and LCC. For this effort, life cycle cost is defined as the sum of acquisition and operations and support costs. Acquisition cost is defined as the total program cost including development, integration, qualification, and recurring (plus associated non-recurring) production and installation cost of the hardware, and logistics program (support equipment, trainers/training, documentation, spares, etc.). Operations and support costs include all costs associated with using the system after being installed in commercial aircraft,

including direct and indirect costs. Direct cost includes such items as spares, scheduled and unscheduled maintenance, training, replenishment, flight line support, and similar. Indirect costs include lost revenue due to displaced capacity in carrying the system, additional fuel costs due to induced drag, cost of additional inspections required to maintain airworthiness, and other costs attributed to impacts caused by the introduction of the system into the civil aviation community.

### 3.2.15.1 Life Cycle Cost (LCC) Analysis

The contractor shall perform a Life Cycle Cost (LCC) analysis for the program to include development, all production phases and operations and support. This LCC analysis shall be the basis used for all design and supportability trade-off analyses. The contractor shall establish a baseline LCC to be used for all subsequent trade-off analyses performed. The C-MANPADS SPO will continue to coordinate the applicable cost-related groundrules and assumptions. The LCC analysis shall be conducted at the lowest feasible equipment level. The LCC baseline shall be updated as input data is further defined or changed. The LCC baseline and trade-off analyses shall be reviewed at each review. The SPO will perform an independent LCC.

### 3.2.15.2 Life Cycle Cost Model

The contractor shall update its Phase I Life Cycle Costs Reduction Strategy Document that models and establishes the overall cost of the system. The LCC Document shall address the basis of estimate (BOE) for each WBS element included in the LCC model and estimate. All aspects of the cost will be scrutinized with initiatives developed and baselined for cost reduction in the Design Phase, the Material / Procurement Phase, the Manufacturing Phase, and the Production Support Phase. Additionally, the contractors shall:

- Determine potential team members and their roles in manufacturing
- Identify cost drivers and indicate approaches to minimize the acquisition, integration, operations, and support costs
- Develop a detailed cost analysis for the Operations and Support Plan (OSP) (applicable to the deployed system)
- Include the initial cost and planned block upgrades in the presented detailed plan/schedule. The plan shall detail the projects required to achieve the contractor-identified cost objectives, including the required non-recurring engineering (NRE), associated savings, detailed risk assessment, and scheduled implementation.

### 3.2.15.3 System Life Cycle Costs Document

The contractor shall deliver two weeks prior to major program reviews updated System Life Cycle Costs Reduction Strategy Document that models and establishes the overall cost of the system. All aspects of the cost will be scrutinized with initiatives developed and baselined for cost reduction in the Design Phase, the Material / Procurement Phase, the Manufacturing Phase, and the Production Support Phase. Additionally, the contractors shall:

- Determine potential team members and their roles in manufacturing
- Identify cost drivers and indicate approaches to minimize the acquisition, integration, operations, and support costs

- Develop a detailed cost analysis for the Operations and Support Plan (OSP) (applicable to the deployed system)
- Include in the detailed plan/schedule presented at the PDR the initial cost and planned block upgrades. The plan shall detail the projects required to achieve the contractor-identified cost objectives, including the required non-recurring engineering (NRE), associated savings, detailed risk assessment, and scheduled implementation.

Total Ownership Cost (TOC) and Life Cycle Cost (LOC) are some of the key factors in the assessment of Phase I performance, and will be a key selection criterion for contractors who continue into Phase II of the program. The SPO will perform an independent detailed analysis of the contractor's System and Life Cycle Costs Document.

### *3.2.16 Technical Design Package*

The contractor will maintain a set of documents as the Technical Design Package (TDP). This set of documents will include: System Specifications, Component Specifications, Hardware CI Development Specifications, Software CSCI Detailed Design Specifications, and all System, Component, Hardware and Software Interface Design Documents (IDD).

The contractor shall propose the exact makeup of the Technical Design Package set in their Phase II proposal.

The TDP shall be made available for government review two weeks prior to major design review discussed in paragraph 3.3.

### *3.2.17 Monthly Management Reports*

The contractor shall provide monthly status reports in accordance with guidance provided by the C-MANPADS SPO during Phase I. At a minimum, it should contain the following.

- Management Summary
- Program Cost and Schedule Execution Data in accordance with the contractor's reporting system
- Key Progress Elements
- Deliverable Status
- Risk Element Status Summary

### *3.2.18 Final Phase II Report*

The Phase II Final Report shall consist of the Production and Installation Readiness Review (PRR) viewgraph package and Phase II final baseline versions of the required documents referenced throughout Section 3.2.

### *3.2.19 Phase III Implementation Plan*

The contractor shall develop a Phase III Implementation Plan that addresses the following areas. The government will provide more details regarding the timing of this deliverable during Phase II. The current assumption is that this will be due four months prior to the end of Phase II.

- Long-lead items for procurement such that delivery optimizes Phase III execution timelines. The contractor shall develop its schedule for delivering the Long Lead Items List to the SPO, including sources, costs, and justifications for each item, and allowing sufficient time for the SPO to assess the list and release justifiable funding to facilitate the timely acquisition of those items.
- Recommendation of which commercial aircraft types, airlines, and scheduled routes shall receive and operate the planned Phase III OT&E units. The priority is applicable U.S. Registered aircraft and then other applicable commercial aircraft. The contractor shall provide the selection criteria and basis for prioritization of the aircraft types, airlines, and scheduled routes recommended.
- A comprehensive schedule and plan for training applicable personnel, installing the OT&E units on selected aircraft, and collecting actual operating and support costs during the 18-30 months of OT&E flights

## *3.3 Phase II Program Reviews*

Contractors shall propose the timing of the Phase II Program reviews and associated payment milestones in the Phase II proposal. MIL-STD 1521(B) will be tailored and used a guide to accomplish program reviews. The SPO will coordinate with the contractors to establish Entrance and Exit criteria prior to each program review.

### 3.3.1 *Critical Design Review (CDR)*

This review shall be conducted when detail design is essentially complete. The purpose of this review will be to complete the following.

1. Determine that the detail design of the C-MANPADS system satisfies the performance and engineering specialty requirements
2. Establish the detail design compatibility among the configuration item and other items of equipment, facilities, computer software, personnel, and security constraints
3. Assess system risk areas (on a technical, cost, and schedule basis)
4. Assess the results of the producibility analyses conducted on system hardware
5. Review the preliminary hardware product specifications; for CSCIs, this review will focus on the determination of the acceptability of the detailed design, performance, and test characteristics of the design solution, and on the adequacy of the operation and support documents
6. Review the adequacy of the operation and support documents, and adequacy of the program protection plan

### *3.3.2 Test Readiness Review (TRR)*

A review conducted to determine whether test procedures are complete and to assure that the contractor is prepared for formal testing. Test procedures are evaluated for compliance with test plans and descriptions, and for adequacy in accomplishing test requirements. The contractor will brief the entrance criteria, test to be conducted, resources required and the exit criteria. The system's readiness for test and the basis for that readiness will be covered. Test metrics, data collection and analysis shall be addressed.

TRR's will be conducted within two weeks of the applicable test(s) as identified in the MTEP.

### *3.3.3 Functional Configuration Audit (FCA)*

The FCA is a formal audit to validate that the development of the system has been completed satisfactorily and that the system has achieved the performance and functional characteristics specified in the functional or allocated configuration identification. In addition, the completed operation and support documents are reviewed. The Functional Configuration Audit (FCA) verifies that all requirements in the specifications, associated test plans and related documents have been tested and that the item has passed the tests or corrective action has been initiated.

### *3.3.4 Physical Configuration Audit (PCA)*

The PCA review is a technical examination of the C-MANPADS system to verify that the system "As Built" conforms to the technical documentation defining the system.

### *3.3.5 Formal Qualification Review (FQR)*

The FQR is a test, inspection, or analytical process by which a group of configuration items are verified to have met specific performance requirements (specifications or equivalent).

The contractor will propose a series of Formal Qualification Reviews (FQRs) reviews to support specified system testing events to assess test objectives, procedures, and resources for testing coordination. These include EMI, environmental and software test reviews which may be conducted in parallel. These events may be tied with payment milestones and shall be proposed by the contractors in the Phase II solicitation package.

### *3.3.6 Phase III Production Readiness Review(s)*

This review is the capstone event concluding Phase II. This review is intended to determine the status of completion of the specific actions which must be satisfactorily accomplished prior to executing a production go-ahead decision. This reviews will occur near the end of Phase II and will cover topics such as production planning, facilities allocation, incorporation of producibility oriented changes, identification and fabrication of tools/test equipment, long lead item acquisition etc. This review will be used to determine the readiness of the contractor for production of the units in Phase III. This review will formally examine the producibility of the production design for Phase III.

### *3.3.7 Program Management Reviews*

Program Management Reviews (PMR) shall be conducted as a way for the SPO to understand current program status outside of major program reviews discussed above. The agenda for each PMR shall be proposed by the contractor prior to the scheduled meeting. PMRs may be conducted via VTC, a combination of telephone conference and Web-Ex, or at the SPO Offices in Arlington, VA. The SPO and contractor shall meet at least every six weeks at either a major review (as discussed above) or a PMR. The contractor shall propose a schedule for PMRs during Phase II as a part of the Phase II Proposal.

# 4 Phase II Payment Milestones

During Phase II, payment will be made through a payment milestone schedule. Upon completion of each payment milestone, the contractor will be paid an agreed-upon amount. The fixed payment milestones for Phase II are detailed below.

As part of the negotiated OT for Prototype agreement, payment will occur at significant milestones, and offeror must satisfy exit criteria to receive the milestone payments. The information below indicates the C MANPADS SPO's suggested seven milestone approach. The offeror should propose the order, timing, and payment associated with each of the proposed milestones. *Note*: Phase II totals must include the cost of long lead items procured during Phase I.

- Payment Milestone A – Phase II Kick-Off Meeting
- Payment Milestone B – Critical Design Review
- Payment Milestone C – Functional Configuration Audit
- Payment Milestone D – Test Readiness Review(s)
- Payment Milestone E – Formal Qualification Review
- Payment Milestone F – FAA Certification
- Payment Milestone G – Production Readiness Review
- Payment Milestone H – Final Deliverables

## *4.1 Payment Milestone A – Phase II Kick-Off Meeting*

The exit criterion for Milestone A is a successful Phase II Kick-Off Meeting, which should be held approximately two weeks after Phase II award. It is anticipated that the Phase II Kick-Off Meeting shall include a comprehensive review of the planned tasks and resources to accomplish all of the Phase II tasks. The review shall include staffing plans, subcontracting status, GFE/GFI, etc. An updated Cost Proposal, meeting the requirements released in this solicitation, will be due at this time.[1]

[1] Section 5.3 of draft 1 of this solicitation will be modified slightly to meet these requirements; final addendum will be released soon.

# 5 Phase II Proposal Preparation Instructions

This section contains the proposal procedures and general Agreement instructions for the offeror. The Phase II proposal will contain three parts:

- Phase II Oral Presentation and Viewgraphs
- Redlined Proposed Agreement Modification with Phase II Attachments
- Phase II Cost Proposal

## *5.1 Phase II Oral Presentation*

The presentation shall include the following topics in any order.

- Past Performance of this team as it relates to its Phase I activities
- Master schedule
- Execution of test and evaluation program
- Reliability growth strategy and plan
- Cost, schedule, and performance risk and mitigation strategies
- System Verification Strategy
- Design, build, integrate, and test of prototypes
- FAA certification plan
- Installation and integration on the SD&D airframes
- Activities scheduled to mature and extend Phase I plans presented at PDR
- Explanation of the anticipated timeline and scope for all items detailed in Section 3 of this solicitation
- Planned key personnel changes – List all key team members and present the personnel qualifications of any new key team members that were not presented during the Phase I oral presentation to include their education, qualifications and experience
- Total Ownership Cost projections and rationale
- Past Performance – Explain the offeror's past performance in system testing, manufacturing, and production of items similar to the system being presented, and information regarding the legacy system components, depot support, reliability, operating & support costs, and mitigation strategies/corrective actions; where possible, please use examples of work completed by the current team

## *5.2 Draft Agreement Modifications and Phase II Attachments*

The offeror shall submit a draft version of its Phase II Agreement Modification, to be used as a basis for negotiations, and Phase II versions of the Agreement attachments: the Task Description Document (TDD), Integrated Master Schedule (IMS), Management Plan (MP), Systems Engineering Management Plan (SEMP), and cost proposal for Phase II.

### *5.2.1 Phase II Task Description Document*

The offeror shall prepare a Phase II TDD that describes in hierarchical fashion the work tasks required to accomplish the Phase II effort. The Phase II TDD shall be in a Work Breakdown Structure (WBS) format detailed to at least the third level. Each task in the Phase II TDD shall describe the work to be carried out, end result of the task, the time allocated, the organization

performing the task, and the resources (labor, material, and services) required. The offeror shall cost the resources to provide a baseline budgeted cost for the task. The Phase II TDD shall be at a level sufficient to define the nature of the work to be carried out, measure progress, and understand the relationship of the tasks to one another.

### *5.2.2 Phase II Integrated Master Schedule*

The offeror shall load the tasks described in the TDD into a resource-loaded network (RLN) to develop an overall program schedule for Phase II. By using resource-loaded tasks, the updated IMS will become the budgeted cost of work scheduled (BCWS) baseline for the program. The costs will be broken out by top-level WBS and month. The critical path, slack, and schedule reserves will be identified. The IMS shall be illustrated in both a Gantt Chart and Network Diagram format. The offeror shall develop the TDD and IMS in commercially available project management software such as Scitor PS-8 or Microsoft Project for delivery to the government.

### *5.2.3 Phase II Management Plan*

The offeror shall develop a Phase II MP, in its own format, that describes the roles and responsibilities of the offeror's team, reporting structures and mechanisms, risk assessment and mitigation, cost and progress allocation and reporting, earned value monitoring, the baseline change process, progress monitoring, and corporate oversight.

### *5.2.4 Phase II Payment Milestone Schedule*

The offeror shall use the materials presented of this solicitation as a guide to develop a series of no less than seven and no more than fourteen critical payment milestones, which shall be the basis for progress payments. The actual milestones will be negotiated as a part of the final Agreement modification. The offeror shall list payment amounts at each milestone in the schedule. Offerors shall base each milestone on the successful completion of a significant phase of the work plan, as outlined in the TDD and scheduled in the IMS. For each payment milestone, the offeror shall propose an unambiguous quantifiable set of accomplishment criteria that the government can verify as a basis for payment. The offeror shall indicate payment milestones in the IMS.

### *5.2.5 Phase II Systems Engineering Management Plan*

The offeror shall deliver a Phase II SEMP. The SEMP should provide the structure, policies, and procedures to foster the integration of the various engineering-related activities needed for system design and development. The SEMP should address the following areas at a minimum.

- Technical Program Planning and Control – address the proposed process for planning and control of the engineering efforts for the system's design, development, test, and evaluation

- Systems Engineering Process – include specific tailoring of the System Engineering process, implementation procedures, trade study methodology, types of models to be used for system and cost effectiveness evaluations, and the generation of applicable documentation and specifications

- Engineering Specialty Integration – describe the integration of technical discipline efforts and parameters into the System Engineering process and include a summary of each technical discipline effort with a cross reference to the specific plan

### *5.2.6 "Other Transaction for Prototype" Questionnaire Response*

Offerors shall update their responses to the questions presented in Section 7.1 to detail how its Counter-MANPADS approach would contribute to a broadening of the technology and industrial base available for meeting DHS needs. In addition, the responses should show how an "Other Transaction for Prototypes" Agreement would foster new relationships and practices that support the national security of the United States. Responses will be used to as a part of the foundation of a DHS(S&T) report to Congress. The offeror is to provide its responses in its preferred format.

## *5.3 Phase II Cost Proposal*

The offeror is to provide a Phase II cost proposal in the format and to the level of detail delivered for the Phase I proposal process. Upon award, the contractor shall deliver the additional information and level of detail listed in an addendum to this document.[2] Other than Long Lead Item funding, which is brought forward from Phase I, no Phase I data should be included.

## *5.4 Proposal Procedures*

Proposals that do not satisfy the following form and format requirements will be rejected without review and returned to the offeror.

### *5.4.1 Oral Presentation*

Offerors shall deliver an oral presentation at a time designated by the SPO during the first week of August 2004 to present the means by which concepts modeled in Phase I will be integrated, tested, and proven during Phase II. The oral presentation shall be no more than four hours in length, not including government questions, and may use viewgraphs, overhead transparencies and wall charts (no more than two). Questions will be asked either at the end of a major presentation topic and at the end of the presentation. Two computer-based projectors with screens will be available. The offeror should also supply twenty hard copies of the viewgraphs to be presented in a standard three-ring, loose-leaf binder with individual pages unbound and printed single sided. The offeror may place no more than two viewgraphs per page. The maximum number of viewgraphs is 250; however, the briefing must be completed in the allotted time. The government reserves the right to consider or not consider, at its sole discretion, any viewgraph not orally presented. In addition, the offeror may provide the following hard copy material for reference purposes along with the viewgraphs:

- A cross reference of the proposal requirements by viewgraph
- An index and list of acronyms

[2] Will be attached with the next version of the draft; will be largely the same as the materials presented as 5.2 of Draft 1 of this solicitation.

- List of key individuals including resumes of any individuals not submitted during Phase I
- A wall chart or fold out covering the IMS and resource loaded network

### *5.4.2 Proposed Agreement and Cost Volume*

The offerors Proposed Agreement, with Attachments, and the Cost Volume should be submitted as a single volume in a standard three-ring, loose-leaf binder with individual pages unbound and printed single sided. The Cost Volume has no page limit. The Proposed Agreement and Attachment should not exceed 195 pages excluding section dividers; the preferred breakdown is 30 pages for the Proposed Agreement, 160 for the Proposed Agreement Attachments. The evaluation team will not consider pages submitted in excess of the page limit. One original and nineteen copies, for a total of twenty, are required.

## *5.5 Proposal Submission Summary*

The following summarize the submission required of potential offerors:

| VOLUME | SECTION | DESCRIPTION | Max # Pages |
|---|---|---|---|
| I Viewgraph Package | 1 | Outline | 4 |
| | 2 | Cross Reference | 2 |
| | 3 | Resumes | 12 |
| | 4 | Viewgraph Package | 250 |
| | 5 | Wall Chart | 2 |
| | 6 | Index | 5 |
| | 7 | List of Acronyms and Abbreviations | 5 |
| | | *Sub-total* | *280* |
| | | | |
| II Proposed Agreement | i | Transmittal Letter | 2 |
| | ii | Cover Page | 1 |
| | 1 | Redlined Proposed Agreement | 30 |
| | 2 | Proposed Agreement Attachments | 160 |
| | 3 | Cost Proposal | Unlimited |
| | 4 | Redlined Section 845 Questionnaire | 2 |
| | | *Sub-total* | 195+ |

### *5.5.1 Page and Print Information*

Each page should be on an 8-1/2" x 11" sheet with a font size of not less than 12 points; figures, charts, labels, headers, and footers may be submitted with a font size of not less than eight points. Margins should be at least 1 inch on all sides. Fold out pages will be counted as multiple pages with the exception of the IMS Gantt Chart. The IMS Network Charts, which may be included as an enclosed wall chart, will be counted against the page count as a single page. Any proposal pages containing restrictions on the dissemination of information must have a legend placed on each affected sheet/page.

### *5.5.2 Proposal Delivery Information*

Authorized representatives of the offeror must sign proposal volumes. Responses not received at the address and time specified below will be considered as a late proposal and will not be reviewed.

#### 5.5.2.1 Delivery Locations

The delivery address for Volumes I and II is:

Counter-MANPADS SPO
1401 Wilson Boulevard, Suite 1200
Arlington, VA 22209-2396
Attn: C-MANPADS Solicitation HSSCST-05-R-AR001

Both Volumes will be delivered at the commencement of the oral presentation.

#### 5.5.2.2 Proposal Schedule and Deadlines

- The deadline for receipt of both Volumes is the commencement of the Oral Presentation.
- The Oral Presentations are tentatively scheduled for the week of 2 August 2004. Each offeror's presentation will commence at 8:00 am on its assigned day. The order of presentations and assignment of days will be directly related to the order of the Phase I milestone reviews.

### *5.5.3 Electronic Information*

Offerors are required to submit both Volumes of their proposal on a CD-ROM in Microsoft Office compatible electronic format.

### *5.5.4 Submission of Classified Information*

Offerors intending to include classified information or data as part of their submissions shall contact, in advance of providing their proposals to the Counter-MANPADS SPO, Mr. Cedric Redmon at (703) 235-0254. This is **required** both for receipt of the information and in preparation of the oral presentations.

Classified and unclassified portions shall be separated for delivery.

### *5.5.5 Solicitation Questions and Answers*

Offerors may contact the Government focal points for any questions or clarifications up until the time that proposals are received. Questions regarding the solicitation or the proposal process will be reviewed and answers, as appropriate, will be provided to the Program Manager and Contracts representatives of each of the three offerors by the Government Program Manager. Once proposals have been received, ONLY the Government Program Manager or Agreements Officer may contact the offeror with questions or clarification requests about the proposal.

The designated focal points are:

Mary Kolarik, Business Manager
C-MANPADS SPO
703-235-0292
Mary.Kolarik@associates.dhs.gov

Jodi Lasky, Publications Editor
C-MANPADS SPO
703-235-0286
Jodi.Lasky@associates.dhs.gov

### *5.5.6 Regulations Governing Objections to Solicitation and Award*

Any objections to the terms of this solicitation, once released in final form, or to the conduct of receipt, evaluation, or award of Agreements must be presented in writing within ten calendar days of (1) the release of this solicitation, or (2) the date the objector knows or should have known the basis for its objection. Objections shall be provided in letter format, clearly stating that it is an objection to this solicitation or to the conduct of evaluation or award of an Agreement, and providing a clearly detailed factual statement of the basis for objection. Failure to comply with these directions is a basis for summary dismissal of the objection. Mail objections to the address listed in the proposal delivery information.

### *5.5.7 Non-Government Experts*

The Government intends to use support offerors, plus other independent experts to assist in processing and administering proposals during the Source Selection, and to provide advice relative to selected technical areas. These personnel are restricted by their contract from disclosing information contained in any proposal for any purpose to anyone outside of the Source Selection for this effort. Moreover, all personnel used in this capacity are required to enter into separate Organizational Conflict of Interest/Non Disclosure Agreements to this effect. By submission of its proposal, the offeror agrees that proposals may be disclosed to these personnel for the purpose of providing this assistance.

# 6 Evaluation Criteria and Extension

## *6.1 Introduction*

The Government will extend existing Agreements into Phase II based on the evaluation of the required elements, as detailed in Section 5 of this solicitation. This section outlines the criteria that the Source Selection Committee will use to evaluate the proposals. Each proposal will be evaluated in a subjective, integrated manner. The government reserves the right to make awards without discussions.

## *6.2 Evaluation Criteria*

This section outlines the criteria that the Government will use to evaluate the proposals. Each proposal will be evaluated in a subjective, integrated manner.

### *6.2.1 Technical*

The technical evaluation considers the C-MANPADS system prototypes design and maturity at the end of Phase II. The review will include the commercial manufacturability of projected systems. In conducting the technical evaluation, the Source Selection Committee will consider how well the proposed system meets/exceeds the technical objectives listed in Section 2.6 of this solicitation. (*Note:* The system must achieve all thresholds by the end of Phase III or risk being eliminated; if not reached by the end of Phase II, include plans for doing so through the end of Phase III.) The following lists technical factors that will be considered.

- The soundness and the feasibility of the SRD, CONOPS, TPM, and PDD
- The completeness of the proposed design and its ability to meet the top-level performance requirements defined in Section 2.6 above
- Maturity and functionality of system and subsystem hardware and software design
- Overall system effectiveness

### *6.2.2 Management*

The management evaluation considers the offeror's ability to execute, in an effective and efficient manner, the Phase II program. Factors to be considered are:

- The offeror's Team organization will be evaluated for stability, delineation of responsibility and authority, lines of communication, and its combined ability to meet Phase II program goals. Also being evaluated is:
  1) The teaming relationship between traditional government contractors and the commercial airline sector
  2) Program Manager experience managing and executing complex system programs
  3) Chief Engineer experience leading engineering team in design, development and flight test of complex systems programs
  4) Analysis Lead experience performing iterative affordability and effectiveness trades to define system attributes for complex systems programs
  5) Capabilities and experience to conduct flight test systems of like complexity

- The offeror's system engineering processes, methodologies, and management practices will be evaluated as to their soundness, completeness, feasibility and effectiveness to complete all the Phase II activities described in their plans (the TDD, IMS, MP, SEMP, and PMS). This evaluation includes, but not limited to:
  - Recognition of program risks and plans to mitigate those risks
  - Soundness of the schedule network (IMS) including its sensitivity to unexpected delays
  - Feasibility of the schedule critical path
  - The assignment of resources to the appropriate elements of Phase II work
  - Visibility into the program, through the offeror's Phase II earned value monitoring
  - Completeness and feasibility of the Phase II O&S concepts:
    - The maintenance approach, including its impact on commercial aviation operations
    - Supportability analysis to include the quality of the analysis and its results
    - Adequacy of the training requirements and plans
    - The installation concept and its impact on commercial aviation operations
    - Soundness of the reliability growth strategy and analysis plan
  - The soundness of the plan to conduct life cycle cost analyses and modeling
  - Soundness of offeror's plan to achieve security and ITAR compliance
  - Completeness and feasibility of the MTEP and the degree to which it adds confidence to the design and installation and degree to which it progressively verifies performance and reduces risk
  - Completeness of the Safety Certification Plan to address system functional hazards, failure modes and analyses, environmental hazards and special procedures to achieve an acceptable level of safety as defined by government and industry standards
  - The completeness of PSCP as determined by assessing the offeror's detailed plans to achieve FAA certification for the proposed configuration; considers tasks, estimated timelines, resources, facilities, FAA personnel involvement, and any other factors required to achieve STC for the proposed design

### *6.2.3 Total Ownership Cost*

The TOC evaluation is a subjective review of the offeror's total ownership cost projections as relates to the Phase III, and beyond, system design and implementation. Lowest reasonable and realistic TOC will receive the highest consideration by the evaluators.

### *6.2.4 Past Performance*

The past performance evaluation considers two areas:

1. The offeror's past performance on design and development of similar infrared countermeasure systems

2. Past experience and existing facilities to mass-produce systems of like complexity.

3. The offeror's follow through on commitments made in Phase I and the delivery of final products and team performance during Phase I

### *6.2.5 Phase II Cost*

The Phase II cost evaluation considers the offeror's ability to achieve all the tasks required by the TDD at $45 M (Threshold) or less. The cost proposals will be evaluated for the realism and reasonableness of costs, and the risk that the Phase II costs could escalate to the point that the combination of government and corporate funding, if any is offered, will not allow completion of the program. The Cost assessment includes an analysis of the offeror's ability to meet the schedule within the resources planned. *Note:* The evaluated cost must achieve cost threshold of $45.0M or risk being eliminated.

## *6.3 Basis for Award*

The government expects to make one or more awards to the offeror(s) whose systems are deemed potentially viable in the eighteen-month time frame allotted for Phase II. The process by which the government makes selections is explained below.

### *6.3.1 Evaluation by Criteria*

Successful Phase II proposals will incorporate a balanced approach that responds to all of the selection criteria. The criteria listed above will be evaluated.

### *6.3.2 Cost and Cost Realism*

The government stated the funding available for this effort and each development in Section **Error! Reference source not found.**. Payment is based on a fixed price paid at pre-defined Payment Milestones. Offerors may bid any total cost and combination of payments they deem realistic. The cost proposals will be evaluated for the reasonableness of costs, and the risk that the development costs could escalate to the point that the combination of government and corporate funding will not allow completion of the program. The government will evaluate the Phase II costs for realism.

### *6.3.3 Selection*

For qualified proposals that have evaluated realistic costs that meet the cost goals, the selection will be based on an approach that is TBD. Cost is less important and will be weighted as such. If the cost goals are not met, the relative weight of cost will increase proportionately.

The government intends to select offers that give an overall portfolio that minimize the risks in achieving the goals of the program.

# 7 Model Agreement

Offeror will draft Model Agreement Modification. The Government will provide guidance for consideration in the area of Intellectual Property at a later date.

## *7.1 "Other Transactions for Prototypes" Questionnaire*

Offerors shall submit responses to each of the two questions, below, with their proposal. Please DO NOT provide "Boiler Plate" answers to these questions. Your response will form the foundation of a submission to DHS(S&T) and Congress.

It is preferable that the response to each question consumes no more than one page. (A series of thought provoking questions are provided to assist you in formulating your responses.) Responses are to be provided in offeror format.

1. To what extent will the DHS(S&T) Counter-MANPADS "Other Transactions for Prototypes" agreement (if awarded to your team) contribute to a broadening of the technology and industrial base available for meeting commercial as well as Department of Homeland Security needs? Your discussion must focus on how the use of this "Other Transactions" agreement will contribute to a broadening of the technology and industrial base available for meeting DHS(S&T)/DoD needs.

2. To what extent will the DHS(S&T) Counter-MANPADS "Other Transactions for Prototypes" agreement (if awarded to your team) foster new relationships and practices that support the national security of the United States? The discussion must focus on how the use of an "Other Transactions" agreement has fostered new relationships and practices that support the national security of the United States.

When formulating your responses to the two "Extent" questions, above, please consider the following:

The intention is for your answers to provide a brief explanation of the ways in which the use of a "Other Transactions for Prototypes" agreement (if awarded to your team), rather than a standard procurement contract/cooperative agreement, will assist the Department of Homeland Security in better meeting U.S. national security policy goals and objectives. Specifically:

1. Will the use of the "Other Transactions for Prototypes" agreement allow you to involve any commercial firms in the project that would not otherwise have participated? If so:

a. Which firms are they?

b. Are there provisions of the DHS(S&T) Counter-MANPADS "Other Transactions for Prototypes" agreement, or features of the award process, that will enable their participation? If so, specifically what they are?

c. What are the expected benefits of your team's participation (e.g., technology that is better, more readily available, or less expensive)? Please be specific about the benefits and explain why you expect to realize them.

d. Why would other firms not participate if a standard instrument were used? For example: Do the firms in question normally not do business with the Government? Do they do business with the Government only through "Other Transactions" or contracts for commercial items? Or,

do they limit their volume of Federal contracts to avoid exceeding a threshold beyond which they would have to comply with cost accounting standards or some other Government requirement?

2. Will the use of the DHS(S&T) MANPADS "Other Transactions for Prototypes" agreement allow you to create new relationships among for-profit firms at the prime or subtier levels; allow you to create new relationships among business units of the same firm; or, allow you to create new relationships between firms and nonprofit performers that will help DHS(S&T) get better technology in the future? If so:

a. Between which participants were the new relationships formed?

b. Why does your team believe that these new relationships will help DHS(S&T) get better technology in the future?

c. Were there provisions of the DHS(S&T) MANPADS "Other Transactions for Prototypes" agreement, or features of the award process, that will enable your participation? If so, specify what they are.

3. Will the use of the DHS(S&T) Counter-MANPADS "Other Transactions for Prototypes" agreement allow traditional Government contractors to use new business practices in the execution of this prototype project that will help DHS(S&T) obtain better technology, get new technology more quickly, or get it less expensively? If so:

a. Who are those contractors and what are the new business practices?

b. What specific benefits do you believe DHS(S&T) will obtain from the use of these new practices, and why do you believe that to be so?

c. Were there provisions of the DHS(S&T) Counter-MANPADS "Other Transactions for Prototypes" agreement, or features of the award process, that will enable the use of these new practices? If so, specify what they are.

4. Are there any other benefits of the use of the DHS(S&T) Counter-MANPADS "Other Transactions for Prototypes" agreement that you perceive will help the Department of Defense better meet its objectives in carrying out this prototype project? If so, what are they; how do they help meet defense objectives; what features of the DHS(S&T) Counter-MANPADS "Other Transactions for Prototypes" agreement, or award process, will enable DHS(S&T) to realize? Please be specific.

# Q. BARDA OT SAMPLE

**OTHER TRANSACTION AGREEMENT (OTA)**

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilmington, DE 19850

AND

THE UNITED **STATES OF AMERICA**
**DEPARTMENT OF** HEALTH **AND HUMAN SERVICES**
**ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE**
330 INDEPENDENCE AVENUE, SW G640
WASHINGTON, DC 20201

CONCERNING

The research and development of a portfolio of new antibacterials to treat antibiotic resistant and biothreat infections

Agreement No.: HHS0100201500029C
PR No.: 05162378
Total Amount of the Agreement: $98,088,337
Total Estimated Government Funding of the Agreement: $50,000,000
Total Estimated Recipient Funding of the Agreement: $48,088,337
Funds Obligated: $50,000,000

Authority: Section 319L(c) (4) (B) and/or 319L{c) (4) (D) of the Pandemic and All-Hazards Preparedness **Act,** P.L. 109-417

Line of Accounting and Appropriation: Object Class: 25103, Appropriation Yr: 2015, CAN: 1992015

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by the Department of Health and Human Services (HHS) and AstraZeneca Pharmaceuticals LP, pursuant to and under U.S. Federal law.

FOR ASTRAZE.NECA PHARMACEUTICALS LP

FOR THE UNITED STATES OF AMERICA
OFFICE OF ACQUISITION MANAGEMENT,
CONTRACTS & GRANTS SECRETARY
FOR PREPAREDNESS AND RESPONSE

John H. Rex, MD rrSq,,1-tU.r Carl A. Newman 9/15/15

(Signature) {Signature)

John H. Rex,
Senior Vice President
(Name, Title) (Date)

earl A. Newman,
Other Transaction Agreement Officer
(Name, Title) (Date)

**TABLE OF CONTENTS**


| ARTICLES | PAGE |
|---|---|
| ARTICLE I: SCOPE OF THE AGREEMENT | 4 |
| ARTICLE II: TERM | 10 |
| ARTICLE III: MODIFICATIONS | 11 |
| ARTICLE IV: MANAGEMENT OF THE PROJECT | 11 |
| ARTICLE V: AGREEMENT ADMINJSTRATION | 13 |
| ARTICLE VI: COST SHARING | 14 |
| ARTICLE VII: OBLIGATION AND PAYMENT | 16 |
| ARTICLE VIII: DISPUTES | 19 |
| ARTICLE IX: DATA RIGHTS | 20 |
| ARTICLE X: PATENT RIGHTS | 23 |
| ARTICLE XI: FOREIGN ACCESS TO TECHNOLOGY | 26 |
| ARTICLE **XII:** TITLE TO AND DISPOSITION OF PROPERTY | 26 |
| ARTICLE **XIII:** SUBCONTRACTING | 27 |
| ARTICLE XIV: CIVIL RIGHTS ACT | 27 |
| ARTICLE XV: EXECUTION | 27 |
| ARTICLE XVI: SPECIAL CLAUSES | 27 |
| ARTICLE XVII: TRANSFERS & ASSIGNMENTS. | 34 |
| ATTACHMENT 1: STATEMENT OF WORK | 35 |
| ATTACHMENT 2: REPORTING REQUIREMENTS | 40 |
| ATTACHMENT 3: PORTFOLIO PERFORMANCE METRICS | 52 |
| ATTACHMENT 4: FOREIGN FIRMS OR INSTITUTIONS EXCLUDED FROM DEFINITION | 54 |
| ATTACHMENT 5: ALLOWABLE COSTS | 57 |

**ARTICLE I: SCOPE OF THE AGREEMENT**

**A. Introduction**

- The objective of this Other Transaction Agreement (OTA) is to create a framework for collaboration between AstraZeneca and the Biomedical Advanced Research and Development Authority (BARDA) to evaluate the efficacy and safety of a portfolio of selected AstraZeneca antibacterial assets in treating hospital and biothreat infections. To support this objective, AstraZeneca will conduct studies to support regulatory approval of each selected product. This includes non-clinical, clinical, and drug manufacturing activities supporting regulatory approval. In addition, data to support biothreat indications will also be generated where agreed to. By mutual consent of AstraZeneca and BARDA, preclinical candidates may ,be included in order to facilitate their progress into the clinical portfolio. This framework will provide BARDA and AstraZeneca the flexibility to. execute a portfolio approach to funding in the complex and uncertain environment of drug development.

- The initial work under this Agreement will support regulatory approval of aztreonam-avibactam (ATM-AVI), an antibiotic designed to treat serious infections caused by multi-drug-resistant Gram-negative organisms.

- The Agreement may be modified by mutual agreement consistent with Article Iii. This approach allows for funds to be flexibly allocated each year between the assets and for other assets to be brought into scope by mutual consent without a lengthy proposal process, such as assets emerging from the pre-clinical pipeline or from AstraZeneca alliances with other companies. This approach is appropriate because asset-specific funding lacks the flexibility that is needed in order to reposition funds in response to attrition. Portfolio-based product development is an important and innovative strategy to manage and reduce overall risk, and to capitalize on emergent opportunities in order to maximize the probability of success. The portfolio-based development approach in this Agreement will enable a more robust and long-term relationship between BARDA and AstraZeneca to address development of multi-use assets.

- Many pharmaceutical companies have stopped developing new antibiotics due to a diminished return on investment.Formation of public-private partnerships with industry helps to sustain research in this area where new drugs are desperately needed to address the growing rate of antibiotic resistance. This Agreement addresses this issue by permitting BARDA to share in the expense of clinical trials for ATM-AVI, along with any additional antibiotics that may be added to the Agreement by mutual consent of the parties. This Agreement will help ensure that at least one experienced pharmaceutical company will remain engaged in antibacterial development to combat the threat of antibiotic resistance. Furthermore, the ability of the Government to enter into an agreement with consortia is a compelling factor for selecting an OTA as the appropriate funding mechanism. In addition, portfolio-based product development reduces risk by allowing for the reallocation of resources across activities and drug candidates if technical or business risks materialize. An agreement that allows for the funding of a portfolio of products instead of just one increases the probability of bringing a successful drug to market.

- AstraZeneca is the US operating subsidiary of a large, global pharmaceutical company with a long history of developing and bringing new antibiotics to the market. The company also has a well-established track record of partnering with other biotechnology companies to advance its antibacterial portfolio. In the mid-1990s to the 2000s, AstraZeneca developed and brought to market MERREM (meropenem), a carbapenem-class antibiotic that remains a mainstay of therapy. ZINFORO (ceftaroline fosamil} is an important licensing acquisition in AstraZeneca's portfolio, exclusively licensed in 2009 from Forest Laboratories, LLC (as successor-in-interest to Forest Laboratories, Inc., and a wholly-owned subsidiary of Allergan pie} for countries outside of the US and Canada, and AstraZeneca has been responsible for successful registrations in 58 markets globally to date. AstraZeneca added further important products to·the infection development pipeline in 2009 with the acquisition of avibactam as part of a deal with Novexel, a French biotechnology company, alongside its license partner Forest. A key component of this acquisition was the initiation of a license and collaboration agreement between AstraZeneca and Actavis for the combination of ceftazidime and avibactam (CAZ-AVI}. AstraZeneca holds the rights to CAZ-AVI worldwide outside of the US and Canada, representing a crucial element of the AstraZeneca infection portfolio. CAZ-AVI is not included within this Agreement. This deal further involved an extension of the existing ZINFORO license to include rights to develop and commercialize the combination of avibactam with ceftaroline fosamil, a combination aimed to extend the activity profile of ceftaroline fosamil against resistant Gram-positive (MRSA} and resistant Gram-negative (ESBL producing *Enterobacteriaceae).* The combination of avibactam with aztreonam (ATM-AVI} was another project added to the AstraZeneca pipeline as part of the avibactam deal, and is the initial focus of this strategic alliance. ATM-AVI is a critically important opportunity for the treatment of a particular type of Gram-negative infection for which there are few or no treatment options. The commercialization rights for the ATM-AVI combination are split between Actavis (US and Canada) and AstraZeneca (rest of world).

- In parallel to the signing of this Agreement, AstraZeneca has signed an associated letter agreement with its alliance and license partner Actavis under which Actavis has provided its full support and alignment to the principles and objectives set out in this Agreement with respect to ATM-AVI. Actavis ·recognizes that a critical objective and component of this Agreement is the aim for ATM-AVI to be ultimately developed, approved and commercialized in the US Territory. As Actavis contractually holds the exclusive commercialization rights for ATM-AVI in US/Canada, Actavis recognizes that its agreement and alignment to the principles contained under this Agreement with respect to ATM-AVI have been required as a precursor to its signature. Actavis has agreed that, to the extent this Agreement requires access to or the exercise of ATM-AVI rights held by Actavis in the US, Actavis will not restrict or obstruct the development and commercialization of ATM-AVI under this Agreement and Actavis shall work with AstraZeneca to ensure the appropriate arrangements are in place to permit the foregoing. Actavis further acknowledges its responsibility to file the NDA and undertake any associated regulatory activities in a timely manner and at the appropriate stage in the development program for ATM-AVI under the Agreement. Actavis has reviewed the terms of this Agreement and will continue to maintain sight over the direction of the ATM-AVI program and progress under this Agreement through regular contact and

updates with AstraZeneca and ad hoc attendance on the Joint OTAR Oversight Committee.

- The current AZ portfolio aligns with both PHEMCE and BARDA's requirements. To ensure a robust portfolio is maintained over time, AZ has identified several antibacterial candidates being developed by other companies that could be considered for in-licensing and funding through the portfolio. A public-private partnership between BARDA and AZ formed under an OTA will allow the technical and business risks of drug development to be mitigated and increase the probability of successful development and approval/licensure of n_ovel antibacterials to address unmet medical needs.

- The proposed partnership with AstraZeneca addresses BARDA's Broad Spectrum Antimicrobials (BSA) Program Strategy to revitalize the antimicrobial pipeline by forming public private partnerships with companies engaged in antimicrobial therapy research and development. Th BSA Program strategy emphasizes programs that address the immediate public health threat of drug resistant community and hospital acquired infections while also providing a biodefense capability in the event that drugs in the Strategic National Stockpile lose efficacy due to the emergence of drug resistant bacteria. The partnership with AstraZeneca also addresses numerous US Government Requirements and Strategies including:

- PHEMCE Product Specific Requirement for Medical Countermeasures to Antimicrobial Resistant Bacterial Infections. ATM-AVI, along with the potential additional antibiotic candidates identified by AstraZeneca, directly address this requirement to develop and license novel products that are able to treat drug-resistant bacteria.

- President's Executive Order for Combating Antibiotic Resistant Bacteria which requires that BARDA shall develop new and next generation countermeasures that target antibiotic resistant bacteria that present a serious or urgent threat to public health. The BSA Program strategy aligns with the Executive Order by seeking to develop novel antimicrobial drugs capable of treating those bacterial threats determined by the CDC to be either urgent (C. *difficile,* Carbapenem-resistant Enterobacteriaceae, drug-resistant *N. gonorrhoeae)* and serious (multidrug-resistant *Acinetobacter,* ESBLs, *Pseudomonas,* MRSA and *Streptococcus pneumoniae}.*

- President's National Strategy for Combating Antibiotic Resistant Bacteria that calls for forming both public private partnerships and international collaborations to enhance and accelerate the research and development of new therapeutics to counter antib1otic resistance. AstraZeneca's development plan for ATM-AVI will include support from both BARDA arid the European Union's Innovative Medicines Institute (IMI). This collaboration, in which BARDA and IMI would each fund distinct activities required for the development and licensure of ATM-AVI, is precisely the type of international collaboration sought by the President in the National Strategy.

- President's National Action Plan for Combating Antibiotic Resistant Bacteria that requires BARDA create portfolio partnerships with industry to accelerate the development of new antibacterial drugs. The formation of a public-private partnership between BARDA and AstraZeneca could help to meet this objective of creating a

portfolio partnership with .the goal of submitting at least one NDA for an antibiotic product within the,next five years.

- Lastly, the proposed partnership aligns with BARDA's and AstraZeneca's support of commonly accepted· international principles of antimicrobial stewardship through responsible promotion and use. AstraZeneca's stewardship objective is to achieve optimal clinical outcomes which minimize toxicity and other adverse events, while supporting appropriate prescribing to limit the selection for antimicrobial resistant strains. AstraZeneca encourages the responsible use of its antimicrobial products by promoting the selection of appropriate patients for treatment and by using the optimal drug regimen, dose and duration of therapy. Responsible promotion is complemented by scientifically trained Medical Science Liaison staff who interact with healthcare professionals to provide educational programs and informed responses to scientific information requests.

Q

**B. Definitions**

**Agreement:** The body of this Agreement and Attachments 1 - **4,** which are expressly incorporated in and made a part of the Agreement.

**Actavis:** A public limited company headquartered in Dublin, Ireland, and successor to the interests of Forest Laboratories in the collaboration agreement with AstraZeneca to develop ATM-AVI. Actavis is now called Allergan pie, following the acquisition of Allergan in March 2015.

**ATM-AVI:** The combination of avibactam with aztreonam, an antibiotic designed to treat serious infections caused by multi-drug-resistant Gram-negative organisms producing metallo-beta-lactamases. ATM-AVI is jointly owned by AstraZeneca and Actavis pursuant to the terms of a March 3, 2010, collaboration agreement. AZ and Actavis have developed ATM-AVI and reduced it to practice and practical application; neither ATM-AVJ nor its constituent drugs aztreonam or avibactam, are a Subject Invention of this Agreement. AstraZeneca and Actavis hold joint worldwide development rights for ATM-AVI. Commercialization rights and ownership of intellectual property is split between AstraZeneca and Actavis with Actavis holding rights to commercialization (and any IP needed for the commercialization) in the US and Canada, and AstraZeneca having equivalent rights in the rest of the world.

**COMBACTE-CARE:** The consortium, Combatting Carbapenem Resistance in Europe, the subject of a March 1, 2015, Project Agreement among multiple parties, including AstraZeneca, and supported through a grant from the European Innovative Medicines Initiative (IMI). The COMBACTE-CARE consortium is involved in delivering a Phase II and the European component of the Phase Ill clinical trial to support the development of ATM-AVI.

**Computer Software:**

(a) Means:

- Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and
- Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

(b) Does not include computer databases or computer software documentation.

**Data:** Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, and trade secrets made in the performance of work under this Agreement within the Field. The term does not include financial, administrative, cost, pricing or .management information.

**Field:** The development of antibacterial assets to treat hospital and biothreat infections.

**Foreign Firm or Institution:** A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any _agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals. Specifically excluded from the definition of Foreign Firm or Institution are the entities listed on Attachment 4 along with their non-US affiliates.

**Government:** The United States of America, as represented by HHS.

**Government Purpose Rights:** The rights to use, duplicate, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

**Invention:** Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

**Know-How:** Information, practical knowledge, techniques, and skill development by Recipient in the performance of work under this Agreement necessary for the Practical Application of a Subject Invention with the Field.

**Limited Rights:** Th rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. DHHS will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

**Option:** An option, entered into by mutual agreement of both parties in this Agreement, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the. Agreement, or may elect to extend the term of the Agreement.

**Other Transaction for Advanced Research (OTAR)** means: A legally binding, non-acquisition instrument (generally called "an agreement") used in instances where the principal purpose is the stimulation and/or support of advanced research and development (as defined below), where a non-traditional Government Awardee participates to significant extent in the work.

**Other Transaction Agreement Officer (OTAO):** Is the responsible government official authorized to bind the government by signing this Agreement and bilateral modifications.

**Other Transaction Agreement Specialist (OTAS):** Is a supporting official that executes agreement modifications on behalf of the Other Transaction Agreement Officer.

**Other Transaction Agreement Technical Representative (OTTR):** Is the primary government official for all technical matters on the Agreement.

**Practical Application:** With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public.

**Program:** Research and development being conducted by the Parties pursuant to this Agreement.

**Property:** Any'tangible personal property other than property actually consumed during the execution of work under this Agreement.

**Recipient:** AstraZeneca Pharmaceuticals LP (AstraZeneca or AZ).

**Subject Invention:** Any Invention conceived in the performance of work under this Agreement (as defined below) within the Field for which Recipient pursues a patent.

**Technology:** Discoveries, innovations, Know-How and Subject Inventions, whether patentable or not, conceived in the performance of work under this Agreement, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights developed under this Agreement.

**Under this Agreement:** When used, for example but without limitation, in the definitions of Data, Know-How, Property, Subject Inventions and Technology, means activities conducted pursuant to this Agreement that are BARDA funded or Binding Cost Share by Recipient.

**C. Scope**

1. The Recipient shall perform an advanced research and development program (AR&D Program) designed to develop novel antibacterial drugs in accordance with the Statement of Work incorporated in this Agreement as Attachment 1. The Recipient will submit or otherwise provide all documentation required by Attachment 2, Reporting Require·ments.

2. The Government will have continuous involvement with the Recipient. The Government will also obtain access to research results and cert in rights in Data pursuant to Article IX. HHS and the Recipient are bound to each other by a duty of good faith and commercially reasonable research effort in achieving the goals of the Program.

3. This Agreement is an "other transaction" pursuant to Sections 319L(c)(4)(B) and 319L(c)(4)(D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417. The Parties agree that the principal purpose of this Agreement is to support commercially reasonable efforts in advanced research in the development of antibacterial assets and not for the acquisition of property or services for the direct benefit or use of the Government.

**ARTICLE** II: **TERM**

**A. Term of this Agreement**

The term of this Agreement commences upon the date of the last signature. This Agreement commences with a five-year base period and four options. The period of performance is a base period of five (5) years during which clinical, non-clinical, manufacturing and development activities supporting the registration of ATM-AVI will be conducted as set forth in Attachment 1. The parties may exercise two one-year option periods to permit the continuation of ATM-AVI development activities. In addition, the parties may agree to two additional one-year option periods to add additional antibacterial candidates to the Agreement for preclinical, clinical, manufacturing and development activities. The option periods may run concurrently or consecutively within the base period.

The Government will give the Recipient a preliminary written notice of its desire to exercise an option at least ninety (90) days before the expiration of one year following the commencement of the Agreement (for the first option) and each option term thereafter, as applicable. The Recipient may decline any option. The Parties may also agree mutually to extend the term of this Agreement and its options by written agreement on or before the expiration of the Agreement. The Government will give the Recipient a preliminary written notice of its desire to extend at least ninety (90) days before the five (5) year period expires. The preliminary notice does not commit the Government to an extension.

**B. Termination Provisions**

Either Party may terminate this Agreement for convenience by providing at least ninety (90) days prior written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement shall be in accordance with the provisions set forth in Article IX, Data Rights. In the event of termination by either Party, the Recipient's and Government termination costs shall be reimbursable pursuant to the terms of Article VI. For purposes of this clause, termination costs shall be those costs identified in Federal Acquisition Regulation 31.205-42 but does not include reprocurement costs unless foreign access to technology Article XI is applicable. The Government and the Recipient will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, including disposition of animals acquired for research use. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VIII, Disputes. In the event of termination, neither party shall have any continuing obligations to perform under the Program except as otherwise specified herein.

**C. Extending the Term**

The Parties may extend by mutual written agreement the term of this Agreement if funding is available and research opportunities reasonably warrant.. Any extension shall be formalized through modification of the Agreement by the OTAO and he Recipient Administrator. If the Recipient desires an extension to the period of performance of this Agreement, the Recipient shall submit a request in writing to the OTAO. Any request for an extension should include a revised milestone/project schedule (if applicable).

**ARTICLE** III: **MODIFICATIONS**

**A. Recommendations for Modifications**

As a result of quarterly meetings, annual reviews, or at any time during the term of the Agreement, research progress or results may indicate that a change in the Statement of Work would i:)e beneficial to program objectives. Any modification to the Agreement, excluding minor modifications discussed below, shall be by,mutual agreement of the parties. Recommendations for modifications, including justifications to support any changes to the Statement of Work, will be documented in a letter and submitted by the Recipient to the OTIR with a copy to the HHS OTAO and OTAS. This letter will detail the technical, chronological, and financial impact (if any) of the proposed modification to the research program.

Q

**B. Minor Modifications**

For minor non material Agreement modifications without effect on any obligation of Recipient or the Government or the terms and conditions of this Agreement (e.g. changes in the paying office or appropriation data, Government or the Recipient's changes to personnel identified in the Agreement, etc.), the Government may make these types of changes unilaterally and no signature is required by the Recipient.

**C. Amending the Agreement**

The OTAO and OTAS shall be responsible for agreeing to any modifications to this Agreement on behalf of the Government.

**ARTICLE IV: MANAGEMENT OF THE PROJECT**

**A. Recipient/BARDA Joint OTAR Oversight Committee**

1. Recipient/BARDA Joint OTAR Oversight Committee (JOC) is comprised of 3 senior level members from Recipient, 3 senior level BARDA participants and the Other Transaction Agreement Officer (OTAO). Assuming no objection by the other party, additional external advisors may also be included in this body on an ad hoc basis, as dictated by the circumstances. Either party may substitute alternate senior level representatives, on either a temporary or ongoing basis, by providing advance written notice.

Oversight Committee Members:

| | |
|---|---|
| John Rex, MD | AstraZeneca VP and Head of Infection GMO |
| Alex Oldham, Ph.D. | AstraZeneca Global Product VP |
| Paul Newell, MD | AstraZeneca Medical Science Director, Infection |
| Joseph Larsen | CBRN Deputy CBRN Division Director/BARDA |
| Melissa Stundick | Chief, Anti-infectives Program/BARDA |
| Richard Hatchet | BARDA Deputy Director |
| Carl Newman | Other Transaction Agreement Officer |

2. The responsibility of the Recipient/BARDA Joint OTAR Oversight Committee· is to mutually interrogate risks and progress of assets covered under this Agreement, endorse potential new assets and agree on modifications to the allocation of funding across activities covered under the Agreement. This Committee will also jointly evaluate achievement of Portfolio Progress Milestones.

3. The Recipient/BARDA Joint OTAR Oversight Committee will meet approximately every six (6) months to review progress. The Committee will recommend the strategy to be covered under this Agreement during the subsequent funding period, as well as how Government and Recipient funding will be allocated across these activities. The recommendations would be submitted, as appropriate, to the relevant Recipient governance board(s) for endorsement and decision. If endorsed by the relevant Recipient governance boards and by BARDA, the recommendations will be incorporated into the Statement of Work and this Agreement through modifications as described in ARTICLE Ill.

**B. Project Meetings**

1. Weekly Teleconferences. A conference call between the OTTR and the Recipient's principal investigator shall occur every two weeks or as directed by the OTTR. During this call, the principal investigator will discuss the activities· during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The principal investigator may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the OTTR. On an as needed basis, the OTTR or principal investigator may assign this responsibility to a delegate.

2. Kick-off and Quarterly Meetings. The Recipient and the Government shall participate in Project Meetings to coordinate the performance of the Agreement. These meetings may include face- to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Recipient and its subrecipients. Such meetings may include, but are not limited to, meetings of the Recipient (and subrecipients invited by the Recipient) to discuss study designs, site visits to the Recipients and subrecipient's facilities, and meetings with the Recipient and HHS officials to discuss the technical, financial, regulatory and ethical aspects of the program. These meetings wil·l also formulate and endorse the activities for the subsequent three months. In order to facilitate review of agreement activities, it is expected that the Recipient will provide data, reports, and presentations to groups of outside experts (subject to appropriate agreements to protect confidential or proprietary data) and Government personnel as requested by the OTTR. The Recipient shall provide itinerary/agenda at least 5 business days in advance of a face to face meeting. Subject to other provisions specified in this Agreement (see for example Attachment 2), the Recipient shall notify the OTTR of formal and informal correspondence with the Food and Drug Administration (FDA) or,other regulatory agencies as specified in Attachment 2.

3. In Process Review Meeting (IPR). On an annual or event driven basis, prior to the exercise of Agreement options, the Government will invite the Recipient to give a presentation at an In Process Review Meeting attended by BARDA, AMCG, and select, invited interagency representatives and other interested parties, as needed. The Recipient will present data generated under the Agreement. Progress against Portfolio Progress Milestones will be assessed. Successes and challenges of the program will be discussed and plans for the coming year will be presented. With respect to ATM-AVI, the Recipient will also provide updates on the separate COMBACTE-CARE project involving a Phase II and the European component of the Phase Ill trial in Europe.

**C. Document Review**

The Recipient shall provide BARDA sufficient opportunity to review study protocols, reports, and regulatory correspondence. BARDA's comments on these documents will be viewed as advisory in nature. Specific timelines for document review and responses are outline in Attachment 2 - Reporting Requirements.

Q

**ARTICLEV: AGREEMENT ADMINISTRATION**

**A. Administrative and contractual matters under this Agreement will be referred to the following representatives of the Parties:**

Government Points of Contact

Other Transactions Agreement Specialist (OTAS}
Juan Wooten
**202-692-4624**
Juan.wooten@hhs.gov

Other Transactional Agreement Officer (OTAO)
Carl Newman
202-205-1156
Carl.newman@hhs.gov

Recipient Points of Contact

Heidi Agostini, Ph.D
Director, Government Project Management
AstraZeneca Pharmaceuticals LP
One MedImmune Way
Gaithersburg, MD 20878
(301) **398-2483**
agostinih@medimmune.com

**B. Technical matters under this Agreement will be referred to the following representatives:**

Government Points of Contact

Other Transactional Authority Technical Representative (OTTR)
Christopher Houchens, Ph.D.
Project Officer, Anti-infectives Program
**202-205-3633**
christopher.houchens@hhs.gov

Alternate OTTR
Melissa Stundick, Ph.D.
Chief, Anti-infectives Program
**202-260-7479**
melissa.stundick@hhs.gov

Recipient Points of Contact

Recipient Program Manager:
Juliet McQuillan, MA, MSc
Director Global Products, Infection
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilmington, DE 19850
(302} 855-3329
juliet.mcquillan@astrazeneca.com

Alternate:
Alex Oldham, Ph.D.
Global Products Vice President, Infection
AstraZeneca
llF Mereside,
Alderley Park, Cheshire SKlO 4TF
England
44-7712-140-330
alex.oldham@astrazeneca.com

**ARTICLE VI: COST SHARING**

**A.** The terms of this Article VI apply to the cost sharing for the five (5) year base period for the clinical studies and registration activities for ATM-AVI. This framework may be applied by mutual agreement to any of the option periods or to any modifications to the effort required under the base period.

**B.** Recipient has entered into a separate agreement with COMBACTE-CARE to conduct Phase II clinical and a component of Phase Ill trials of ATM AVI within the European Union. COMBACTE-CARE's contribution is not included in the scope of work or cost sharing to be completed under this Agreementand the COMBACTE-CARE agreement is not a subcontract under this Agreement.

**C.** Based upon Recipient' s commercial estimating practices, Recipient estimates that the cost of the completing the five (5) year base period for ATM-AVI is $98,088,337. This amount reflects Recipient's estimate and may overstate or understate the actual cost of performing this Agreement. The Recipient agrees to fund a minimum of 20%, in the aggregate, of the activities proposed under the Base Period. Minimum cost sharing percentages for any Option periods will be subject to mutual agreement.

The total project cost of completing the five (5) year base period for ATM-AVI under this agreement shall include all costs incurred by the Recipient in connection with the work performed during the base period of performance (POP) that are reflected in Recipient's Financial Status Report. The Government's maximum obligation for the five (5) year base period for ATM-AVI is fifty million dollars ($50,000,000).

**TOTAL PROJECT COST SUMMARY**

| | |
|---|---|
| DIRECT LABOR | $8,411,775 |
| FRINGE BENEFITS | $3,394,266 |
| OVERHEAD | $27,000,415 |
| SUBCONTRACTS | $46,030,804 |
| MATERIALS | $6,309,779 |
| DIRECT TRAVEL | $1,194,079 |
| General & Administrative | $2,890,277 |
| Government Agreement Compliance Admin | $2,856,942 |
| **Total Costs** | **$98,088,337** |

**COST SHARE**

| | |
|---|---|
| **ASTRAZEN.ECA PHARMACEUTICALS LP** | **$48,088,337** |
| DIRECT LABOR | $8,411,775 |
| FRINGE BENEFITS | $3,394,266 |
| OVERHEAD | $27,000,415 |
| SUBCONTRACTS | $17,000 |
| **MATERIALS** | $44,500 |
| DIRECT TRAVEL | $1,194,079 |
| Other Direct Costs not funded by BARDA | $2,279,083 |
| General & Administrative | $1,253,942 |
| Government Agreement Compliance Admin | $1,239,479 |
| Voluntary AZ absorption of BARDA Portion of G&A And Contract Compiiance Admin | $3,253,798 |
| **US GOVERNMENT** | **$50,000,000** |
| **SUBCONTRACTS** | $46,013,804 |
| MATERIALS | $6,265,279 |
| Other Direct Costs not funded by BARDA | $-2,279,083 |
| General & Administrative | $1,636,335 |
| Government Agreement Compliance Admin | $1,617,463 |
| Voluntary AZ absorption of BARDA Portion of G&A And Contract Compliance Admin | $-3,253,798 |

**PROJECTED FUNDING PROFILE**

| Government Fiscal Year | Total Program | Government Share |
|---|---|---|
| **FY15** | **$98,088,337** | **$50,000,000** |
| **FY16** | **TBD** | Up to $30,000,000 |
| **FY17** | **TBD** | Up to $30,000,000 |
| **FY18** | **TBD** | Up to $30,000,000 |
| **FY19** | **TBD** | Up to $30,000,000 |

Q

**D.** BARDA will reimburse Recipient for Recipient's actual direct costs paid to approved subrecipients under this Agreement and materials during the Base Period up to the amounts obligated to this Agreement in paragraph C of this Article.

**E.** Recipient will not be entitled to reimbursement for its program management costs, including all indirect costs. The costs that are not subject to reimbursement under this Agreement constitute Recipient's contribution or cost share of performing the Statement of Work. This contribution may include Recipient efforts to manage the clinical studies performed by COMBACTE-CARE but will not include the direct costs of these clinical studies.

**F.** Recipient will provide a Financial Status Report to BARDA identifying the total actual costs of performing this Agreement. This report. is for informational purposes only. Recipient's accounting for government-reimbursed and Recipient costs shall be in accordance with Recipient's accounting practices but must comply with Generally Accepted Accounting Principles or other international standards. Recipient's accounting in order to determine total actual costs is not required to comply with the Cost Accounting Standards or the cost principles at Federal Acquisition Regulation Subpart 31.2; however, Recipient must comply with the cost principles set forth in Article VII for Government reimbursed costs.

**G.** For purposes of the Financial Status Report, Recipient shall report Recipient costs of performing this Agreement using the indirect rates identified in its June 29, 2015, Cost Proposal to determine its actual costs for the duration of the Base Period. Recipient's costs charged to the project must be allocated to the project on the basis of beneficial and causal relationships.

**H.** Recipient's entitlement to reimbursement for its actual direct costs paid to approved subRecipients under this Agreement is not contingent upon Recipient's cost share equaling any specific ratio or percentage of total costs. The Parties' sole remedy to address the total cost exceeding or falling below the estimated total cost to perform the Statement to Work .is to agree to a mutual modification of the Agreement or termination of the Agreement.

**ARTICLE VII: OBLIGATION AND PAYMENT**

**A. Obligation**

The Government's liability to make payments to the Recipient is limited to only those funds obligated under the Agreement or by modification to the Agreement. The Government's obligated funds for the Base Period and the optional periods is set forth in Article *VI.* The parties agree that the optional periods of performance do not represent an obligation by the government until exercised, following a negotiation on scope and cost.

**B. Payments**

The Recipient has an established and agrees to maintain an established accounting system which complies with Generally Accepted Accounting Principles and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds. An acceptable accounting system is one in which all costs, cash receipts and disbursements for which Recipient is entitled to reimbursement under Article VI are controlled and documented properly. The Recipient will invoice the Government on a monthly basis in accordance with

Article VII. The Recipient's shared costs incurred during the reporting period shall be reported in the Financial Status Report and monthly invoice. The Recipient properly prepared invoice(s) will be submitted for payment not more than once per month in Adobe Acrobat (.pdf) format. The invoice shall be uploaded to a shared electronic file server, with an email copy to the OTAO, OTAS and OTIR cited below. As directed by the OTAO, the invoice shall be accompanie by adequate documentation to support the payment. After verification of the accomplishment of the work for which reimbursement is sought by the OTAO, the OTAS and OTTR will forward the invoice(s) to the.Program Support Center (PSC). Each invoice must contain the following information in order to be deemed properly prepared:

1. Name and address of Recipient
2. Invoice Date and Invoice Number
3. Agreement Number
4. Description, quantity, unit of measure, unit price, and extended price
5. Recipient Cost Share
6. Name and address of OTAR official to whom voucher is to l;>e sent
7. Name, title, phone number, and mailing address of person to notify in the event of a defective invoice.
8. Taxpayer Identification Number (TJN)
9. Electronic funds transfer (EFT) banking information.

Documents should be delivered electronically to the OTAO, OTAS, OTTR, PSC, and e-room electronically. Unless otherwise specified by the OTAO all deliverables and reports furnished to the Government under the resultant Agreement (including invoices) shall be addressed as follows:

| | | |
|---|---|---|
| **NAME**<br>Carl Newman (OTAO)<br>carl.newman@hhs.gov<br><br>and<br><br>Juan Wooten (OTAS}<br>Juan.Wooten@hhs.gov<br><br>**HHS/ASPR/AMCG**<br>330 Independence Avenue, S.W., Room G640<br>Washington, DC 20201<br>Email: Name@hhs.gov | **NAME**<br>Christopher Houchens (OTTR)<br>christopher.houchens@hhs.gov<br><br>**HHS/ASPR/BARDA**<br>330 Independence Avenue, S.W., Room G640<br>Washington, DC 20201<br>Email: Name@hhs.gov | Email invoices to:<br><br>PSC lnvoices@psc.hhs.gov<br><br>and<br><br>E-Room:<br><br>Link: TBD |

Monthly invoices must include the cumulative total costs submitted for reimbursement to date, adjusted (as applicable) to show any amounts suspended by the Government.

The Recipient will convert foreign currency costs to US dollars each month using the closing spot exchange rate published by Reuters on the last working day of each month at:

http://www.reuters.com/finanee/currencies/quote?srcAmt'"1.00&srcCurr'"GBP& destAmt=&destCurr=USD

The Recipient agrees to promptly notify the OTAO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base segment or any option segment{s) and the reasons for the variance.

The Government will pay in US dollars all proper invoices within 30 days of receipt or pay interest on any amounts due in accordance with the Prompt Payment Act.

**C. Limitation of Payments**

It is herein understood and agreed that Government funds are to be used solely for this Agreement and must be reasonable in nature and amount. The following cost principles are effective under this agreement for determining the allowability of costs for which reimbursement is sought under this Agreement. The cost principles are not applicable to Recipient's contribution and the Financial Status Report.

1. Allocability shall be determined in accordance with the standards set forth in FAR § 31.201-4. The Cost Accounting Standards do not apply to the Recipient or any subRecipient. Costs shall be accounted for in accordance with the Recipient's or subRecipient's commercial accounting practices.

2. To be reasonable, a cost must: be generally recognized as an ordinary or necessary part of the business; follow sound business practices; follow what a prudent bus.iness person would accept; comply with federal, state, and local laws; and be consistent with the Recipient's or subRecipient's established practices.

3. In addition, Recipient's costs that are passed onto the Government for reimbursement shall comply with the procedures and cost principles set forth in this paragraph:

(a) Reimbursement is subject to restrictions on allowable costs listed in Attachment 5. It is anticipated that this list will require revision and the Government and the Recipient agree to update this list in a timely manner.

(b) The cost principles set forth in subparagraphs (a) shall only apply to the reimbursement of direct costs under cost-type subAgreements. These cost principles will be applicable to the pricing of fixed priced subAgreements only to the extent required by FAR31.102.

(c) A cost-type subRecipient will propose indirect rates as a component of its proposal to Recipient. The Government will review these indirect rates as part of the subRecipient approval process set forth in Article XIII. . The Government's approval to issue the subAgreement constitutes the Government's agreement that the proposed indirect rate(s) may be used during the performance of the subAgreement to determine the subRecipient's reimbursable indirect costs. The apprnved indirect rate(s) will not be subject to audit or adjustment based upon the subRecipient's actual cost experience during the performance of thesubAgreement.

**D. Financial Records and Reports**

As directed by the OTAO, the Recipient shall maintain adequate records to account for all funding under this Agreement and shall maintain adequate records to account for Recipient funding provided under this Agreement in support of the Financial Status Report required under Article VI. Upon completion or termination of this Agreement, whichever occurs earlier, the Recipient Administrator shall furnish to the OTAO a copy of the financial report required by Attachment 2, Section *D:* Deliverables. The Recipient's relevant financial records are subject to examination or audit on behalf of HHS by the Government for a period not to exceed three (3) years after expiration of the term of this Agreement. The OTAO or designee shall have direct access to sufficient records and information of the Recipient, to ensure full accountability for all amounts reimbursed by HHS under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon at least two weeks prior written notice and shall be subject to the security requirements of the audited party.

**E. Comptroller General Access to Records**

To the extent that the total Government payment under this Agreement exceeds $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records relating to performance under this Agreement of any entity that participates in the performance of this Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any entity that participates in the performance of the Agreement that has not entered into any other Agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a Government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement.

**ARTICLE VIII: DISPUTES**

**A. General**

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

**B. Dispute Resolution Procedures**

1. For any disagreement, claim or dispute between HHS and the Recipient concerning questions of fact or law arising from or in connection with this Agreement, whether or not involving an alleged breach of this Agreement, the Parties agree to make a Good Faith effort to utilize the procedures described in paragraphs 2, 3 nd 4 of this Article.

2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which was known, or should have been known, more than six (6) months prior to the notification made under subparagraph B.3 of this Article constitute the basis for relief under subparagraph 8.3 of this Article. Either party may waive this requirement. Any waiver on behalf of HHS shall be made by the Head of Contracting Activity for AMCG.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the OTAO or the Recipient's Administrator, as the case may be} in writing of the relevant facts, identify unresolved issues, and specify the clarification or remedy sought. Within five (5} working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the HHS Senior Procurement Executive, and a Recipient Senior Executive appointed by the Recipient. The other Party shall submita written position on the matter(s) in dispute wit_hin thirty (30} calendar days after being notified that a decision has been requested. The HHS Senior Procurement Executive and the Recipient Senior Executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty {30) calendar days of receipt of such written position.

4. In the absence of a joint decision, upon written request to the HHS, made within thirty (30) calendar days of the expiration of the time for a decision under subparagraph B.3 above, the dispute shall be further.reviewed. The Assistant Secretary for Preparedness and Response (ASPR) HHS may elect to conduct this review personally or through a designee or jointly with a Senior Executive appointed by the Recipient. Following the review, the Secretary of HHS or designee will resolve the issue(s) and notify the Parties in writing. If a decision has not been made within 120 days the request may be deemed denied.

5. The parties stipulate that any decision reached under B.4 of this Article, including a deemed d·enial, may be submitted to the Court of Federal Claims or the Court of Appeals for the Federal Circuit to the extent permitted by law.

6. The pendency of a dispute shall not interfere with each Party's right to terminate the Agreement pursuant to Article JI.B and recover any resulting terminations costs.

**C. Limitation of Damages**

Except for claims of non-payment of amounts due under Article VI, any claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of HHS funding disbursed as of the time the dispute arises. In no event shall Recipient or HHS be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, re-procurement costs, or other indirect damages. Either party may recover interest on any amounts submitted for payment and denied during the disputes process. Interest on an amount found due on a disagreement, claim or dispute shall be paid for the period beginning with the date the HHS Senior Procurement Executive receives a request for a joint decision made pursuant to subparagraph B.3 of this Article until the date of payment of the claim. Simple interest shall accrue and be paid at the same rate as that which the Secretary of the Treasury shall specify as applicable for each successiye 6-month period under the Prompt Payment Act.

**ARTICLE IX: DATA RIGHTS**

**A. Allocation ofPrincipal Rights**

1. For Data other than computer software, the Recipient grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, nontransferable, nonsublicensable, irrevocable, worldwide license in such Data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government, subject to the limitations

applicable to the Government's use of Limited Rights Data and except as expressly provided elsewhere in this Agreement. For computer software,,the Recipient grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of the Government.

2. Data in any document that would disclose a Subject Invention will be subject to Limited Rights until publication of patent application in accordance with Article X of this Agreement.

3. Recipient agrees to retain and maintain in good condition all Data necessary to achieve Practical Application of any Subject Invention in accordance with the Recipient's established record retention practices. In the event of exercise of the Government's March-in Rights as set forth under Article X, Recipient agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request. The Government shall retain Limited Rights, as defined in Article I above, to this delivered **Data.**

4. Recipient's right to use Data is not restricted and includes he right under Recipient's established business policies to make public research data (especially human research data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by makingtrial patient-level data available for third-party analysis.

5. The parties acknowledge that Recipient may grant access to Data to participants in the COMBACTE-CARE consortium to the extent necessary to fulfil obligations under the COMBACTE-CARE project agreement. The parties further acknowledge that clinical data developed in the course of ATM-AVI trials delivered by COMBACTE-CARE may be subject to data restrictions in the COMBACTE-CARE project agreement and the Government agrees to abide by these restrictions to the extent permitted by law. The participants in the COMBACT-CARE consortium have agreed to provide BARDA with access to ATM-AVJ related data arising from clinical studies delivered under the COMBACTE-CARE project agreement.

**B. Marking of Data**

Pursuant to paragraph A above, the Recipient will mark any Data delivered under this Agreement with Limited Rights with the following legend:

"LIMITED RIGHTS" The Government's right to use, modify, reproduce, perform, display, or disclose this Data is restricted by Agreement HHS0100201500029C between the Government and the Recipient (disclosure is limited within the Government). Any reproduction of this Data or portions thereof marked with this legend must also reproduce the markings."

**C. Lower Tier Agreements**

The Recipient shall include this Article, suitably modified to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

**D. Identification and Disposition of Data**

The recipient shall keep copies of all Data required by the Food and Drug Administration (FDA) relevant to this Agreement for the time specified by the FDA. In addition, the Recipient shall provide regulatory data to the OTIR and OTAS in accordance with Attachment 2: Reporting Requirements. HHS reserves the right to review any other data determined by HHS to be relevant to this Agreement. HHS further acknowledges that, with respect to ATM-AVI, Actavis holds the commercialization rights in the US and will be responsible for registration with the FDA.

**E. Publication and Publicity**

No Data obtained under this Agreement shall be released or publicized without concurrence from the Recipient. For purposes of this Agreement, "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing Data generated under this Agreement must be submitted to the Recipient and the OTIR for review and comment no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. BARDA support shall be acknowledged in all such publications substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health a.nd Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under OT number HHS0100201500029C.

The parties acknowledge that the European Innovative Medicines Initiative and the COMBACTE-CARE are not subject to the obligations in this Section E. Recipient agrees to provide the Government with advance notice of any planned publication of ATM-AVldata. by COMBACTE-CARE and to take reasonable efforts to coordinate any publication plans between the COMBACTE-CARE consortium and the Government. BARDA further acknowledges that Recipient will acknowledge the contribution of the IMI and COMBACTE-CARE in any publication or press release involving Data deyeloped during performance of the COMBACTE-CARE project agreement.

**F. Review of Press Releases**

Recipient agrees to accurately and factually represent the work conducted under the OTA in all press releases. Misrepresenting results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to ariy medium, excluding peer-reviewed scientific publications. Each party agrees to provide the other with an advance copy of any press release related to the OTA not less than ten (10) business days prior to the issuance of the press release. BARDA support shall be acknowledged in all such press releases substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under OT number HHS0100201500029C.

**ARTICLE X: PATENT RIGHTS.**

**A. Allocation of Principal Rights**

Unless Recipient shall have notified HHS (in accordance with subparagraph C.2 elow) that Recipient does not intend to retain title, in which case title shall vest with the Government, Recipient shall retain the entire right, title, and interest throughout the world to each Subject Invention developed under this Agreement, consistent with the provisions of this Article and 35 U.S. § 202. With respect to any Subject Invention developed under this Agreement, in which Recipient retains title, HHS shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. For any Subject Invention relating to ATM-AVI, this license is restricted to practice of such Subject Invention for use in the Field.

**B. Invention Disclosure, Election of Title, and Filing of Patent Application**

1. Recipient shall disclose each Subject Invention to HHS within four (4) months after the inventor discloses it in writing to his/her company personnel responsible for patent matters. The disclosure to HHS shall be in the form of a written report and shall identify the Agreement under which the Subject lm!'ention was made and the identity of the inventor(s). It shall be sufficiently_ complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention. The disclosure shall also identify any publication, sale, or public use of the Subject Invention and whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. Recipient shall also submit to HHS an annual listing of Subject Inventions.

2. If Recipient determines that it does not intend to retain title to any such Subject Invention, Recipient shall notify HHS, in writing, within two (2) years of disclosure to HHS. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by HHS to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

3. Recipient shall file its initial patent application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. Recipient may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

4. Requests for extension of the time for disclosure election, and filing under this Article X, paragraph B, may, at the discretion of HHS, and after considering the position of Recipient, be granted.

**C. Conditions When the Government May Obtain Title**

Upon HHS's written request, Recipient shall convey title to any Subject Invention to HHS under any of the following conditions:

1. Jf Recipient fails to disclose or elects not to retain title to the Subject Invention within the times specified in paragraph B of this Article; provided, that HHS may only request title within sixty (60) calendar days after learning of the failure of Recipient to disclose or elect within the specified times.

2. In those countries in which Recipient fails to file patent applications within the times specified in paragraph B of this Article; provided, that if Recipient has filed a patent application in a country after the times specified in paragraph B of this Article, but prior to its receipt of the written request by HHS, Recipient shall continue to retain title inthat country; or

3. In any country in which Recipient decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

**D. Minimum Rights to Recipient and Protection of Recipient's Right to File**

1. Recipient shall retain a nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if Recipient fails to disclose the invention within the times specified in paragraph B of this Article. The Recipient license extends to the Recipient's subsidiaries and affiliates, if any, within the corporate structure of which Recipient is a party and includes the right to grant licenses of the same scope to the extent that Recipient was legally obligated or permitted to do so at the time the Agreement was executed. The license is otherwise transferable only with the.approval of HHS, except when transferred to the successor of that part of Recipient's business to which the Subject invention pertains. HHS approval for license transfer shall not be unreasonably withheld.

2. The Recipient license may be revoked or modified by HHS to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or non«;!xclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Recipient's license shall not be revoked in that field of use or the geographical areas in which Recipient has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

3. Before revocation or modification of Recipient's license, HHS shall furnish Recipient a written notice of its intention to revoke or modify the license, and Recipient shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

**E. Action to Protect the Government's Interest**

1. Recipient agrees to execute or to have executed and promptly deliver to HHS all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Recipient elects to retain title, and (ii) convey title to HHS when requested under paragraph D of this Article and to enable the Government to obtain patent protection throughout the world in that Subject Jnventior:,.

2. Recipient agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters .and in a format suggested by Recipient each Subject Invention made under this Agreement in order that Recipient can comply with the disclosure provisions of

paragraph C of this Article. Recipient shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

3. Recipient shall notify HHS of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

4. Recipient shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement HHS01002015D0029C, awarded by HHS. The Government has certain rights in the invention."

**F. Lower Tier Agreements**

Recipient shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

**G. Reporting on Utilization of Subject Inventions**

1. Recipient agrees to submit, during the term of the Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Recipient or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by Recipient, and such other data and information as the agency may reasonably specify. Recipient also agrees to provide additional reports as may be requested by HHS in connection with any march-in proceedings undertaken by HHS in accordance with paragraph H of this Article. Consistent with 35 U.S.C. § 202(c)(S), HHS agrees it shall not disclose such information to persons outside the Government without permission of Recipient.

2. All required reporting shall be submitted to the OTAS, OTAO, and OTTR.

**H. March-in Rights**

The Recipient agrees that, with respect to any Subject Invention in which it has retained title, HHS. has the right to require Recipient, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license within the Field to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Recipient, assignee, or exclusive licensee refuses such a request, HHS has the right to grant such a license within the Field itself if HHS determines that:

1. Such action is necessary because Recipient or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve Practical Application of the Subject Invention; or

2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by Recipient, assignee, or their licensees.

**ARTICLE XI: FOREIGN ACCESS TO TECHNOLOGY**

This Article shall remain in effect during the term of the Agreement and for five (S) years thereafter.

**A. General**

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national security, and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. Recipient agrees to comply with all applicable laws regarding export controls and not to export any Technology to any US embargoed countries.

The Recipient shall provide timely notice to HHS of any proposed transfers from the Recipient of Technology developed under this Agreement to Foreign Firms or Institutions; provided that, this Article shall not apply to transfers by Recipient of Technology to affiliates of Recipient or as part of the sale, merger, or acquisition of Recipient, or as part of the sale or transfer of that part of Recipient's business to which the Technology developed under this Agreement pertains. If HHS determines that a transfer may have adverse consequences to the national security interests of the United States, the Recipient, its vendors, and HHS shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to the Recipient.

In any event, the Recipient shall provide written notice to the OTIR and OTAO of any proposed transfer to a foreign firm or institution at least thirty (30) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within fifteen (15) calendar days of receipt of the Recipient's written notification, the OTAO shall advise the Recipient whether it consents to the proposed transfer. In cases where the OTAO does not concur or fifteen (15) calendar days after receipt and HHS provides no decision, the Recipient may utilize the procedures under Article VI, Disputes. However, no transfer shall take place until a decision is rendered.

In the event of a transfer of Technology by Recipient to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to Federal Acquisition Regulation Subpart 25.7: (a) the Government may terminate this Agreement for cause and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government, the Recipient shall provide written confirmation of such licenses.

**B. Lower Tier Agreements**

The Recipient shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

**ARTICLE XII: TITLE TO AND DISPOSITION OF PROPERTY**

The Government is solely reimbursing subrecipients and materials up to the limits set forth in Article VI and Government fundi.ng is not being used to acquire any property or equipment.

**ARTICLE XIII: SUBRECIPIENTS**

For any firm-fixed price, time and materials, or labor hour subAgreement reimbursed under this Agreement with a value in excess of $150,000 or any cost-reimbursable contracts, the Recipient will provide the OTAO the opportunity to review all subcontracting agreements and related justification for cost or price reasonableness ten {10) calendar d ys before execution. This shall include the nature of the work that the subrecipient is going to perform, an estimated period of performance and the proposed costs for the work. The OTAO will in submit a written response within ten (10) calendar days stating approval or disapproval of the subrecipient agreement. In the event that the OTAO disapproves of the subrecipient agreement, the OTAO must provide written.justification to support his/her decision. If a written response is not provided by the OTAO within. ten (10) calendar days, the recipient will elevate concerns to the AR&D Section Chief to immediately address the outstanding request. Recipient will provide the OTAO with an el.ectronic copy of the final subcontracting document.



**ARTICLE XIV: CIVIL RIGHTS ACT**

Performance of this Agreement in the US is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended {42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. The Recipient has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

**ARTICLE XV: EXECUTION**

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the Recipient and the HHS OTAO. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of whi'ch taken together shall constitute one and the same instrument.

**ARTICLE XVI: SPECIAL CLAUSES**

**A. Protection of Human Subjects**

1. The Recipient agrees that the rights and welfare of human subjects involved in research under this OTA shall be protected in,accordance with 45 CFR Part 46 and with the Recipient 's current Assurance of Compliance on file with the Office for Human Research Protections {OHRP), Office of Public Health and Science (OPHS}. The Recipient further agrees to provide certification that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects, in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Recipient shall bear full responsibility for the performance of all work and services involving the use of human subjects under this Agreement and 'shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that Recipient retains the right to control and direct the performance of all work under tMs OTA. Nothing in this OTA shall be deemed to constitute Recipient or any sub consortium, agent or employee of Recipient, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government.

Recipient agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent consortium without imputing liability on the part of the Government for the acts of the Recipient or its_ employees.

3. Jf at any time during the performance of this OTA, the HHS OTAO's determines, in consultation with the OHRP, OPHS, ASH, that the Recipient is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this OTA until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to. complete corrective action within the period of time designated in the OTAO's written notice of suspension, the HHS OTAO may, in consultation with OHRP, OPHS, ASH, terminate this Agreement in a whole or in part, and the Recipient's name may be removed from the list of those performers with approved Health and Human Services Human Subject Assurances.

**B. Human Materials (Assurance of OHRP Compliance)**

1. The acquisition and supply of all human specimen material (including fetal material) used under this OTA shall be obtained by Recipient in full compliance with applicable Federal, State and Local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

2. The Recipient shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this OTA, by collaborating sites, or by subrecipients identified under this OTA, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Recipient.

3. Provision by the Recipient to the HHS OTAO's of a properly completed "Protection of Human Subjects Assurance Identification/IRS Certification/Declaration of Exemption", Form 0MB No. 0990-0263 (formerly Optional Form 310), certifying IRS review and approval of the protocol from which the human materials, were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRS Certification/ Declaration of Exemption", Form OMS No. 0990-0263(formerly Optional Form 310).

**C. Research Involving Human Fetal Tissue**

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart S. The Recipient shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Recipient.

**D. Needle Exchange**

The Recipient shall not use Agreement funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

**E. Care of Live Vertebrate Animals**

1. Before undertaking performance of any OTA involving animal related activities, the Recipient shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Recipient shall furnish evidence of the registration to the Agreement Officer.

2. The Recipient shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.

3. The Recipient agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this OTA will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture **(see** 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1- 4). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this Agreement, the HHS OTAO's determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Recipient is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this Agreement until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the HHS OTAO's may, in consultation with OLAW, NIH, terminate this Agreement in whole or in part, and the Recipient's name may be removed from the list of those organizations with approved PHS Animal Welfare Assurances.

**Note:** The Recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office below or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

**F. Animal Welfare**

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: http://grants1.nih.gov/grants/o1aw/references/phspo1.htm. Primate studies will not begin until the CRO's IACUC and the Recipient's Animal Welfare Department provide final approval of the study protocol.

**G. Protection of Personnel Who Work with Nonhuman Primates**

All Recipient personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled,

"Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http:ljwwwl.od.nih.gov/oma/manualchapters/intramural/3044-2/.

**H. Information on Compliance with Animal Care Requirements**

Registration with the U.S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http:ljwww.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http:ljgrants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http:ljgrants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Recipient does not have an assurance and will be utilizing a subrecipient to perform the animal work then the Recipient and subrecipient must have an Inter-Institutional Assurance in place to allow the Recipient to utilize the assurance of the subrecipient to meet the HHS requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by BARDA on behalf of the Recipient..

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals http:ljwww.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http:ljawic.nal.usda.gov/final-rules-animal-welfare-9-cfr-parts-1-2-and-3 issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http:ljwww.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given" the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies http://www.fass.org.

**I. Approval of Required Assurance by Law**

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Recipient for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Recipient under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 is submitted by Recipient 30 days prior to commencing research involving live vertebrate animals and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve Jive vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-

2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants.nih.gov/grants/olaw/olaw.htm.

Registration with the Select Agent Program for Work Involving the Possession, Use, and/or Transfer of .Select Biological Agents or Toxins

Work involving select biological agents or toxins shall not be conducted under this Agreement until the Recipient and any affected subrecipients are granted a certificate of registration or are authorized to work with the applicable select agents.

Q

For prime or subagreements awards to domestic institutions who possess, use, and/or transfer Select Agents under this OTA, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subagreements awards to foreign institutions who possess, use, and/or transfer Select Agents under this OTA, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsore.d by these funds before using these funds for any work directly involving the Select Agents. The Recipient must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the OTAO, the Recipient shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Recipient must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and ppropriate individuals have access to Select Agents under the OTA.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

**J, Product Approval**

The Recipient agrees to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents.

The Recipient agrees to advise the HHS OTAO and OTTR promptly of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility during the term or this Agreement. The Recipient also agrees to advise the HHS OTAO's and OTTR immediately if at any time during the term of this Agreement, the items under this OTA fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

**K. Manufacturing Standards**

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of this OTA, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CDER, the Recipient shall have sixty (60) calendar days from the time such material failure is identified to initiate corrective action designed to cure such material failure within three (3) months. If the Recipient fails to initiate such an action within the sixty (60) calendar day period, then the Agreement may be terminated.

**L. Anti-Bribery and Anti-Corruption**

HHS acknowledges that it has received and read Recipient's 'Prevention of Corruption - Third Party Guidelines'. Each Party agrees to perform its obligations under this Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Agreement, to terminate this Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article XVI Section M.

**M. Salary Rate Limitation**

1. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date an expense is incurred is an unallowable cost under this Agreement and shall be addressed in accordance with Article VII.C.

2. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. A.n individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under the OTAR. Direct salary excludes any income that an individual may be permitted to earn outsid of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also .referred to as indirect costs or facilities and administrative [F&A] costs).

**Note:** The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract, order, or OTAR; it merely timits the portion of that salary that may be paid with Federal funds.

3. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year OTAR, it may be subject to unilateral modification by the OTAO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

4. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

**N. Man-In-Plant**

With seven (7) days advance notice to the Recipient in writing from the OTAO/OTAS, the Government may place a man-in-plant in the Recipient's facility, who shall be subject to the Recipient's policies and procedures regarding security and facility access at all times while in the Recipient's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Recipient plant.



**O. Reporting Matters Involving Fraud, Waste and Abuse**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

**P. Prohibition on Contractor Involvement with Terrorist Activities**

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Agreement.

**Q, Materials Transfer Agreement**

For distribution to third-party parties of any material developed under this Agreement, the Recipient must provide BARDA and AMCG a Materials Transfer Agreement (MTA). Following finalization of the MTA, the Recipient must provide notice of the requests/transfers in the monthly technical report along with copies of the final MTA.

With respect to ATM-AVI, the Government acknowledges that the European component of the clinical trials delivered by the COMBACTE-CARE project agreement are not subject to this restriction and that Recipient may transfer materials necessary to satisfy Recipient's obligations under that agreement in accordance with the requirements of the COMBACTE-CARE project agreement. The Government further acknowledges the right of Recipient to transfer material to Actavis and any successor to Actavis interests without Government notice or approval.

**R. Inspection and Acceptance**

1. The OTAO or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this Agreement.

2. For the purpose of this Section, the designated OTTR is the authorized representative of OTAO. The OTTR will assist in resolving technical issues that arise during performance. The OTTR; however, is not authorized to change any OTA terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

3. Inspection and acceptance will be performed at:

Biomedical Advanced Research and Development Authority/Office of Acquisition Management, Contracts, and Grants (AMCG)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 Independence Ave, SW Room G644
Washington, D.C. 20024

**ARTICLE XVII: TRANSFERS & ASSIGNMENTS**

All transfers and/or assignment will be conducted in a manner that is consistent with the Assignment of Claims Act (31 U.S. Code § 3727) and the Prohibition on transfer of contract and certain allowable assignments (41 U.S.C.A. § 6305).

**ATTACHMENT** 1:
**STATEMENT OF WORK**

Revision 1 as of 09/09/2015

Proposed Duration of Effort: 60 Months
Recipient: AstraZeneca Pharmaceuticals

Q

## Statement bf Work

**Overall Objectives and Scope**

The overall objective of this Agreement is to advance the development of a portfolio of antibacterial therapeutics for the treatment or prevention of multi-drug resistant (MDR) infections. The Parties agree to focus their initial efforts on completing preclinical, clinical, and manufacturing development activities, and associated regulatory, quality assurance, management, and administrative activities to support the registration of ATM-AVI. The Research and Development (R&D) effort for ATM-AVI and antimicrobial portfolio will progress in specific stages that cover the Base Period, and Option Periods as specified in this Agreement. The Contractor must complete specific tasks required in each of the discrete Work Periods.

The scope of work has been broken into a Base Period and four Potential Option Periods:

1. Base Period: CUN #1
2. Potential Option Period #1: CUN #2
3. Potential Option Period #2: CUN #3
4. Potential Option Period #3: CUN #4
5. Potential Option Period #4: CUN #5

The CUN structure and the specific SOW items within each CUN are based on current plans and are subject to modification under this Agreement as the development plan for each compound progresses and funding allocations are agreed upon between the Recipient and BARDA.

**1.0 Base Period: CUN #1**

**1.1 Program Management (WBS 1.1)**

Perform Agreement administration, biothreat study coordination, technical management, subrecipient management, regulatory support, and financial management of the Agreement. Communicate with the Government and ensure timely delivery of all deliverables required under the Agreement.

**1.2 Non-Clinical Toxicology (WBS 1.2)**

Perform ADME, DMPK, and/or toxicology/exploratorytoxicology/reproductive toxicology studies. These studies may be GLP and/or non-GLP studies that are required for the characterization of the non-clinical safety assessment of the compound and for understanding the PK, absorption, distribution, metabolism and excretion processes for a compound. The scope may also include other studies as required by regulatory authorities or as needs arise based on emergent data for any of the antibacterial candidates within the portfolio.

**1.3 Non-Clinical Studies (WBS 1.3)**

**1.3.1 Microbiology (WBS 1.3.2)**

Generate *in vitro* and *in vivo* data with public health or biothreat pathogens to support progression and registration of the compound. This may include, but may not be limited to characterization of *in vitro* microbiological attributes, development and evaluation of antimicrobial susceptibility test methods,

resistance testing, anti-infective property determination, surveillance studies; PK/PD, and performing the experiments necessary *(in vitro, in vivo)* to define target *in vivo* exposures to support clinical studies. Additionally, efforts may include the development and use of diagnostic devices to help enrich the target patient population recruited into a clinical study.

1.3.1.1 Yearly surveillance studies to evaluate the potency of ATM-AVI against contemporary Gram-negative pathogens of -interest. The bacterial organisms will be collected from. multiple centers in numerous countries covering the main geographical areas of North America, Latin America, Europe, Asia/Pacific, and Middle East/Africa. Susceptibility testing using ATM-AVI and numerous comparator compounds will be_performed using standard broth micro dilution testing methods. These studies will enable an understanding of the spectrum of microbiological ihhibition afforded by ATM-AVI, and will also enable the evaluation of any emerging resistance trends.

Q

**1.3.2 Efficacy and Safety (WBS 1.3.3)**

Perform in vivo efficacy studies to assess efficacy of candidate antibacterials in suitable animal models of disease, including but not limited to therapeutic dose determination and modeling.

**1.4 Clinical studies (WBS 1.4)**

Perform Phase 1, Phase 2 and/or Phase 3 clinical studies to provide robust information for product labeling including dosage, treatment duration, efficacy, safety and tolerability as they relate to particular disease settings.

**1.4.1** Set up activities, commence study and complete recruitment, results analyses and deliver a study report for a Phase 3 pivotal study with ATM-AVI. As set forth in the Agreement, Recipient's ability to deliver a study report for a Phase 3 pivotal study is dependent in part on successful performance of the European component under the COMBACTE-CARE project agreement, and non-performance or delay under that project agreement will constitute an excusable delay. Schedule risk for the COMBACTE-CARE project will be mitigated by Recipient's scientific leadership of the projects and progress monitoring infrastructure, including periodic reporting to the IMI executive office, that can result in significant project amendments to improve performance and, in exceptional circumstances, to Recipient's withdrawal of ATM-AVI from the project.

**1.4.2** Perform non-intervention studies to examine practice patterns for patients who have MBL to profile costs and outcomes for managing these patients. This data will be used to develop and populate an economic model which is a core requirement for payer dossiers.

**1.4.3** Perform Resistant Pathogen Study Set-up activities with ATM-AVI.

**1.5 Regulatory Affairs (WBS 1.5)**

Work with Actavis to prepare and file submissions to regulatory authorities including, but not limited to, IND filings, updates to a filed IND, study report submission, protocol submission, NDA filings, sNDA filings. Request and participate in meetings with regulatory agencies and prepare post-meeting documentation.

**1.5.1** Prepare materials for and request, schedule and participate in a joint meeting with the FDA and EMA. Provide BARDA with (i) the initial draft and final FDA minutes and (ii) the written Scientific Advice received from the EMA.

**1.5.2** Submit the Phase 3 protocol for Special Protocol Assessment (SPA) feedback, if necessary.

**1.5.3** Prepare documents and submit the IND with clinical trial protocol(s) to include the Phase 3 study protocol. IND amendments will be submitted as needed to support the clinical trial program.

**1.5.4** Prepare and submit the Clinical Trial Applications in Europe, etc., as needed to conduct the Phase 3 study. Amendments to the CTAs will be submitted as needed to support the clinical trial program.

**1.6 Chemistry Manufacturing and Controls**

**1.6.1** Perform formulation and manufacturing development for the ATM-AVI product to define the formulation, develop the intermediate drug product blend, initial manufacturing process development and development of analytical methods.

**1.6.2** Perform L-arginine and AVI Drug Substance technology transfer and establishment activities to accommodate the process in their plant

**1.6.3** Manufacture, analyze, and clear clinical trial materials (Avi lyophile).

**1.6.4** Perform Packaging, storage & Distribution of Clinical Trial supplies for Phase 3, RP and Renal Impairment/DOI study and ordering of comparators.

**1.6.5** Secure the order of Final Intermediate (SU) for the manufacture of AVI Drug Substance Licensure batches.

*All of the activities detailed above are non-severable activities. All of the activities detailed above will be completed within the base period of performance, none will span option segments. Each will be fully funded with base period funding.*

**2.0 Potential Option Period #1: CLIN #2 (Oct'16-Sept'17)**

Activities include, but are not llmited to, program management, non-clinical, clinical, biodefense, regulatory and CMC activities to advance the portfolio program. Additional activities may be added if determined to be necessary to support the advancement of the portfolio program.

*All of the activities detailed above are non-severable activities. All of the activities detailed above will be completed within Option Period #1, none will span other performance segments. Each will be fully funded with Option Period #1 funding.*

**3.0 Potential Option Period #2: CLIN #3 (Oct'17 - Sept'18)**

Activities include, but are not limited to, program management, non-clinical, clinical, biodefense, regulatory and CMC activities to advance the portfolio program. Additional activities may be added if determined to be necessary to support the advancement of the portfolio program.

*All of the activities detailed above are non-severable activities. All of the activities detailed above will be completed within Option Period #2, none will span other performance segments. Each will be fully funded with Option Period #2 funding.*

**4.0 Potential Option Period #3: CLIN #4 (Oct'18-Sept'19)**

Activities include, but are not limited to, program management, non-clinical, clinical, biodefense, regulatory and CMC activities to advance the portfolio program. Additional activities may be added if determined to be necessary to support the advancement of the portfolio program.

*All of the activities detailed above are non-severable activities. All of the activities detailed above will be completed within Option Period #3, none will span other performance segments. Each will be fully funded with Option Period #3 funding.*

**5.0 Potential Option Period #4: CLIN #5 (Oct'19-Sept'20)**

Activities include, but are not limited to, program management, non-clinical, clinical, biodefense, Tegulatory and CMC activities to advance the portfolio program. Additional activities may be added if determined to be necessary to support the advancement of the portfolio program.

*All of the activities detailed above are non-severable activities. All of the activities detailed above will be completed within Option Period #4, none will span other performance segments. Each will be fully funded with Option Period #4 funding.*

**------End of Statement of Work-----**

**ATTACHMENT 2:**
**REPORTING REQUIREMENTS**

**A. TECHNICAL REPORTS**

A conference call between the Agreements Officer's Technical Representative and the principal investigator shall occur once every two weeks or as directed by the OTTR. During this call, the principal investigator will discuss the activities during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The first reporting period consists of the first full mor.,th of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. The principal investigator may. choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the OTTR. On an as needed basis, the OTTR or principal investigator may assign this responsibility to a delegate.

**B. PROJECT MEETINGS**

The Recipient shall participate in Project Meetings to coordinate the performance of the Agreement as requested by the OTTR. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Recipient and its subrecipients. Such meetings may include, but are not limited to, meetings of the Recipient (and Subrecipients invited by the Recipient) to discuss study designs, site visits to the Recipients and subrecipient's facilities, and meetings with the Recipient and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Recipient must provide data, reports, and presentations to groups of outside experts (subject to appropriate agreements to protect confidential or proprietary data) and Government personnel as required by the OTTR in order to facilitate review of Agreement activities.

**C. REPORT DELIVERABLES**

Unless otherwise specified by the OTAO, delivery of reports to be furnished to the Government under this Agreement (including invoices), shall be delivered electronically along with a concurrent email notification to the OTAO, OTAS, and OTTR summarizing the electronic delivery.

For electronic delivery of final versions of the deliverables listed below, the Recipient shall upload documents into the appropriate folder on https://eroom.bardatools.hhs.gov/eRoom("eRoom") which is the designated USG file sharing system. The USG shall provide two Recipient representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the USG prior to gaining user access. A notification email should be sent to the OTAO, OTAS, and OTTR upon electronic delivery of any documents.

**D. DELIVERABLES**

Successful performance of the final agreement shall be deemed to occur upon performance of the work set forth in the Statement of Work dated September 9, 2015 set forth in Attachment #1 of this agreement and upon delivery and acceptance, as required by the Statement of Work or elsewhere in this Agreement, by the Agreement Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule below:

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 1. | Project Meeting | Every two weeks or as amended by OTAO and OTTR | The Recipient and BARDA will participate in teleconferences every other week to discuss the performance of the Agreement. The Recipient will prepare a proposed agenda and will record, maintain and provide draft-meeting minutes to the OTTR for review and concurrence. The Recipient will send a final version of the meeting minutes to the OTTR. The OTTR will distribute the draft and final version to the OTAS and other **BARDA** staff. (For avoidance of doubt, financial information is not expected at these updates, which will be technically focused. BARDA reserves the right to include financial personnel in these project meetings, if needed. | • The Recipient provides agenda to the OTTR, OTAO, and the OTAS within 2 business days of meeting.<br>• OTTR (with OTAS concurrence) distributes agenda to BARDA participants prior to meeting.<br>• The ReciP,ient provides meeting minutes within 3 business days of the meeting.<br>• OTTR reviews and comments on minutes within l'O business days. | 1 Electronic and 1 Hard Copy ' to OTTR;and OTAS Final will be uploaded into eRoom |
| | | Every third month (Quarterly) | The Recipient and BARDA will participate in quarterly face-to-face site visits or teleconferences in Washington, D.C. and/or at work sites of the Recipient and its subrecipients to discuss the performance of the Agreement. The meetings will be used to discuss Agreement progress in relation to the Work Breakdown Structure (WBS), Integrated Master Schedule (IMS), and Agreement Performance Reports {APR) as well as study designs, technical, financial, regulatory, and ethical aspects of the program. These meetings may also include site visits to the Recipient and subrecipient's facilities. The Recipient will provide data, reports, and presentations to groups of outside experts and USG personnel. | • The Recipient shall provide itinerary and agenda at least 5 business days in advance of site visit.<br>• OTTR review and distributes itinerary and agenda within 3 business days of meeting. | |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| | | AZ/BARDA Joint OTAR Oversight Committee meeting (every 6 months or on an *ad hoc* basis as needed) | Members of the JOC will meet approximately every six months as detailed in Article IV. | • Meeting minutes will be taken by the Recipient and provided to the OTTR, OTAO, and OTAS within 3 business days of the meeting.<br>• OTTR will distribute the minutes to the JOC members and return any BARDA edits or comments to the Recipient within 3 business days of original receipt of the draft minutes. | |
| 2. | Monthly Status Report | The 30th calendar day of each month following the fractional portion of the initial month and first full month of the OTA award. Monthly reports are due each month within 30 days after the last day of that month, except on the month when the Annual Technical Progress Reports are due. The reporting period will reflect the prior month's activities. | The Monthly/Annual Status Report will address the items listed below and cross-referenced to the Work Breakdown Structure (WBS), Scope of Work (SOW}, Integrated Master Schedule (IMS), Performance Measurement Baseline Review (PMBR) report, Agreement Performance Reports (APR), and approval strategy.<br>1. An Executive Summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities. The Executive Summary should be limited to 2-3 pages and highlight critical issues for that reporting period.<br>2. The report should detail the planned and actual progress of the SOW activities during the period covered, explaining occurrences of any differences between the two, and the corrective steps.<br>3. The report should list any regulatory submissions relevant to the antibiotic candidates covered under this Agreement that have taken place during the reporting period. | Monthly Reports:<br>• The Recipient provides Monthly Status Report deliverables within 30 days after the last day of that month reflecting the prior month's activities.<br>• OTTR and OTAS will review Monthly Reports with Recipient and provide feedback. | 1 Electronic and 1 Hard Copy to OTTR and OTAS Final will be uploaded into eRoom |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 3. | Integrated Master Schedule (IMS) | Within 60 days of OTA award and updated monthly | The Recipient will provide an IMS and monthly status updates in the monthly report to reflect changes in schedule, performance, and critical path. The Recipient will include BARDA Portfolio Management Milestones in their IMS and provide monthly updates within their **IMS.** The **IMS will** be a standalone schedule containing only those activities that are applicable to the SOW. Individual project schedules for the assets within the portfolio agreement will also be provided on a monthly basis. | • The Recipient shall provide an IMS within 60 days of OTA award and updated within 30 days after the last day of each month.<br>• IMS shall be in both PDF and Microsoft Project Form.<br>• BARDA shall provide the Recipient with a written list of concerns in response to the Recipient's submitted IMS, and the Recipient must address, in writing, all concerns raised by BARDA within 10 business days of R cipient's receipt of this list of concerns. | 1 Electronic Copy(PDF and Microsoft Project Schedule (.mmp) format to OTTR and OTAS; Upload to eRoom. |
| 4. | Financial Status Report | The 30th calendar day of each month following the fractional portion of the initial month and first full month of the OTA award. Financial Status Reports and updated monthly within 30 days after the last day of that month in the Project Status Report. | Recipient will provide a monthly Financial Status Report at an agreed upon WBS level using a format agreed upon with BARDA. | • Recipient shall provide a Financial Status Report within 30 days after the last day of that month.<br>• Recipient must address in writing all concerns raised by BARDA staff to the satisfaction of BARDA. | 1 Electronic and 1 Hard Copy to OTTR and OTAS; Upload to eRoom. |
| 5. | Risk Management Plan | 90 days following OTA award and updated quarterly (additional submissions as requested by OTAS or OTTR) | The Recipient wjll provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule and performance objectives. The Risk Management Plan will include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance. | • The Recipient will provide a Risk Management Plan 90 days following OTA award and update Quarterly in their Monthly or Annual Project Status Reports.<br>• BARDA will provide the Recipient with a written list of concerns (if any exist) in response to the Recipient's submitted Risk Management Plan, and Recipient must address in writing all concerns raised bv BARDA within 20 business days of Recipient's receipt of this list of concerns. | 1 Electronic Copy to OTTR and OTAS; Upload to eRoom. |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 6. | Deviation Notification and Mitigation Strategy | As needed | Process for changing IMS activities associated with cost and schedule as baselined at the PMBR. | • The Recipient will notify BARDA of significant changes to the IMS. This includes increases in cost above 5% or schedule slippage of more than 30 days, which would require a POP extension. The Recipient will provide a high level management strategy for risk mitigation. | 1 Electronic Copy to OTTR and OTAS; Upload to eRoom. |
| 7. | In-Process Review Presentation | Annual or event driven review following completion of a pre-defined stage of product development and prior to initiation of a new stage | The Recipient will provide a presentation to BARDA and other Intergovernmental agency invitees on the Portfolio Progress at an In-Process Review meeting. | • The Recipient will provide an update to technical progress made towards Portfolio Progress at an In-Process Review meeting and provide the presentation to BARDA 10 business days prior to the meeting. | 1 Electronic and 1 Hard Copy to OTTR and OTAS; Upload to eRoom. |
| 8. | Incident Report | Within 24 or 48 hrs of activity or i.ncident | The Recipient will communicate and document all critical programmatic concerns, r)sks or potential risks with BARDA within 48 hours. Recipient shall communicate via email or telephone.<br><br>In addition, the Recipient will report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products within 24 hrs of activity or incident. Recipient will communicate via email, oral or written communication. | • Recipient will notify (orally or in writing) BARDA OTTR and OTAS within 48 hrs of Recipient identifying a critical project risk or potential risk and within 24 hrs for Security activities or incident.<br>• Recipient will provide additional updates within 48 hrs of additional developments, additional information and/or understanding.<br>• The Recipient will submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.<br>• If corrective action is recommended, the Recipient must address in writing its consideration of concerns raised by BARDA<br>• The Recipient will address BARDA's concerns in writing within 5 business days. | 1 Electronic and 1 Hard Copy to OTTR and OTAS; Upload to eRoom. |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 9. | Draft and Final Technical Progress Report | Draft 75 calendar days before and Final shall be submitted on or before the completion date of the POP | A draft of Final Technical Progress Report containing a summation of the work performed and the results obtained for the entire OTA period of performance. The draft report shall be duly marked as 'Draft'.<br><br>The Final Technical Progress Report incorporating the feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire Agreement period of performance. This final report shall detail, document and summarize the results of the entire Agreement. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final'. | • The Recipient shall provide a draft Technical Progress Report 75 calendar days before the end of the POP and the Final Technical Progress Report shall be submitted on or before the completion date of the POP.<br>• Subrecipient prepared reports will be submitted to the OTTR and OTAS for review and comment no later than 5 business days after receipt by the prime Recipient.<br>• OTTR provides edits and additional feedback to draft report within 15 calendar days of receipt, which the Recipient will consider incorporating into the Final Technical Progress Report.<br>• The Recipient will submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the Agreement.<br>• The Recipient will submit one (1) copy of a comprehensive final report to the OTAS and one (1) copy (one electronically on a CD) to the OTTR. | 1 Electronic Copy to OTTR and OTAS; Upload to eRoom. |

Q

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 10. | Study Protocols | At least 10 business days prior to FDA Submission | The Recipient will provide Pre-Clinical/Non-Clinical/ Clinical Trial Protocols to **BARDA** for evaluation, prior to FDA submission.<br><br>The OTAS and OTIR reserve the right to request within the period of performance a non-proprietary Study Proto&ol for distribution within the United States Government (USG). | • The Recipient and BARDA will collaboratively develop draft and final protocols for all Pre-Clinical/Non-Clinical/ Clinical activities within the SOW.<br>• The Recipient will submit draft and final protocols to BARDA for review and comment.<br>• If the draft protocols are to be **submitted to the FDA, BARDA** review will take place prior to FDA submission.<br>• BARDA will return comments to Recipient on the protocols no later than 10 business days from the date of receipt.<br>• The Recipient will address, in writing, all concerns raised by **BARDA.**<br>• The Recipient shall communicate BARDA's concerns and/or recommendationsto Actavis prior to FDA submission.<br>• The Recipient and Actavis are not required to make.any protocol revisions based on BARDA's concerns and/or recommendations.<br>• In the event that BARDA disagrees with the final study protocol design, BARDA will notify the Recipient of non-concurrence in writing.<br>• Final FDA submissions shall be submitted to BARDA concurrently or no later than 5 calendar days after its submission to CDER. | 1 Electronic **CopytoOTIR and OTAS;** Upload to eRoom. |

| # . | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 11 . | Study Reports | Within 5 (five) calendar days of the reports being available to AZ and 15 business days prior to anticipated submission to FDA | The OTAS and OTIR reserve the right to request within the period of performance a non-proprietary Study Report for distribution within the USG.<br><br>The Recipient will submit an interim study report to BARDA for any severable discrete work segments. If funding for a severable study is scheduled in two separate periods of performance than an interim study report is due on or before the completion date of the POP. | • The Recipient will provide Draft and Final Pre-Cli nical/ Non-Clinical Study Reports to BARDA for review and comment within . 2 (two) calendar days of these reports being available to AZ.<br>• The Recipient will submit proposed Pre-Clinical/Non-Clinical Study ReP?rt to **BARDA** at least 15 business days prior to anticipated FDA Submission.<br>• If corrective action is recommended, Recipient will address, in writing or by corrective action, all concerns raised by BARDA.<br>The Recipient will work with Actavis to consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission .<br>• Final FDA submissions shall be provided to BARDA concurrently or no later than 2 business days of its submission to CDER. | 1 Electronic Copy to OTIR and OTAS; Upload to eRo om. |
| 1 2. | Manufacturing Campaign Reports (For avoidance of doubt, this relates to the clinical supply material during the PoP aild not once the product Is commerciallv available) | Within 30 calendar days after receipt of batch records and 15 business days prior to submission to FDA | The OTAS and OTIR reserve the right to request within the period of performance Manufacturing Campaign Reports for distribution within the USG. | • The Recipien t willsubmit Batch Analysis Reports or Manufacturing Campaign Report s to BARDA at least 15 business days prior to anticipated FDA Submission.<br>• If corrective action is recommended, Recipient will address in writing or by corrective action all concerns raised by BARDA.<br>• The Recipient willwork with Actavis to consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission.<br>• Final FDA submissions shall be submitted to BARDA electronically concurrently or no later than five calendar days after its submission to CDER. | 1 Electronic Copy to OTIR and OTAS Upload to eRoom. |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 13. | Regulatory Meeting Notification | Within 24 hours of the anticipated scheduling Type A, Bore meetings OR within 48 hours of meeting occurrence for ad hoc meetings | The Recipient will forward the dates and times of any anticipated meeting with the regulatory agency to BARDA and seek to arrange for appropriate BARDA staff to attend the regulatory meetings relevant to BARDA-funded work. BARDA staff shall include up to a maximum of four people. | • The Recipient will notify BARDA of an upcoming meeting with the regulatory agency within 48 hours of being informed that a meeting is scheduled. | 1 Electronic and 1 Hard Copy to OTIR and OTAS; Upload to eRoom. |
| 14. | Regulatory Correspondence and Meeting Minutes | Within three (3) business days of receiving correspondence from Actavis or the Regulatory Agency | The Recipient will forward Recipient and CDER-issued draft minutes and final minutes of any meeting with the Regulatory Agency to BARDA relevant to the portfolio program. All documents shall be duly marked as either 'Draft' or 'Final'. | • The Recipient provides Regulatory correspondence and meeting minutes within three (3) business days of receipt of the meeting or correspondence. | 1 Electronic and 1 Hard Copy to OTIR and OTAS; Upload to eRoom. |
| 15. | Regulatory Submissions | At least 10 calendar days prior to anticipated submission to FDA | The Recipient will provide BARDA the opportunity to review and comment upon regulatory documents before anticipated submission to the Regulatory Agency. Such documents shall include responses/comments/questions that the Regulatory Agency has passed on to the sponsor regarding the compounds in this Agreement as well as the name and address of the IRBs involved in clinical studies. All documents will be duly marked as either 'Draft' or 'Final'.<br><br>(Note: BARDA will have already seen the Study Reports prior to submission.)<br><br>For avoidance of doubt, the Recipient is not required to provide to BARDA routine, general correspondence or information amendments. (e.g. routine emails). | • The Recipient will coordinate with Actavis to submit draft Regulatory Meeting Briefing Packets to BARDA at least 10 calendar days prior to anticipated submission to the Regulatory Agency. **BARDA will** provide comments to Recipient within 5 business days of receiving the briefing.<br>• If corrective action is recommended, Recipient will address, in writing its considerations of all concerns raised by BARDA.<br>• The Recipient will work with Actavis to consider revising documents to address BARDA's concerns and/or recommendations prior to submission to regulatory authorities.<br>• Final Regulatory submissions shall be submitted to BARDA concurrently or no later than 5 business days of its submission to CDER. | 1 Electronic **Copy to OTIR and OTAS;** Upload to eRoom. |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 16. | **FDA Audits** | Within 10 business days of a scheduled audit or within 48 hours of an *ad hoc* site visits/ audits if the FDA did not provide advanced notification | The Recipient will notify the OTTR and OTAS within 24 hours of FDA's arrival to conduct site visits/audits by any regulatory agency. In the event of an FDA inspection which occurs as a result of this Agreement and for this product, or for any other FDA inspection that has the reasonable potential to impact the performance of this Agreement, the Recipient will provide BARDA with an exact copy (non-redacted) of the FDA Form 483, and the Establishment Inspection Report (EIR); Recipient shall provide the OTTR and OTAS copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report within 10 business days, status updates during the plans execution, and a copy of all final responses to the FDA. The Recipient shall also provide redacted copies of any FDA audit report received from subrecipients that occur as a result of this Agreement or for this product within five business days of receiving correspondence from the FDA and/or third party. The Recipient shall make arrangements, where practical, for a BARDA representative(s) to be present during the final debrief by the regulatory Inspector for audits of the Recipient. | • The Recipient will notify the OTTR and OTAS within 10 business days of a scheduled audit or within 24 hours of receiving notice of an ad hoc site visit(s)/audit(s) if the FDA did not provide advanced notification.<br>• The Recipient will also provide copies of any FDA audit report received from subrecipients that occur as a result of this Agreement or for this product within five business days of receiving correspondence from the FDA and/or third party.<br>• Within 10 business days of audit report, the Recipient will provide OTAS with a plan for addressing areas of nonconformance, if any exist. | 1 Electronic and 1 Hard Copy to OTTR and OTAS; Upload to eRoom. |

Q

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 17. | QA Audit Reports | 5 business days of report completion | The Recipient will inform the OTIR and OTAS of upcoming, ongoing, or recent audits/site visits of subreclpients as part of the weekly communications, including goals and agenda. BARDA reserves the right to participate in the audits. Upon completion of the audit/site visit the Recipient shall provide a report capturing the findings, results and next steps in proceeding with the s subrecipient . If action is requested of the subrecipient , details addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. Recipient shall provide responses from the subrecipients to address these concerns and plans for corrective action execution For avoidance of doubt, as our subrecipients may be involved in other activities for the Recipient, the reportable audit information will only pertain to that which materially affects those programs funded under the portfolio partnership. | • The Recipient will inform the OTTR and OTAS of upcoming, ongoing or recent audits/site visits of subrecipients.<br>• The Recipient will notify the OTIR and OTAS within 5 business days of report completion . | 1 Electronic Copy to OTIR and OTAS; Upload to eRoom. |
| **18.** | BARDA Audit | *Ad Hoc* | The Recipient shall accommodate for periodic or *ad hoc* site visits by BARDA. If BARDA, Recipient or other parties identifies any issues during an audit, Recipient shall capture the Issues, identify potential solutions and provide a report to **BARDA.** | • If BARDA, the Recipient or other parties identifies any issues during an audit, Recipient shall capture the issues, identify potential solutions and provide a report to BARDA with in 10 business days.<br>• The OTIR and OTAS will review the deliverable and provide a response to Recipient.<br>• Once any corrective action undertaken by Recipient is completed, Recipient will provide a final report to BARDA. | 1 Electronic Copy to OTTR and OTAS; Upload to eRoom. |

| # | Type of Deliverable | Frequency/Time Periods | Description of Deliverable | Reporting Procedures | Quantity/Form |
|---|---|---|---|---|---|
| 19. | Technical Documents<br><br>- | Within 10 business days upon request by OTAS/OTIR and 15 business days prior to anticipated submission to FDA | The Recipient will provide the OTIR and OTAS upon request with deliverables from the following contract funded activities: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, S0Ps, Master Production Records, Certificate of Analysis.<br><br>(The OTAS and OTIR reserve the right to request within the period of performance a non-proprietary technical Documents for distribution within the USG). | • The Recipient will provide technical documents within 10 business days upon request by OTAS/OTIR.<br>• If additional time is required, Recipient will request additional time from BARDA on a per deliverable basis.<br>• If corrective action is recommended, Recipient will address, in writing or by corrective action, concerns raised by BARDA.<br>• The Recipient will submit proposed FDA technical documents to BARDA at least 15 business days prior to anticipated FDA submission.<br>• The Recipient will work with Actavis to consider revising technical documents to address BARDA's concerns and recommendation prior to FDA submission. | For Final Documents;<br><br>1 Electronic Copy to OTIR and OTAS; Upload to eRoom. |
| 20. | Animal Model or Other Technology Transfer Package | Within 10 business days of request by OTAS/OTIR | The Recipient shall provide Animal Model or Other Technology Transfer Package relevant data. | • The Recipient will provide Animal Model or other Technology Transfer Package within 10 business days of request by OTAS/OTIR. | 1 Electronic Copy to OTIR and OTAS; Upload to eRoom. |
| 21. | Raw Data or Data Analysis | Within 20 business days, or as available, after receipt of request by OTAS/OTIR | The Recipient shall provide Raw Data or Data Analysis for review by BARDA, if requested. (For avoidance of doubt, clinical data will be subject to human subject privacy policies.) | • The Recipient will provide Raw Data or Data Analysis within 20 business days (or as available) of request by OTAS/OTIR. | 1 Electronic Copy to OTIR and OTAS; Upload to eRoom. |

**ATTACHMENT 3:**
**PORTFOLIO PERFORMANCE METRICS**

Portfolio Performance Metrics (PPM) will be collaboratively developed by the Joint OTAR Oversight Committee and prior to the exercise of any options. These metrics should span all aspects of the program and should include metrics for all molecules within the portfolio partnership.

In-Process Review (IPR) meetings will be held in an annual or event driven manner following completion of a pre-defined stage of product development and prior to initiation of a new stage (e.g. Option award). At least 30 days prior to an IPR meeting, the Recipient and OTTR will discuss the progress to date under the portfolio and activities planned for the next stage of development. The Recipient will prepare and present a PowerPoint presentation during the IPR which provides an update on the technical progress made towards achieving the Portfolio Performance Metrics. The Recipient will provide a copy of the final PowerPoint presentation to the OTTR and OTAO 10 business days prior to the meeting.

At the JPR, BARDA will assess the overall portfolio and progress, and decide at its sole discretion if an offer to progress to the next Option will be offered to Recipient.

Below are the Port olio Performance Metrics for the Base Period at the time of Agreement award. These may be modified by the Joint OTAR Oversight Committee during the base period of the Agreement. The Portfolio Performance Metrics below will be achieved through the performance <?f the non-seYerable activities contained only in the base period. Option exercise is not required for the Recipient to achieve any of the metrics listed below.

**Base Period Portfolio Performance Metrics**

| DG# | Delivery from CLIN | Milestones/Deliverables | Go | No-Go | Decision for |
|---|---|---|---|---|---|
| DI | CUN 1 (BASE) 1.5.1.1 1&2&3 | Phase 3 set up: European Scientific Advice (SA) & FDA minutes available for P3 study design and registration programme. P3 protocol final IND submitted for P3 Feasibility complete and RP CTA submissions for P3 study | EMA/FDA Sci Advice joint consult minutes demonstrate agreement for programme. Final protocol available IND open feasibility complete SO% P3 CTA submissions completed | Programme not agreed through EMA/FDA joint consult Protocol is not finalized IND not open P3 CTA submissions in <50% of countries | CUN2 (Optn 1) |
| D2 | CUN 1 1.S.1.2 & 3 | RP study set up progress: IND submitted for P3 and final protocol available | IND open and final protocol available | IND not open | CUN2 (Optn 1) |
| 03 | CUN 1 1.6.3.2 & 1.6.3.1 | Clinical trial supply available for P3 and RP | Clinical trial material CofAs available Material, labeled, packed and distributed to central depot(s) for site activation. | Clinical trial material CofAs not available Material distribution incomplete to central depot(s). | CUN2 (Optn 1) |
| D4 | CUN 1 1.6.1.1 | TI & Manufacture of AVI API report | AVIAPI manufacturing n successful as demonstrated by QA report. | AVI API manufacture unsuccessful. | CUN3 (Optn 2) |
| 0S | CUN 1 1.6.1.2 | Formulation Blending process development report | Formulation process evaluation successful; drug product meets specifrcation criteria. | Formulation process evaluation not successful; drug product does not meet specification criteria. | CLIN3 (Optn 2} |
| D6 | CUN 1 1.6.3.3 | Agreement with CMQ for commercial manufacturing faciljty. | Agreement executed for manufacture of registration batches Facility available for manufacture. | No Agreement executed for manufacture of registration batches Facility not available for manufacture. | CUN2 (Optn 1} |

Q

**ATTACHMENT 4:**
**LIST OF ENTITIES EXCLUDED FROM DEFINITION OF FOREIGN FIRM OR INSTITUTION**

**AstraZeneca pie**
2 Kingdom Street
London W2 6BD

**Allergan pie**
1 Grand Canal Square
Docklands, Dublin 2, Ireland

**University Medical Center Utretch**
100 Heidelberglaan
Utrecht, 3584 CX, Netherlands

**Universite de Geneve**
24 Rue de General-Dufour
Geneve 4, 1211, Switzerland

**Centre Hospitaller Universitaire de Limoges**
2 avenue Martin Luther King
Limoges, 87042 France

**Servicio Andaluz de Salud**
18 Avenida de la Constituci6n
Sevilla, 41071, Spain

**Universitatsklinikum Koln**
University Hospital of Cologne, UKK
62 Kerpener Str.
Koln, 50937 Germany

**Tel-Aviv Sourasky Medical Center**
6 Weizmann
Tel Aviv, 64239, Israel

**National and Kapodistrian University of Athens**
Medical School
6 Christou Lada Street
Athens, 10561, Greece

**Institut National de la Sante et de la Recherche Medicale**
CHU Purpan
Toulouse, 31024
Cedex 3, France

**St Georges University of London**
Crammer Terrace
Tooting, London SW17 ORE

**National Institute of Public Health of Kosova**
Rr. Nena Tereze pn
Rrethi i spitalit
Prishtina, 1000 Kosova

**The University Medical Center Groningen**
1 Hanzeplein
Groningen, Netherlands

**The Health Corporation**
8 Ha'Aliyah Street
Haifa 30196, Israel

**Cardiff University**
30-36 Newport Road
Cardiff, CF24 ODE, United Kingdom

**Servicio Madrileno de Salud**
7 PLAZA CARLOS TRIAS BERTRAN
28020 Madrid, Spain

**Fundacio Centre de Recerca en Salut International de Barcelona**
132 Calle Rosselle
Barcelona 08036, Spain

**Academisch Medisch Centrum bij de Universiteit van Amsterdam**
9 Meibergdreef, Amsterdam
1105 AZ, Netherlands

**Universiteit Antwerpen**
13 Prinsstraat
2000 Antwerp, Belgium

**University of** Ulm
16 Helmholtzstrasse
D-89081, Ulm, Germany

**GlaxoSmithKline Research and Development**
980 Great West Road
Brentford, Middlesex
TWS 9GS, United Kingsom

**Basilea Pharmaceutica International AG**
487 Grenzacherstrasse
PO Box4005
Basel, Switzerland

**Innovative Medicines Initiative**
Avenue de la Toison d'Or 56-60
B-1060 Brussels, Belgium

**ATTACHMENT 5:**
**ALLOWABLE DIRECT COSTS UNDER OTA and SUBRECEIPIENTS**

**Version 1 as of 09/15/2015** ,

**Subject to revision by request of either the Government or the Recipient, allowable direct costs are limited to:**

1) Supplies and Services used or purchased pursuant to the contract. Includes subcontracts, professional or consultant costs, lab supplies, contract-specific security costs, manufacturing and production costs, shipping materials, shipping costs, etc. Supplies and services will be reimbursed conditionally on those costs being reasonable, allocable and allowable.

2) Materials used in development or placed in the production process for use on the contract. Material costs will be reimbursed conditionally on those costs being reasonable, allocable and allowable.

3) Labor costs incurred pursuant to the contract.
   a. Direct salary ceilings are capped at Executive Level II ($183,300 direct costs per year per person.)
   b. If the rates are burdened, those rates are evaluated at its direct rate and the overhead/indirect rate(s). The rates will be authorized if reasonable, allocable and allowable to this contract.

4) Legal costs incurred as a direct result of a specific term or condition of a Federal contract; or as a result of compliance with specific written direction of the contracting officer.

S) Service and warranty costs necessary for the proper performance of the agreement. Service and warranty costs include those arising from fulfillment of any contractual obligation of a contractor to provide services such as installation, training, correcting defects in the products, replacing defective parts, and making refunds in the case of inadequate performance. When not inconsistent with the terms of the contract, service and warranty costs are allowable. However, care should be exercised to avoid duplication of the allowance as an element of both estimated product cost and risk.

6) SubRecipient indirect costs set pursuant to Article Vll(C)(2)(c).

This page is intentionally left almost blank.

# R. SAMPLE ARTICLES OF COLLABORATION

**ARTICLES OF COLLABORATION**
**FOR**
**(INSERT NAME)**
**CONSORTIUM**

**REV. "Q"**

These Articles of Collaboration (hereinafter "Articles") are entered into among the following parties:

(INSERT COMPANY NAMES)

hereinafter collectively identified as "Parties" and individually identified as a "Party", to establish the (INSERT NAME) Consortium (hereinafter "Consortium").

WHEREAS the Parties have complementary research interests and wish to apply their talents and experiences to (INSERT PURPOSE) ; and

WHEREAS the principal purpose of this Consortium is neither to supply property or services for the direct benefit or use of the U.S. Government, nor to transfer a thing of value to State or local governments or other recipient to carry out a public purpose of support or stimulation authorized by U.S. laws, and thus it is not feasible or appropriate for the Parties and the Agency (defined below) to enter into a procurement contract, or grant agreement with any U. S. Government Agency; and

WHEREAS the Parties anticipate receiving partial and incremental funding from a U. S. Government agency to perform the Statement of Work; and

WHEREAS each Party reserves their right to review and accept the terms of any ARPA Agreement prior to any active participation in any Consortium project described herein; and

WHEREAS the Parties wish to enter into a joint research and development venture as such term is defined in the National Cooperative Research Act of 1984 through a cooperative agreement pursuant to 31 U.S.C. §6305;

Hereinafter the following definitions apply:

- (INSERT COMPANY NAME) once having executed these Articles, is the Lead Party (hereinafter "Lead Party").

- Each of the PARTIES, once having executed these Articles, is a "Party."

- (INSERT COMPANY NAME), once having executed these Articles shall act as, or arrange for, the Financial Service Provider to the Consortium. (See para. 7a)

- The U.S. Governmental Agency identified as providing funding to the Consortium as a whole is the Advanced Research Project Agency (hereinafter "ARPA") during the period such funding is available or being used.

- Intellectual Property means any inventions, creations, processes, mask works, works of authorship, software or other developments or improvements thereto, whether patentable, copyrightable or not. "Intellectual Property Rights" means any Rights in Intellectual Property including patents, copyrights, trade secrets and confidential information.

NOW THEREFORE, the Parties agree as follows:

1. (a) The Parties hereby establish a joint research and development Consortium to engage in a collaborative research effort of limited duration to gain further knowledge and understanding of the technologies described or identified in the ARPA Agreement, for the purposes and within the Statement of Work set forth therein.(Appendix A)

(b) Subject to the availability of ARPA funding, the Parties individually agree to expend "reasonable efforts," within the terms of the ARPA Agreement to achieve the goals assigned to them as defined therein. By execution of these Articles, each Party authorizes the Management Committee or its designees, as its agent to enter into a single "other transaction" with ARPA pursuant to 10 U.S.C. §2371 that shall hereinafter be referred to as "the ARPA Agreement," and under which ARPA shall fund the Consortium in accordance with the Schedule of Payments and Payable Milestones. During the performance of the Statement of Work, if the Management Committee reasonably determines that any Party has used its "reasonable efforts" to perform the tasks assigned to that Party in the Statement of Work for any given goal, the Management Committee will instruct the Financial Service Provider to disburse to that Party, the funds associated with that goal, such funds as have been provided by ARPA. The Management Committee shall not unreasonably withhold funding from any Party after the submission of properly prepared invoices, provided that funding has been provided by ARPA to the Financial Services Provider.

(c) These Articles shall not preclude any Party from developing at its own expense derivative complementary technology derived from its Consortium Intellectual Property but outside of the Statement of Work (hereinafter "Proprietary Technology") provided that the Proprietary Information and other rights of other Parties hereinunder are not violated. The developing Party under this subparagraph reserves all Intellectual Property Rights in such Proprietary Technology so developed.

2. (a) Subject to the terms and conditions stated herein, the Consortium will be managed and governed by a "Management Committee," which is empowered to determine all policy, business, financial, legal, and technical issues of the Consortium and to represent the Consortium and the Parties in reporting progress, in negotiating, and in transacting business with ARPA. Specifically and without limitation, the Management Committee is empowered to redirect the research, redefine the tasks and goals of the Parties, and to proportionally equitably adjust to all Parties the amount of funding provided by ARPA.

(b) The "Voting Representative" from each Party, shall be the voting representatives which will comprise the Management Committee. The Management Committee will meet in regular meetings at alternating locations or as is mutually acceptable to the Management Committee Parties. As specified in the ARPA Agreement, all Parties and ARPA may attend these meetings. The voting rights of the parties shall be as defined in Appendix B.



Each voting representative may, with prior permission of the Management Committee, be accompanied by other employees of the Party, including, without limitation, financial, business, and legal personnel. Third parties, including other Government agencies, may attend other committee meetings at the invitation of the Management Committee. The Management Committee reserves the right to designate the representatives that may attend non-(CONSORTIUM) related committee meetings.

Each Party shall have the right to specify an Alternate Voting Representative, in writing, if its designated Voting Representative is otherwise busy, and to change its designated Voting Representative from time to time with written notice.

(c) The host representative to the Management Committee will act as chair of the committee meetings, and will deliver notification to all Parties and ARPA regarding meetings of the Management Committee. Any Voting Representative may call a special meeting of the Management Committee.

A Voting Representative from at least 75% of the Parties must be present in person or by telephone, to constitute a quorum of any meeting.

(d) Subject to the consent of the Management Committee, (INSERT COMANY NAME) will appoint a Financial Service Provider to the Consortium, who will attend the committee meetings and will provide a single point of contact to the financial officers of the Parties, ARPA or their designees.

(e) The Party hosting the Management Committee meetings will appoint an individual who will assure that minutes of the meetings are recorded and distributed to all Parties, within 15 days after each meeting.

(f) In the event that the Management Committee is unable to resolve any intra-consortium dispute, the dispute will be elevated to the Vice President and General Manager of, (INSERT COMPANY NAME) for resolution with the appropriate executive management of the other Parties of the Consortium. Unless (INSERT COMPANY NAME) is one of the parties involved in the dispute, the role of the (INSERT COMPANY NAME) Vice President and General Manager shall be limited to that of facilitating the dispute resolution process.

3. A two-thirds majority agreement of the entire Management Committee is required to make the following decisions for the Consortium:

(a) Revise the Articles of Collaboration;
(b) Accept modifications to or terminate any Funding Agreement with ARPA;
(c) Delegate authority of Management Committee to the Financial Service Provider and Chairman of the Management Committee;
(d) Change or eliminate any ARPA funding allocated to any Party as technically and/or financially justified, but a Party experiencing any reduction in ARPA funding may pro rata reduce its internally funded participation in the Consortium;
(e) Approve annual program plan for funding and adjusting funding to all Parties.

(f) Admit new Parties in accordance with Article 4.

(g) Define or redefine, allocate or reallocate the tasks within the scope of the Statement of Work or the ARPA Agreement.

(h) Appointment of a negotiating team and delegation of the authority to one or more Parties to negotiate and execute on behalf of the Consortium,

a single "Other Transaction" with ARPA as set forth in Article 1 (b) herein which is acceptable to the Consortium.

ARPA approval will be obtained as required in accordance with the ARPA Agreement for any of the items listed above.

Unless otherwise specified by these Articles, a simple majority vote will be required for all other issues to be passed by the Management Committee.

4. The Management Committee may consent to admit a new member to the Consortium. Such new member shall become a Party upon its execution of these Articles. The Management Committee will consider admitting new Parties on a non-discriminatory basis, but only if the new Party's technical contributions can be justified and only on relatively comparable financial terms as the existing Parties, recognizing the risk of their contributions to date. The factors taken into consideration will include without limitation whether the new Party will bring to the Consortium technology otherwise unavailable on the time scale of the program or will allow the technology of the Consortium to be applied to new markets, whether the entry of the new Party will not substantially adversely affect the Intellectual Property Rights of the then existing Parties, whether the added effort would not substantially change the ongoing Consortium program, and whether the new Party could participate without diminishing ARPA funding provided to the original Parties. Notwithstanding the above, the Management Committee may consider any factor in addition to those above, and its decision on admitting new Parties is discretionary and final.


5. (a) Any Party may terminate its participation from the Consortium at will, after it has provided written notice, termination budget and revised statement of work to the Management Committee thirty (30) days in advance of the effective date of the termination. The termination shall include the terminating Party's recommended replacement, if applicable. During the 30-day period, the terminating Party shall orderly wind down its effort. Subject to the availability of ARPA funding, the Management Committee shall not unreasonably withhold funding to the terminating party related to the orderly winding down efforts.

(b) The terminating Party shall make a "reasonable effort" to transfer its portion of Consortium work to other Parties or a prospective new Party of the Consortium. The resigning party must have used reasonable efforts to achieve the goals for which ARPA funding was provided, or refund the unexpended funding to the Consortium. The terminating Party must provide a license to its Consortium Intellectual Property to the Party or Parties ("the Replacing Party") designated by the Management Committee

to replace the terminating Party solely for the purpose of performing the terminating Party's tasks under these Articles or under the Funding Agreement as of the date of the termination notice ("terminating Party's tasks"). This license to the Replacing Party shall be royalty-free, non-exclusive, perpetual, sub-licensable only for the purpose of allowing the Replacing Party to subcontract the fulfillment of the Terminating Party's Tasks, except that the Replacing Party may transfer its rights under this license if it terminates its participation in the Consortium. This should be accomplished within the 30 day wind down period, if possible.

(c) The Management Committee may terminate the participation of a Party if that Party has committed a material breach of this Agreement. The Management Committee may give a Party written notice of a material breach and affording the opportunity to cure such breach, only if at least seventy-five (75%) percent of the Management Committee members vote ("Notice Vote") that the Party has committed a material breach of this Agreement. Such termination shall be effective only if the Management Committee members vote unanimously that the Party has not substantially cured the breach within 30 days after such notice, and the meeting occurs between 31 and 45 days after the notice. The Party subject to the termination shall have the opportunity at both meetings to demonstrate that it has not breached the Agreement. For the purposes of calculating the percentages in this Paragraph, the Party subject to the termination shall not be included.

(d) Any exiting Party shall receive the pro rata portion of any funding due for any full or partial completion of milestones under ARPA Agreement as of the effective date of the termination.

6. (a) Except as provided in 6.(b), each Party shall retain title to Intellectual Property developed in the course of the Consortium including but not limited to inventions, technical data rights and other data developed solely by its employees as a result of the performance of the Statement of Work of ARPA Agreement. Inventions or technical data jointly developed by employees of more than one Party are jointly owned by the respective inventing Parties.

(b) Consortium Intellectual Property is that Intellectual Property developed by and in the course of identified tasks assigned to and performed by any Party whether performed under ARPA funding or funding provided by a Party as agreed to as in-kind contribution in the Funding Agreement and/or in these Articles. The identified tasks shall be those tasks (i) agreed to by the Party in the Statement of Work of the ARPA

Agreements, (ii) agreed to by the Party with other Parties of the Consortium, or (iii) assigned to the Party by the Management Committee.

However, Consortium Intellectual Property does not include (1) background Intellectual Property: (2) Pre-existing or concurrently developed Intellectual Property independently funded outside of the Consortium (including, but not limited to, Proprietary Technology); or (3) continuation (improvement or subsequent) Intellectual Property of the respective Parties.

(c) All Parties grant to each other a nontransferable, royalty free, non-exclusive, sublicensable license to use their Consortium Intellectual Property, provided that such licenses and use shall be restricted solely to the performance of tasks under these Articles or under the Statement of Work of the ARPA Agreement. In addition, a party shall transfer its rights under this license if it terminates its participation in this Consortium. Such transfer shall be solely for the purpose of allowing the other Parties of the Consortium to fulfill their tasks under these articles or the ARPA agreement. Such licenses shall survive the resignation of any granting Party from the Consortium.



(d) All Parties agree to negotiate with other Parties to grant royalty bearing licenses with reasonable terms and conditions to Consortium Intellectual Property which they own for the purpose of developing and providing Trauma Care Information Management Systems.

(e) The Consortium favors, subject to ARPA requirements, an open-publication policy to promote the commercial acceptance of the technology for (INSERT PURPOSE), but simultaneously desires to protect the Proprietary Information of the Parties developed both within and without the Consortium because successful commercialization of aspects of the technology by some of the Parties may depend on the proprietary nature of the information. Each Party will individually decide whether to publish its own technical data or maintain it as proprietary. However, as a result of its participation in this Consortium, proprietary information or hardware of one Party will necessarily be disclosed to or used by another Party. A Proprietary Information Exchange Agreement is incorporated herein and is found at Appendix "C", and will govern proprietary information exchanged among the Parties. The exchange of proprietary information between the Consortium and ARPA will be governed by a similar Proprietary Information Exchange Agreement to be executed by ARPA as a part of the ARPA Agreement.

(f) Notwithstanding the Proprietary Information Exchange Agreement, when one Party's work depends upon the Proprietary Information of another Party, the technical data may be published to the extent that such

data (i) is required for a description of the one Party's work, (ii) does not disclose proprietary information, and (iii) relates primarily to system performance and characteristics. However, publication of the proprietary information may be delayed by its owner for a time period enabling filing of patent applications, or a period of no more than twelve (12) months, whichever is lesser. In the event that the Party's work depends on proprietary information developed by another Party in tasks outside the Consortium, the proprietary information may be published only with the express written consent of the owner.

(g) Each Party will select its inventions for which it applies for patents. The Party is further responsible for prosecuting those applications and maintaining the resulting patents, both in the U.S. and in foreign countries. Any Party jointly owning an invention may file a patent application for it, and the co-owning Parties will in good faith cooperate in the filing and prosecution.

(h) Any patent application filed claiming Consortium Intellectual Property shall include the provision required by the ARPA Agreement stating the interest of the U.S. Government.

The inventing Party will report a patent application claiming any Consortium Intellectual Property to the Management Committee within one month of the filing and upon request, provide a copy of the application including a short abstract but without claims, to the Management Committee. The Management Committee will timely report the invention including the short abstract to all applicable Parties and to ARPA, as required by ARPA. All Parties agree to cooperate with each other and the Management Committee in resolving questions related to Intellectual Property, the abstracts and potential ownership rights. Any such patent information shall be covered by the Proprietary Information Exchange Agreement and shall not be disclosed by ARPA to non-governmental personnel until the respective patents have issued.

(i) ARPA Agreement may provide for the government to obtain certain rights in the Consortium Intellectual Property. Each Party agrees to such government rights in its Consortium Intellectual Property subject to the exclusions of §6(b). The Intellectual Property Rights provided to the Consortium by the ARPA Agreement shall be provided in turn to the Parties according to the terms of these Articles. The Parties will cooperate with the Management Committee in performing any reporting, election, and rights predetermination to ARPA regarding Intellectual Property as required and to provide the required information to the Management Committee.

7. (a) The Financial Service Provider will receive funds from ARPA, deposit such funds in a deposit account opened in the name of the

Consortium or its Parties, disburse such funds as directed by the Management Committee or as required by Attachment 3 of the ARPA Agreement, and will report quarterly to the Management Committee on the finances of the Consortium. Additionally, the Financial Service Provider shall prepare all financial reports required by the ARPA Agreement and submit such reports to ARPA and the Management Committee, in accordance with the appropriate schedules. Each Party shall provide the required financial inputs to permit the Financial Service Provider to meet the reporting requirements. The financial reporting will not include any Party's proprietary financial or pricing information. The tasks performed by the Financial Services Provider shall be allowable expenses to the Consortium.

(b) The ARPA Agreement Statement of Work will provide for certain rights of the government to audit the financial records of the Consortium. Each Party agrees that it will reasonably cooperate with an audit of the Consortium and will allow an audit of its own applicable financial records as required by the law and upon reasonable notice. The Financial Service Provider shall be the primary facilitator for supporting these audits. All audit rights shall be limited to U.S. Government employees or the audits shall be performed by a mutually acceptable independent outside auditor.


8. THE PARTIES DISCLAIM ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS, THE IMPLIED WARRANTIES FOR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TO EACH OTHER, TO ANY AGENCY, AND TO THIRD PARTIES FOR ACTIONS, OMISSIONS, PRODUCTS, NON-CONFORMITIES, DEFECTS, LIABILITIES, OR INFRINGEMENT ARISING OUT OF THE ACTIVITIES OF THE CONSORTIUM. The Parties are bound to each other and to ARPA entering into an agreement with the Consortium by a duty of only good faith and "reasonable efforts" research in achieving the goals of the Consortium. Joint and several liability will not attach to the Parties of the Consortium so that no Party is responsible for the actions of another Party but is responsible only for those tasks assigned to it and to which it agrees in a the ARPA Agreement. THE PARTIES FURTHER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, INDIRECT, OR SPECIAL DAMAGES. IN NO EVENT SHALL A PARTY'S LIABILITY UNDER THIS AGREEMENT EXCEED THE FUNDING IT HAS RECEIVED UP TO THE TIME OF INCURRING SUCH LIABILITY. Any Party may waive any right, breach or default which such Party has the right to waive, provided that such waiver shall not be effective against the waiving Party unless it is in writing, is signed by such Party, and specifically refers to these Articles. No waiver of any breach of any agreement or provision herein contained shall be deemed a waiver of any preceding or succeeding breach thereof nor of any other agreement or provision herein

contained. Nothing contained herein shall constitute a release to any Party for breach of the Proprietary Information Exchange Agreement attached hereto or infringement of intellectual property rights of the Parties.

9. No one Party has the obligation to disclose to another Party (i) information not required for the cooperative research set forth above, or (ii) any market data or plans except as such information is made publicly available.

10. (a) These Articles are not intended to be, nor shall they be construed, by implication or otherwise, as an agreement to establish a partnership (limited or otherwise), a corporation or other formal business organization or as a procurement "contract" or a "grant agreement" as described under 31 U.S.C. Sections 6303 and 6304, respectively. No Party can be bound by another Party acting as its agent except as specifically stated in Paragraph 1(b) of this Agreement. Each Party acts as an independent contractor subject only to the terms and conditions stated herein and in the ARPA Agreement.

(b) No Party shall be obligated to provide any capital contribution, loan, guarantee, or other financing commitment for the benefit of the Consortium, unless required for such Party's portion of the Statement of Work and such Party agrees in writing herein or otherwise.

11. Except and to the extent as specifically set forth herein, nothing in these Articles shall be construed as conferring by implication, estoppel or otherwise any license or right under any patent, copyright, trade secret, trademark or other proprietary right of any Party.

12. Except for the disclosure of basic information regarding this Consortium, i.e., membership, purpose and a general description of the technical work, formal written approval by all Parties is required for any specific publicity or advertising relative to this Consortium Agreement. However, the Parties agree that notification of the establishment of this joint research and development venture shall be filed by Rockwell on behalf of the Parties with the U.S. Attorney General and the Federal Trade Commission in accordance with the provision of the National Cooperative Research Act of 1984 within 90 days of execution of these Articles and after adequate review by all Parties. The costs of this filing shall be borne by the Consortium.

13. (a) These Articles and the Consortium shall continue after execution of these Articles until [INSERT DATE] or terminated earlier under any provision of sub-section (b) hereof. It may be renewed at any time prior to the expiration of the term of these Articles by letter agreement

signed by the authorized representatives of all the Parties who are Parties at that time.

(b) These Articles shall terminate if (i) disapproved by the Attorney General or the Federal Trade Commission; (ii) the funding of the Statement of Work is terminated by ARPA; or (iii) funding is not provided by ARPA by [INSERT DATE]. In the event of Termination for any reason, this agreement shall remain in full force until it is specified by the Management Committee that all business matters between the Parties have been properly settled and closed out.

(c) The obligations of confidentiality set forth in Section 6 hereof shall survive termination of these Articles.

14. The ARPA Agreement will impose requirements upon the Consortium or its Parties regarding reporting, accounting, civil rights, Intellectual Property, and technology transfer information or transferring of Intellectual Property generated with funds provided by ARPA. A Party, by acceptance of such ARPA funds, agrees to conform to such requirements and to reasonably cooperate with the Consortium in conforming to such requirements, subject however to the Party's right to resign as stated in 5(a) above.


15. Any notices or other communications among the Parties required or permitted hereunder shall be sufficiently given if sent by telecopier or confirmed by registered or certified mail, postage prepaid, addressed as follows:

(INSERT NAMES AND ADDRESSES)

Or such other addresses or telecopier or facsimile numbers as shall be furnished by like notice by such Party. Any such notice or communication given by mail shall be deemed to have been given three (3) business days after the date so mailed, and any such notice or communication given by telecopier shall be deemed to have been given when sent by telecopier and the appropriate answer back received.

16. Neither these Articles nor any rights hereunder, in whole or in part, shall be assignable or otherwise transferable without the prior written consent of all other Parties except to the Parties' wholly owned subsidiaries, corporate parents or such corporate parents' wholly owned subsidiaries.

17. (a) These Articles shall first become effective on the date all Participants have signed these Articles. These Articles shall be effective

as to any new Parties on the date such new Party(ies) execute these Articles.

(b) These Articles may be executed in counterparts each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

18. The Parties shall further execute, sign or do or procure to be executed, signed and done all such further deeds, documents and acts as may be reasonably required to enable the Parties freely and fully to pursue the goals assigned to them in the Statement of Work.

19. These Articles shall be construed under the laws of the State of (INSERT APPROPRIATE JURISDICTION).

20. These Articles constitute the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof.

21. If any provision of these Articles is deemed to be invalid, illegal or unenforceable by any court of competent jurisdiction, such provision will be deemed amended to conform to applicable laws of such jurisdiction so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the Parties, it will be stricken and the remainder of these Articles will remain in full force and effect.

22. It is understood and agreed that the Consortium will be operated in such a manner as to minimize any taxes for which the Consortium may become liable. If this Consortium is treated as a partnership for tax purposes, Rockwell as the Financial Services Provider, shall make the election for the Consortium to expense research and development costs.

IN WITNESS WHEREOF, each of the Parties has caused these Articles to be executed by its duly authorized representatives on the respective dates entered below.

LINES FOR SIGNATURES OF PARTIES.

APPENDIX "B"

VOTING ARRANGEMENTS FOR CONSORTIUM

-

R

**APPENDIX "C"**
TO
ARTICLES OF COLLABORATION
FOR
(INSERT NAME) CONSORTIUM

PROPRIETARY INFORMATION EXCHANGE AGREEMENT
20 Jan 94

1. During the term of this Agreement, all parties of the (INSERT NAME) Consortium (hereinafter referred to as "parties") agree to exchange proprietary information (hereinafter referred to as "data") with Parties having a need to know, for the purpose of developing the (INSERT PURPOSE) . The effective date of this Proprietary Information Exchange Agreement shall be _____.

2. Notwithstanding that the term of this Agreement will have expired, for a period of five years from the receipt, each party agrees to keep in confidence and prevent the use (except for the purposes of this Agreement) or the disclosure to any person or persons outside the receiving party's organization, and limit the disclosure inside its organization to employees having a need-to-know, of all data received under this Agreement which is designated in writing, or marked by an appropriate stamp or legend, by the disclosing party to be of a proprietary or confidential nature. The parties shall take every reasonable effort to keep the information confidential to the extent permitted by such laws or acts. In order to be protected hereunder, data which is first disclosed orally or by demonstration must be identified as proprietary or confidential at the time of disclosure and shall be reduced to writing or other tangible form, marked as proprietary and a copy delivered to the receiving party by the disclosing party within thirty (30) days after such disclosure or demonstration of any such data. All protection and restrictions as to use and disclosure shall apply during such thirty (30) day period. Any markings, stamps, or legends identifying proprietary or confidential information hereunder shall not impose any obligations on either party inconsistent with this Agreement.

3. The above restrictions on use and disclosure shall not apply to such data if the same:

a. Is in the public domain or in the possession of the receiving party without restriction at the time of receipt under this Agreement;

b. Is used or disclosed with prior written approval of the disclosing party;

c. Is used or disclosed after five (5) years from the date of first receipt under this Agreement;

d. Is independently developed by the receiving party;

e. Becomes known to the receiving party from a source other than the disclosing party without breach of this Agreement by the receiving party;

f. Is made available by the disclosing party to a third party on an unrestricted, non-confidential basis; or

4. No party shall be liable for inadvertent, accidental or mistaken use or disclosure of data obtained under this Agreement despite the exercise of the same reasonable precautions as the receiving party takes to safeguard its own proprietary information. Any copies of the data made by the receiving party shall reproduce the proprietary markings and any other legends contained thereon.

R

No party warrants that the data it discloses hereunder will meet the requirements of the other party or that such data, when combined with other information, or when used in a particular manner by the recipient will be sufficient or suitable for the recipient's purposes. Neither party assumes responsibility or liability whatever under this Agreement for any use of data by the recipient or its customers or agents.

5. Nothing in this Agreement shall grant to any party the right to make commitments of any kind for, or on behalf of, any party without the prior written consent of any other applicable party. Nothing herein shall grant, expressly or impliedly, any ownership right or license to use (except for the purposes stated above) data disclosed hereunder.

6. The term of this agreement, during which data may be exchanged, shall be for a period of five (5) years from the date hereof.

7. All notices hereunder shall be given by letter addressed as specified in paragraph 15 of the Consortium Agreement.

8. Security: To the extent that the obligations of the parties hereunder involve access to information classified "Top Secret", "Secret", or "Confidential", the provisions of FAR 52.204-2 Alt 1, or corresponding regulations of the appropriate Government agency, as applicable, shall apply.

9. The recipient of information transmitted under this Agreement acknowledges its obligations to control access to technical data under the U.S. Export Laws and Regulations and agrees to adhere to such Laws and Regulations with regard to any technical data received under this Agreement.

# S. CASE STUDIES

# Case #1: Airborne Video System

Contracting Officer Jane Doe received the attached information concerning a new program to be started in FY98. Ms. Doe's organization has been authorized to utilize all available contract tools: contracts, grants, cooperative agreements, OT's for Research and OT's for Prototypes.

Examine this material. Discuss the issues surrounding all five instrument types or "tools", i.e., procurement contracts, grants, cooperative agreements, OT's for Research and OT's for Prototypes. Which do you think is best in this case?

# PROPOSER INFORMATION PACKAGE (PIP)

**Airborne Video Surveillance**
**(AVS)**
**Broad Agency Announcement**
**(BAA 97-42)**

**Defense Advanced Research Projects Agency**
**(DARPA)**

The information provided in this Proposer Information Package (PIP), in addition to that provided in the Commerce Business Daily (CBD) Announcement, BAA 97-42, constitutes a Broad Agency Announcement as contemplated in FAR 6.102 (d)(2)(i).

## Summary of Important Dates

| | |
|---|---|
| 28 August 1998 | Industry Briefing |
| 7 October 1998 | Proposal Due Date |
| 7 October 1998 | BAA 97-42 Closes |
| 1 March 1998 | Tentative Contract Award |
| 2 April 1998 | AVS Program Kickoff Meeting |

## I. INTRODUCTION

### Background

In the very near future, battlefield commanders will be able to rapidly task Unmanned Aerial Vehicles (UAVs) and obtain large volumes of surveillance imagery. Some UAV surveillance systems in early deployment have the capability to collect and provide video imagery directly to ground exploitation systems and command posts. Motion video data is proving to be quite powerful in these deployments for a number of reasons. Some examples are:

- The operator is in real time control of the sensor, so re-tasking is immediate.
- Critical scene motion (moving vehicles, weapon impacts) is evident, even in temporally compressed imagery.
- Critical targets may be visually detected and separated from clutter using motion.
- Targets may be tracked in real time.
- Critical temporal events may be captured and recorded to support intelligence analysis.
- Large areas can be covered at high resolutions by forming large area mosaics from individual video frames.

Because of these and other advantages, and because endurance UAVs are being designed to dwell over battle areas for long periods, video imagery from airborne platforms will be a critical component of existing and future battlefield surveillance systems.

DARPA is soliciting proposals for the Airborne Video Surveillance (AVS) program to address some of these requirements and to explore and evaluate ways of converting AVS systems *from remotely controlled surveillance sources returning video streams* to *semi-autonomous active surveillance systems performing designated tasks.*

## Goals

The AVS program will develop and integrate PVR, MTS and AM technology subsytems to form a real-time video surveillance system.

This system must be able to operate in either single mode (one technology subsystem only) or multiple mode (e.g., MTS and AM using PVR functions to locate moving vehicles and activities).

Real operational scenarios will dictate that these technologies, when combined with automated sensor control and intuitive operator displays, will be employed in innovative and unpredictable combinations. Therefore, it is important that all elements of the AVS technology program work together in a modular, "toolkit" framework.

Since these systems must be demonstrated and evaluated on an airborne platform, extensive infrastructure (in the form of airborne testbed, airborne testbed systems, and ground applications) will be provided as part of the program. The technology developers must work closely with these other program participants.

The challenges, potential candidate techniques, evaluation metrics, and specific performance goals for each of these technologies are described below. It is expected that offerors to each of these areas will be able to identify their current existing capabilities and how they will achieve the desired AVS performance goals.

### Precision Video Registration (PVR)

The challenges in PVR are in developing algorithms that are extremely accurate and robust with respect to large variations in viewing geometry, variable atmospheric conditions, and seasonal variations. Candidate approaches are envisioned to include registering video frames to orthophotos and any other reference imagery, recovering depth from sensor motions when reference imagery is inadequate, and employing multiple look registration techniques for missions where reference imagery is unavailable.

The goals for PVR are to perform registration of imagery (including imagery of moving targets) at 1 Hz with two classes of performance:

- Class 1: (< 40 degrees line of sight -LOS- variation between reference imagery and mission imagery, good contrast, small seasonal variations) 95% of video frames registered within 2 meters RMS error.
- Class 2: (> 40 degrees LOS variation, lower contrast, large seasonal variations) 80% of video sequences registered within 2 meters RMS error.
- The PVS system must be capable of supplying accurate geo-location for wide-area mosaic imagery as well as single frames.

### Multiple Target Surveillance (MTS)

The challenge of MTS is to provide the operator with a virtual field of view to simultaneously monitor and track a number of targets in a large field of regard.

The goals for MTS are to:

- generate a 120 degree spherical virtual field of regard,
- track up to 12 simultaneous targets,
- track humans and tactical sized targets moving up to 50 MPH,
- characterize tracking performance with respect to metrics such as signal-to-noise ratio (SNR) and signal-to-clutter ratio (SCR),
- accommodate periodic start/stop maneuvers and temporary occlusions and shadows,
- produce virtual video streams,
- provide a coherent visualization of both the virtual video streams and the registered imagery for the imagery analyst, and
- characterize MTS performance versus scene/image metrics.

**Activity Monitoring (AM)**

The goals for active monitoring are to:

- demonstrate the accurate monitoring of 12 simultaneous video streams by a single image analyst,
- characterize AM performance versus scene/image metrics, and
- be capable of onboard processing in a subsequent program.

## II. TECHNICAL OVERVIEW: MAJOR AVS WORK PACKAGES

This section outlines at a high level the five major work packages identified as part of the AVS effort. They are:

- AVS Technology Subsystem Research and Development (TSRD) Work Packages:
  - Precision Video Registration (PVR)
  - Multiple Target Surveillance (MTS)
  - Activity Monitoring (AM)
  - Other Advanced Video Surveillance Techniques
- AVS Systems Integrator (SI)
- Airborne Testbed Integration and Operations (ATIO)

Each work package section has the following general outline:

- High level goals
- General scope of work package
- Major collaborations (with other AVS participants) required
- Number of awards anticipated
- Budget estimates and guidance
- High level systems or subsystems issues and requirements

**Major Collaboration Required**

TSRDs will collaborate extensively with the AVS SI to develop CONOPS, CAGS, and to conduct the scheduled integrations, demonstrations and field experiments. The

extent and general requirements for the collaboration are outlined in the TSRD Work Package Scope section above.

**Awards**
It is anticipated that, at minimum, three TSRD awards may be made, one in each of the following categories:

- Precision Video Registration (PVR)
- Multiple Target Surveillance (MTS)
- Activity Monitoring (AM)

Awards may be made in the following unspecified technology category if sufficient technical and mission benefits are evident and program funds are available.

- Other Advanced Video Surveillance Techniques

**Work Package 1: Precision Video Registration (PVR)**

**Work Package 2: Multiple Target Surveillance (MTS)**

**Work Package 3: Activity Monitoring (AM)**

**Work Package 4: Other Advanced Video Surveillance Techniques**
DARPA is interested in any proposed TSRD that will improve video surveillance technology and surveillance mission efficiency. Offerors are encouraged to explicitly explain and enumerate the benefits of, and goals for such proposed techniques and submit proposals conforming to general TSRD requirements and technical challenges listed above.

**AVS TSRD Budget Estimates and Guidance**
*The following table contains "rough order of magnitude" (ROM) estimates of the budget that is anticipated to be available for all of the TSRD work packages, as determined in preliminary program planning efforts. The division of funding over these work packages will depend in part on how many individual TSRD awards are made (3 or 4 are anticipated). The funds will not necessarily be divided equally across the TSRD work packages awarded; offerors should bid costs consistent with their proposed level of effort.*

| | Estimated Budget ($M) | | | | |
|---|---|---|---|---|---|
| Work Package | FY 98 | FY 99 | FY 00 | FY 01 | FY 02 |
| Total AVS Funding Available for All TSRD Work Packages (1-4) | $0.9M | $3.5M | $3.7M | $2.1M | $0.6M |

**AVS TSRD Incremental Annual Capability and Performance Goals**

Each TSRD should propose to develop, demonstrate and evaluate increasingly capable subsystems, at the annual fall demonstrations, throughout the duration of the program. Deliveries of systems will be made 60 days prior to the annual fall demonstrations. Suggested incremental technology goals, based on preliminary program planning efforts, are listed below. Offerors are encouraged to propose aggressively planned annual TSRD capability and performance goals consistent with their research and development plans.

**1998:**

(PVR): Laboratory demonstration of accurate georegistration of individual video frames to controlled, accurately georeferenced imagery of the collection site.

(MTS, AM): Laboratory demonstrations of base technology on collected imagery.

**1999:**

(PVR): Laboratory demonstrations of orthomosaicing of multiple video frames. Airborne demonstrations of orthomosaicing of Class 1 data, with 80% of the video frames registered to within 2 meter RMS error.

(MTS): Laboratory demonstrations of tracking and re-acquisition of targets from collected imagery.

(AM): Laboratory and airborne demonstrations of point monitoring.

(All TSRD): Demonstrations and evaluations of analyst HCIs for the TSRD systems.

**2000:**

(PVR): Airborne demonstrations of multiple-frame orthomosaics, with 90% of Class 1 and 75% of Class 2 data registered to better than 2 meter RMS error.

(MTS): Laboratory and airborne demonstrations of tracking of three distinct targets.

(AM): Laboratory and airborne demonstrations of point , area and LOC monitoring applications.

(All TSRD): Demonstrations and evaluations of analyst HCIs for the TSRD systems.

**2001 - 2002**

Airborne demonstrations will be conducted in conjunction with field exercises.

(PVR): Airborne demonstration of multiple-frame orthomosaics to full specifications for both Class 1 and Class 2 imagery.

(MTS): Laboratory and airborne demonstration of tracking of twelve targets.

(AM) Airborne demonstrations of point, LOC and area monitoring in user missions.

(All TSRD): Demonstrations and evaluations of analyst HCIs for the TSRD systems.

**2002:**
Airborne demonstration in conjunction with field exercises of tracking twelve live targets. Demonstrations and evaluations of analyst HCIs for the systems are also required at this time.

## Work Package 5: AVS System Integrator (AVS SI)

### High Level AVS SI Goals

Since AVS technology is new and emerging, the goal of the program is to develop and mature AVS technology while exploring and evaluating its use in realistic surveillance scenarios. A successful AVS program, at closure, will have explored numerous TSRD approaches and matured the most promising of them into demonstrable prototype systems that have clear benefit to surveillance systems users. This clear benefit will be established by mission-level AVS system evaluations. Simultaneously, the performance envelope of TSRD subsystems will have been characterized with respect to variability in real world conditions.

It is extremely important that the AVS SI be visionary, creative, and aggressive in exploring the potential space of user needs, mission payoffs, and TSRD capabilities. The AVS SI will be the conceptual leader of the AVS team, and must find ways to incorporate the best of TSRD into user-relevant systems, not discard aggressive technology because it is risky or hard to implement.

### Major Collaboration Required

- AVS SI will coordinate with ATIO to carry out integration, tests, and field demonstrations and exercises.
- AVS SI will collaborate extensively with TSRDs to develop CONOPS, CAGS, and integration/demonstrations.
- AVS SI sill interact extensively with government customers and users to define and refine CONOPS, perform demonstrations and eveluations, and deliver an integrated AVS product.

### Awards

- One award is anticipated in this category.

### AVS SI Budget Estimates and Guidance

The following table contains ROM estimates of the budget that is anticipated to be available for this AVS Work Package, as determined in preliminary program planning effots.

All proposers should offer the best technical approach and plan to meet the goals of the AVS program, within the constraints of these program planning estimates. The offeror may also propose optional tasks and associated costs for additional effort judged to be of high value in enhancing or extending AVS capability.

| Work Package | Estimated Budget ($M) | | | | |
|---|---|---|---|---|---|
| | FY 98 | FY 99 | FY 00 | FY 01 | FY 02 |
| AVS System Integration | $0.6M | $3.4M | $3.3M | $2.3M | $1.2M |

### AVS SI System Issues and Requirements

The following presents an overview of high-level system issues and requirements for the AVS SI effort. AVS SI proposals should address these.

### AVS CONOPS and High-Level Design

- Airborne CAGS executive control (e.g. managing communications and processing) and data/control communications between air and ground.
- Ground image or motion sequence processing, including enhanced ground-based real time video processing as required by certain TSRD modes.
- Ground CAGS executive control (e.g. managing communications, processing, operator input), including both single TSRD-mode mission management as well as hybrid TSRD-mode mission management (multiple TSRD elements are combined to perform a mission).
- Ground CAGS human computer interface.
- All APIs to allow TSRDs to develop subsystem for integration and evaluation.

## Work Package 6: Airborne Testbed Integrator and Operator (ATIO)

DARPA has arranged with the US Army CECOM Night Vision and Electronic Sensors Directorate (NVESD), Fort Belvoir, VA to provide the testbed and all integration and operation support as outlined in this work package as government furnished equipment (GFE). A detailed description of NVESD's proposed support package will be presented at the AVS Industry Briefing.

DARPA also solicits proposals from qualified contractors who may be capable of providing ATIO services, in lieu of NVESD, to the AVS program more cost-effectively or with less risk. If, for example, a potential AVS systems integrator also has assets and skills that meet Work Package 6 requirements, they should submit separate proposals for both Work Packages 5 and 6 and cross-reference these proposals in their executive summary.

Based on BAA proposal evaluations, DARPA will select the ATIO services provider which best meets all of the AVS program's ATIO requirements.

### High Level ATIO Goals

### ATIO Work Package Scope

- Provide and operate a manned or unmanned airborne video testbed system (including EO/IR sensors, gimbal systems, GPS/INS systems and communications links) to support AVS technology development, system integration, field demonstrations, and field exercises.

- Provide and operate an air/ground operations site to support AVS development, integration, test and demonstrations. This will include the conduct and ground-truthing of vehicle and other activities required to develop the AVS system.

### Major Collaboration Required

- The ATIO will primarily cooperate with the AVS SI, with DARPA and the Contractual Agent overseeing this collaboration. The ATIO will also collaborate with and supervise the ground operations sites needed to carry out AVS field data collections and demonstrations. The ATIO will directly support the AVS SI in its role as program integration and demonstration lead.

### Awards

- Zero or one award is anticipated in this category.

### ATIO Budget Estimates and Guidance

The following table contains rough order of magnitude (ROM) estimates of the budget that is anticipated to be available for this AVS work package award, as determined in preliminary program planning efforts.

All proposers should offer the best technical approach and plan to meet the goals of the AVS program, within the constraints of these program planning estimates. The offeror may also propose optional tasks and associated costs for additional effort judged to be of high value in enhancing or extending AVS capability.

| | Estimated Budget ($M) | | | | |
|---|---|---|---|---|---|
| Work Package | FY 98 | FY 99 | FY 00 | FY 01 | FY 02 |
| Airborne Testbed, System Operations | $0.7M | $1.2M | $1.0M | $1.2M | $1.2M |

### ATIO Flight Operations Requirements

The following table outlines the number of testbed flight days DARPA estimates that the testbed will be available to the AVS Team for either airborne mission flights or ground-based system installation and verification.

| | FY 98 | FY 99 | FY 00 | FY 01 | FY 02 |
|---|---|---|---|---|---|
| Estimated Testbed Access Days | 20 | 50 | 40 | 40 | 40 |

In FY98, the 20 days allotted are intended for installation and testing of the AVS sensor, including core software, and performing data collection to support AVS TSRDs. The ATIO will be primarily responsible for these tasks. The AVS SI will be responsible for gathering and prioritizing data collection requirements from the TSRDs, as well as distributing the collected data to the TSRDs. It is extremely important that the core AVS testbed and sensor be integrated as soon as possible to insure collected data can be available to support early laboratory work by TSRDs.

In FY99 through FY02, several mission days will be available each year for standalone field operations/test by each TSRD category. These days are intended to support technology experiments and data collections specific to each TSRD area. The AVS TSRDs will specify these missions in cooperation with the ATIO and the AVS SI. The bulk of the mission days available in FY99 through FY02 are intended for Air and Ground Systems Integration. The AVS SI will be responsible for scheduling this time,

and it will be used for integrating the AVS CAGS developed by the SI. Note that there are ten additional mission days set aside in FY99 to accommodate the initial build and test of the CAGS. The remaining mission days in FY99-02 will be available for Subsystem Integration and Demonstration. The AVS SI will be responsible for scheduling this time, and it will be used for:

1. Integrating code from multiple TSRDs into the CAGS.
2. Debugging, testing and refining the overall system.
3. Performing internal mid-year (generally May) program field demonstrations and evaluations designed to drive program progress and measure performance.
4. Performing external end-of-year (generally November) field demonstrations, exercises, and evaluations designed to present and characterize AVS capability to UAV Surveillance Systems Developers and Users.

In all Air/Ground Systems Integration and Subsystem Integration and Demonstration operations, the AVS SI will collect data to support TSRD requirements.

# Case #2: AVS

Using the same material as discussed in case #1, how should Ms. Doe proceed? What solicitation method should be used? Why?

# Case #3: AVS - Teaming

Mr. Tom Jones of Ablard Enterprises, Inc. (AEI) notices a new announcement in the CBD entitled AVS, BAA-97-01. He has heard about Cooperative Agreements and OT's and wonders about their applicability in this U.S. Government solicitation. Being a small business noted for its expertise in airborne gimbal-mounted video sensors, he is very interested in his chances in winning a part of the action. Since the solicitation indicates teaming may be important, he comes to you, his Business Development Specialist, and asks for your advice.

What additional information do you need to help him? Summarize the advantages and disadvantages of teaming in Cooperative Agreement and OT (R) situations?

# CASE MATERIAL #4

# RESOURCE SHARING

# AIRBORNE VIDEO SYSTEM (AVS)

S

## CONSORTIUM MEMBER CONTRIBUTIONS

| MEMBER | CONTRIBUTION AMOUNT |
|---|---|
| DTT, Corporation (Lead) | $ 1,870,500 |
| Company 2 | $ 550,625 |
| Company 3 | $ 701,400 |
| Company 4 | $ 800,000 |
| | $ 3,922,525 |

DTT CORP

| | | | |
|---|---|---|---|
| 1. | **"In-kind Value"** | $ | 242,000 |
| 2. | **Cash** | | |
| | A. Funding from NASA | $ | 150,000 |
| | B. Labor Cost | $ | 447,000 |
| | C. Materials | $ | 158,000 |
| | D. Subcontracts | $ | 50,000 |
| | Subtotal Cash Contributions | $ | 805,000 |
| 3. | **IR&D** | $ | 823,500 |
| | **TOTAL COST CONTRIBUTIONS:** | $ | 1,870,500 |

S

Company 2

1. **In-kind**

| | | |
|---|---|---|
| A. Database on Audio processes & scenarios, technical legacy | $ | 140,000 |
| B. JKASE Tools (commercially available JKASE tools commercial list price) | | |
| -Business Process Engineering (BPE) Methodology | $ | 80,000 |
| -4 Copies of Business Construction Facilities, (BCF) 8K each | $ | 32,000 |
| -Training in BPE, 4 people $800 each | $ | 3,200 |
| -Training in BCF, 6 People $2500 each | $ | 15,000 |
| -4 Copies of Business Audio Directive, (BAD) (54,000*3) | $ | 162,000 |
| -SAM systems Development Workstation | | |
| BFF with Construction Kit for Client/Server | $ | 50,000 |
| VG-Platform Generation Kit | $ | 35,000 |
| additional IGF Database | $ | 3,000 |
| Training in BFF, 6 People ($5,000 each) | $ | 30,000 |
| 1 copy of BFF Encyclopedia for Workstation | $ | 425 |
| **TOTAL COST CONTRIBUTIONS:** | $ | 550,625 |

Company 3

1. **In-kind**

Commercial Hardware and Software (usage fee)

| | | | | | |
|---|---|---|---|---|---|
| Hewlett Packard Unix Workstations ($13,000 * 3) | | | | $ | 39,000 |

2 **Cash**

| | | | | | |
|---|---|---|---|---|---|
| Burdened Labor Cost* | 120 | 3 | 1840 | $ | 662,400 |

The program will require 3 scientist at $120per hour burdened rate.
The annual productive hour per employee is 1840

| | | |
|---|---|---|
| **TOTAL COST CONTRIBUTIONS:** | $ | 701,400 |

S

Company 4

| | | | | |
|---|---|---|---|---|
| 1. | **In-kind** (Usage fee) | | | |
| | A. | lease - CED Work Station | $ | 20,000 |
| | B. | Dupress Software Package | $ | 45,000 |
| | C. | Depreciation for HP workstation | $ | 15,000 |
| 2. | **IR&D** | | | |
| | Advance Audio Sensor (AAS) * | | $ | 450,000 |
| | (the AAS license is based on the fair market value of the basic research) | | | |
| 3. | **Cash** | | | |
| | A. | Equipment | | |
| | | Vacuum Fissing System** | $ | 90,000 |
| | | Audio Digital Splicer | $ | 180,000 |

4. Use/Specific Requirements:
*IR&D for the AAS was not funded by government IR&D pool. The technology was patented and a license price was based on the fair market value.

**Company will purchase these machines at the beginning of the program and dedicate them to AVS for the life of the program. The salvage value will be given to the government.

| | | |
|---|---|---|
| **TOTAL COST CONTRIBUTIONS:** | $ | 800,000 |

CASE MATERIAL #5

INTELLECTUAL PROPERTY

AIRBORNE VIDEO SYSTEM
(AVS)

1) What questions do the government negotiators need to know before proceeding with the negotiations?

2) Under the sample clause, proposed by an industry consortium, who has title to subject inventions? How does this differ from traditional FAR based contracts?

3) Are the government's data license rights adequate? Why? Why not?

**Technology Transitioning**

This Airborne Video System (AVS) is formed with one of the prime considerations being to include corporations with the capability of transferring this experimental prototype technology into commercial and military application spin-offs.

The potential spin-offs from this work include laser and detectors arrays for multi-wavelength application, acousto-optic tunable filters, and modular networks for a wide variety of applications, both commercial and military.

Technology transitioning will be achieved by publication of the results of our investigations and by considerations of the market and manufacturing issues for the technologies involved at the conclusion of the project.

The transition of technology into commercial sector will be affected by intellectual property rights and is addressed in the section below. In that section, we proposed contractual provisions that addresses intellectual property and data rights concerns.

**SAMPLE Intellectual Property Clause**

Each Consortium retains title to inventions, technical data rights, and other intellectual property made by its employees. Inventions or technical data jointly developed by employees of more than one Member or Vendor are jointly owned by the respective employers.

Both the Government and the Consortium Members obtain licensing rights, as describe hereunder, in each Member's intellectual property developed by and in the course of both the Government-funded and the cost-share portions of the identified tasks of the Consortium. However, these licensing rights do not attach to (1) background: (2) concurrently developed but independently funded; or (3) continuation (improvement or subsequent) intellectual property of the respective Members.

Government rights do not attach to inventions conceived outside of the Consortium even though first reduced to practice under Government funding.

Government obtains a royalty-free, government purpose license for patents and obtains limited data rights for Consortium intellectual property. However, the Government may exercise these rights on a respective Member only if that Member fails to adequately commercialize within a reasonable time after that Member's contribution to the overall technology of the Consortium.

When march-in rights are exercised, the government-purpose license is royalty free, and the government may also commercially license the invention or technical data with the

licensing fees accruing to the title holder. However, the reasonable time allotted to the Member for practical utilization of the inventions shall not be less than five years from the first actual reduction to practice of the invention or technical data.

## Intellectual Property Exercise

The Agency for National Research (ANR) is the central research agency for the federal government. The Agency works in conjunction with other federal agencies to perform research and development programs that are later turned over to the agencies for completion through production contracts.

For this particular program, the U.S. Marine Corps have asked ANR to work with them to develop a new version of the Humvee motor vehicle. The Marines need a smaller, more transportable version of the Humvee that be moved around the world within 72 hours. After much discussion the Marines and ANR decide that the vehicle cannot be larger than 48 inches wide, must be capable of carrying four men with provisions for three days, and must be capable of evading detection by enemy forces.

After publishing a solicitation and conducting a source selection, ANR and the Marines have chosen a team of contractors consisting of a large defense contractor, a commercial automobile manufacturer, a small sensor technology firm, and a university to build the mini-Humvee. Each of the team members has individual plans and needs that must be addressed in this program:

- The large defense contractor is accustomed to working with the government under traditional procurement contracts but is interested in contributing some of the intellectual property that was developed under independent research and development (IR&D) projects. This intellectual property has not yet been reduced to practice, but the contractor already has invested a great deal of money in the property and would like to retain more rights than it might ordinarily expect to keep. The contractor also would like to team with the auto manufacturer and sensor firm to create a civilian version of the vehicle for law enforcement agencies.

- The auto manufacturer has never had a government contract and is unfamiliar with the procurement regulations. The manufacturer has little interest in pursuing further government work but will be incorporating chassis and cockpit designs into this vehicle that it would like to include on other commercial vehicles. The manufacturer would like to team with the defense contractor and sensor firm to create a law enforcement version of the vehicle for sale to federal and state agencies.

- The small sensor firm has accepted a few government contracts in the past but is primarily a commercial firm. It brings to the program an existing reconnaissance sensor suite that will be adapted to government uses on the vehicle, and it will be expected to develop a group of new sensors to ensure the survivability of the vehicle. The firm has plans to market these sensors both to commercial customers for use in other applications, and in conjunction with its teammates on a law enforcement version of the vehicle.

- The university is joining the team to conduct some basic and applied research into new materials for use in the chassis to make the vehicle as light as possible. Another group within the university is investigating new electric propulsion systems for the vehicle to assist in reduced fuel consumption and heightened survivability. The university is accustomed to performing government work under grants directly with the various agencies and has never participated on a team before. It is primarily interested in developing the materials and propulsion technologies and publishing the results of its experiment, but it would like to keep open the possibility that it could license some of the resultant technology to a commercial firm. As an added wrinkle, at least half of the university team consists of foreign students who are in the United States on student visas.

- The government has informed the team that it is open to considering all types of contractual arrangements. The government needs at least enough rights in the intellectual property to analyze the information by government experts and certain support contractors. It also needs sufficient information to share with other agencies that may be interested in acquiring additional vehicles for their own use. The government has not yet decided if it will conduct a full and open competition to award the production versions of the vehicles, and, although that is the preference, it can still be persuaded to consider other options.

Each teammate needs to consider what intellectual property rights it would like to retain in the course of this program, considering its past development work and future plans. Each teammate also needs to consider what type of contracting instrument would best suit its needs and how it plans to accommodate the anticipated desires of the other teammates as well as the government.

This page is intentionally left almost blank.

# T. JUSTIFICATION FOR USE OF OTA

**JUSTIFICATION** FOR USE OF OTHER TRANSACTION AUTHORITY (OTA)

I. Contracting Organization:

II. Description of vision of the agreement: *(also insert period of performance).*

III. Description of Supplies/Services within the scope of the agreement;

IV. Authority: (*Cite the applicable OT authority)*

V. Applicability of Authority:

*The OTAO must determine that an OTA is more beneficial than other types of instruments. In conjunction with government program officials, the OTAO must justify this decision and may consider the benefits noted below:*

- *What is a specific technology or research methodology that would be available with an OTA, but unavailable via another funding instrument?*
- *Would prospective vendor(s) not participate if an instrument other than an OT was used? Identify the ways the OTA minimizes these barriers to nontraditional participation, including but not limited to;*
    - *Consortia comprised of the entities above who collaborate as peers with the government to manage the project and share its costs;*
    - *Non-profit entities that have an interest in the goals of the OT program; and*
    - *Individuals.*

- *What program needs require fluid implementation of a program - awards need to begin quickly on a small scale, with additional funds added later if milestones are met, or awards may need to be downsized or discontinued?*
- *What nontraditional review and award management practices are needed because the science is expected to be highly evolving, with requirements for additional aims or expertise added to, or removed from, the project throughout the award period?*
- *What program requirements cause a need for collaborative involvement by the government in the technical direction and oversight of the research, which can be akin to partnering? Examples of involvement can include participation in progress reviews and decisions on future efforts or direction. The government may also be a voting or non-voting member of the consortium.*

VI. Efforts to Obtain Competition *(Is there competition? If not, why is the proposed recipient the only source that can perform the proposed agreement?)*

RECOMMENDATIONS_____

Other Transaction Agreement Officer Date

T

*The Contracting Officer's signature on the **Justification** Review Document evidences that he/she has determined this document to be both accurate and complete to the best of his/her knowledge and belief.*

*Supporting documentation from the technical/scientific personnel should be available or attached.*

APPROVAL:_____

Signature of Appropriate Senior NIH Official Date

*As evidenced by their signatures on the **Justification** Review Document, the technical and/or requirements personnel have certified that any supporting data contained herein, which is their responsibility, is both accurate and complete.*