

**NAVY STANDARD
COOPERATIVE RESEARCH
AND DEVELOPMENT AGREEMENT
(NSCRADA)**

HANDBOOK



**2nd EDITION
FEBRUARY 2009**

**COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)
HANDBOOK**

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DEPARTMENT OF THE NAVY
OFFICE OF NAVAL RESEARCH
875 NORTH RANDOLPH STREET
SUITE 1425
ARLINGTON VA 22203-1995

IN REPLY REFER TO:

Ser 03TSB/25
2 Feb 2009

From: DON Technology Transfer Program Office (Code 03TSB)

Subj: NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(CRADA) HANDBOOK

Ref: (a) 10 U.S.C. Section 5022
(b) SECNAVINST 5430.7P of June 26, 2008

Encl: (1) Navy CRADA Handbook

1. Enclosed is the revised edition of the Navy Cooperative Research and Development Agreement (CRADA) Handbook. It is a reference guide for the Navy technology transfer community and is available on CD for easy access and convenience.
2. If there are additional topics that you would like to include in the Handbook, please submit a draft article to NavyTechTransfer@onr.navy.mil, for consideration and adoption.

A handwritten signature in black ink, appearing to read "Dorothy F. Vincent".

DOROTHY F. VINCENT
Navy Technology Transfer Program Manager

Distribution:
Navy Technology Transfer Community

Letter from CRADA Handbook Committee Chairman

To All Navy ORTAs:

The second edition of the Handbook offers a new arrangement of content and more information than the previous edition. The Handbook is now arranged in six major sections, ordered in a manner that provides greater accessibility and ease of use. A more detailed table of contents is provided at the beginning of the document as well as in the various sections and subsections, including, where appropriate, introductory text.

In addition, by clicking on the table of contents' blue hyperlink, it will take you to the respective sections and subsections. In the Templates section, the hyperlink will direct you to the first page of each template (the individual template pages are not numbered). The sections are:

Section I	Instructions
Section II	CRADA Processes
Section III	Templates
Section IV	Examples
Section V	Guidelines and Discussions
Section VI	Appendices

Section I provides the basic instructions for completing the Navy Standard CRADA template along with approved alternative language to be used depending on the type of Non-Navy Collaborator. CRADA Processes that may be used in defining the CRADA relationship and developing its content are provided for you in Section II. Templates for the Navy Standard CRADA, its Appendices, and other CRADA templates are found in Section III. In Section IV Examples, information is provided on sample non-disclosure agreements and language that has been used in specific Articles of the Navy Standard CRADA. Guidelines and Discussions, Section V, on CRADA Definitions, the use of contractors, classified CRADAs, FOCI, public release, patent rights, U. S. Competitiveness, and SBIRs are provided for reference. The last section, Appendices, provides you with a short reference and description of important technology transfer legislation and Department of Defense and Department of Navy Directives, Guidelines, and Instructions.

The second edition of the Navy CRADA Handbook has been a Herculean effort that would not have been accomplished without the efforts of many individuals within the Navy technology transfer community. I would like to publicly acknowledge their contributions to this effort. My thanks are extended to the following:

Maryam Azarian, Naval Research Laboratory
J. Scott Deiter, Naval Surface Warfare Center, Indian Head Division
Gregory L. Edlefsen, Naval Research Laboratory
Lorraine E. Flanders, Naval Surface Warfare Center, Dahlgren Division
John L. Forrest, Naval Sea Systems Command
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Rita C. Manak, Naval Research Laboratory
Charles Schlagel, Naval Medical Research Center
Michael D. Seltzer, Naval Air Warfare Center Weapons Division, China Lake and Pt. Mugu
Mary L. Sylvia, Naval Undersea Warfare Center, Division Newport
Deirdre Zammit, Naval Research Laboratory

A particular note of appreciation to Hans Kohler of L-3 Communications for making a thorough review and critique of this Handbook; this is a much better document thanks to his efforts.

A special thanks is extended to Regina Coeby of L-3 Communications for her diligence in responding to my many frequent requests for yet one-more draft or reorganization of the Handbook.

Please address all comments and questions on the Handbook to the Office of Naval Research Technology Transfer Office:

Dottie Vincent
Office of Naval Research
Technology Transfer Program, Code 03TSB
875 North Randolph Street
Arlington, VA 22203-1995
dorothy.vincent@navy.mil

Wishing you the best in CRADAs,

A handwritten signature in cursive script that reads "Edward C. Linsenmeyer".

Edward C. Linsenmeyer
CRADA Handbook Committee Chairman

SECTION I
INSTRUCTIONS

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Section I - 1

The Navy Standard CRADA

There are no standard written articles for a Cooperative Research and Development Agreement (CRADA) required by Public Law; however, general authority, enumerated authority, and contract considerations for Cooperative Research and Development Agreements are described in Title 15 United States Code Section 3710a to provide themes that should be covered. In executing this law, each Federal agency has established its own policy and guidance for CRADA format and content.

CRADA authority to Navy laboratories is delegated by the Secretary of the Navy in SECNAVINST 5700.16A. This instruction is currently under revision and is expected to be published by the fourth quarter of FY08.

There are certain limitations under 3710a that the Navy has adopted as policy for the creation of CRADAs. The Navy Standard CRADA and approved alternative Articles reflect this policy. A CRADA that deviates from the conditions of the Standard is called a Non-Standard CRADA and must conform to Navy policy. Both CRADAs are required to have local legal review before signature, and the local laboratory is fully responsible for its contents. When registering a CRADA with the Office of Naval Research, a description of any changes differing from the Standard is required. General Instructions regarding the Navy Standard Cooperative Research and Development Agreement (NSCRADA) are located in Section I - 2. The template for the NSCRADA is located in Section III - 1.

Section I - 2

CRADA Instructions

Instructions for Use of the 5th Edition, Revision 1, 1 May 2002, Navy Standard Cooperative Research and Development Agreement (NSCRADA) Template

The Navy Standard Cooperative Research and Development Agreement (NSCRADA) template is designed as an agreement between one Navy laboratory and one U.S. commercial entity. Approved alternative paragraphs are provided in this instruction for the case in which the Non-Navy Collaborator is a U.S. entity that is a State or local government organization, a public or private foundation, or a nonprofit organization, including a college or university. Any Navy laboratory can agree to revised clauses to the NSCRADA with the Non-Navy Collaborator without prior approval by ONR, subject to local legal review. The laboratory assumes responsibility for changes to the NSCRADA.

A CRADA will be considered “Standard” if the following conditions are met:

1. The CRADA template is used WITHOUT MODIFICATION to the Articles listed below or uses approved alternative language for a Collaborator who is a State or local government, a public or private foundation, a nonprofit organization, including a college or university, or a single individual.
 - Article 1 (Definitions)
 - Article 7 (Intellectual Property)
 - Article 8 (Tangible Property)
 - Article 9 (Liability)
 - Article 10 (General Provisions)
 - Article 11 (Modifications and Notices)
 - Article 12 (Surviving Provisions)
2. The CRADA does not provide more than \$1,000,000 per year to the Navy Collaborator.
3. The original CRADA duration is three years or less. A CRADA may be extended up to another two years by amendment with appropriate review.
4. The CRADA is unclassified.
5. The CRADA does not use unclassified Militarily Critical Technology.
6. The CRADA is with a single Non-Navy Collaborator.
7. The Non-Navy Collaborator is:
 - (a) a U.S. entity: i.e. company, State or local government, public or private foundation, or nonprofit organization, including a college or university;
 - (b) *not* a consortium;
 - (c) *not* a venture capitalist;
 - (d) *not* directly or indirectly controlled by a foreign company or government (FOCI) (Executive Order 12591, Section 4(a)).
 - (e) *not* SBIR funded.
8. The CRADA *is not* used for an agreement with an intermediary or technology “broker” for technology transfer or patent licenses.

The following CRADAs are also considered Standard:

1. Limited Purpose CRADAs;
2. CRADAs with State and Local Government;
3. CRADAs with a College or University;
4. CRADAs with an Individual.

Signature Authority:

Each Federal agency may authorize the director of any of its Federal laboratories to enter into a CRADA (15 USC 3710a). The Secretary of the Navy (SECNAV), Head of the Department of the Navy (DON), has delegated authority for technology transfer to the Chief of Naval Research (CNR), (10 USC 5022). In turn, the CNR has allowed, under SECNAVINST 5700.16A dated 7 March 2000, the Heads of Navy laboratories to conduct technology transfer on behalf of DON. The Head of a DON laboratory is the commanding officer and has the authority to enter into a CRADA and sign such Agreements for the DON provided that:

- (a) The following qualifications are met:
 1. Procedures are established for entering into CRADAs.
 2. Personnel with training or experience in technology transfer are designated to be responsible for implementing the procedures.
 3. A single point of contact for interface with the Office of Naval Research (ONR) is sent to ONR.
 4. Personnel responsible for implementing the procedures receive at least eight hours of training in technology transfer every year.
- (b) A legal review, including review by laboratory intellectual property counsel, is obtained prior to entering into an agreement to ensure that the CRADA conforms to all statutes, regulations, Executive Orders, and binding instructions issued within DoD.
- (c) Reports and executed copies of CRADAs are submitted as directed by ONR.
- (d) The U.S. Trade Representative and the appropriate Navy Foreign Disclosure Official are notified for all CRADAs with entities that are directly or indirectly controlled by a foreign company or government, as required by Executive Order 12591, Section 4(a).

SECNAV Instruction 5700.16A also authorizes all DON laboratories and technical activities to enter into CRADAs that deviate from the standard agreement. In such cases, a written explanation of the reasons for the deviation shall be prepared and local legal review obtained prior to entering into the Non-Standard CRADA. The Navy laboratory assumes responsibility for any result caused by any deviation from the NSCRADA language. Copies of the explanation and review are to be attached to the copies provided to ONR.

The following CRADAs are considered Non-Standard:

1. The CRADA involves Unclassified Militarily Critical Technology;
2. The Non-Navy Collaborator is transferring SBIR funds to the Navy Collaborator;
3. The Non-Navy Collaborator is Foreign Owned, Controlled, or Influenced;
4. The CRADA involves three or more Collaborators;
5. The CRADA involves clinical trials.

Note: If a Non-Standard CRADA is negotiated and approved by local authority, you MUST change the word "STANDARD" to "NON-STANDARD" on the Title page and the Top of page 1.

Instructions in Brackets:

Bolded text in brackets, e.g. **[xyz]**, indicates text that is to be replaced when preparing a draft CRADA. Bracketed text in bold italics, e.g. ***[xyz]***, are instructional notes to be deleted entirely when drafting a CRADA. In the final document, all bracketed text in the CRADA template is to be replaced or deleted as required.

The phrases **[Navy Collaborator]** and **[Non-Navy Collaborator]** are to be replaced with the full name of each Collaborator, together with its accepted acronym or abbreviation in parentheses, in the following locations:

1. Title page.
2. Top of page 1, in the heading “STANDARD NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT BETWEEN...”
3. Paragraph 1 of the PREAMBLE (page 1).
4. Article 7.1.1.3.2 and 7.1.1.3.3: In markings used to mark Proprietary Information, Restricted Access Information, or Data subject to 35 USC 205.
5. Article 7.2.3: In the required copyright statement.
6. Title page of Appendix A (Statement of Work).

Use the acronym or abbreviation for all other references to **[Navy Collaborator]** and **[Non-Navy Collaborator]**, including in the Table of Contents.

The variables in the Agreement Number on the title page represent the following:

NCRADA	=	Navy-issued CRADA
XXXXXXXXXX	=	accepted acronym of issuing Navy activity
YY	=	last two digits of <u>Calendar</u> Year issued
ZZZ	=	three digit serial numbering starting at 001. Do <i>not</i> restart at 001 in each new year. This should be a sequential numbering of <i>all</i> CRADAs entered into by a given Navy activity.

Appendices:

Appendices to the NSCRADA are required to provide additional information concerning the performance of tasks and the administration of the Agreement. The following listing describes various Appendices that make up your CRADA package. If your CRADA does not require Appendices C, D, or E, re-label as appropriate. Other approved CRADA templates may require additional appendices (i.e., SBIR Partner, Clinical Trials CRADA). See Section III of this document for additional appendices.

Appendix A - Statement of Work

The Statement of Work is the required Appendix A of the CRADA. The SOW is divided into separate sections that list tasks to be performed solely by each Collaborator as well as those to be performed jointly, if applicable, and is intended to clearly state the exact responsibilities of each Collaborator. The SOW should give sufficient detail to allow the Collaborators, and if necessary an outside party, to understand and know who will do what, when and where. The SOW is not releasable to the public (Article 10.5). Examples of SOWs may be found in Section IV - 4.

Appendix B - Confirmatory License Agreement

This Appendix is required in all Navy CRADAs. Blocks 5 - 7 are to be completed as part of your signed final CRADA. If a Subject Invention is created under the CRADA, contact your local counsel or patent attorney regarding the use of the Confirmatory License Agreement. When the Navy is the signatory for this agreement, it is to be signed by the laboratory commanding officer.

Appendix C - Third Party Agreement (Non-Navy Collaborator)

This Appendix is required when the Non-Navy Collaborator is using a third party to perform work described in Appendix A, Statement of Work.

Appendix D - Third Party Agreement (Navy Collaborator)

This Appendix is required when the Navy Collaborator is using a third party to perform work described in Appendix A, Statement of Work.

Appendix E - DD Form 2345

This Appendix is required if Militarily Critical Technology (MCT) is involved. Attach a copy of the completed DoD Military Critical Technical Data Agreement, DD Form 2345, as this Appendix.

Reporting Requirements:

ONR Registration

Within TEN (10) days after the CRADA has been signed, you MUST provide ONR the following items:

1. One electronic copy of the final signed CRADA which may be in pdf form. (E-mail to dorothy.vincent@navy.mil OR send on a CD-ROM.)
2. A copy of the signed legal review which may be in pdf form.
3. Provide a public releasable summary of the objectives as noted on Page II - 16 of the Handbook.

Correspondence should be addressed to:

Office of Naval Research
Technology Transfer Program, Code 03TSB
875 North Randolph Street
Arlington, VA 22203-1995

DTTIS Reporting

Reporting of CRADAs to the Department of Defense is accomplished through the Navy version of the Defense Technology Transfer Information System (DTTIS) database. The Navy Technology Transfer Program Office reports agreements through the Navy DTTIS. This database is available at http://www.onr.navy.mil/sci_tech/3t/transition/dttis. All Navy Technology Transfer offices should contact Dottie Vincent (Code 03TSB) at 703-696-4792 to register for this database.

Section I - 3

Approved Alternative Articles

The following subsection provides you with approved alternative language that may be used depending on the nature of the Non-Navy Collaborator. CRADAs that are Non-Standard are specified at the beginning of each subsection.

Subsection Number:

- I - 3a The Collaborative Work Involves Unclassified **Militarily Critical Technology**;
- I - 3b The Non-Navy Collaborator is a **State or Local Government Entity**;
- I - 3c The Non-Navy **Collaborator is a Public or Private Foundation** that is not a Corporation;
- I - 3d The Non-Navy **Collaborator is a U.S. College or University**;
- I - 3e The Non-Navy **Collaborator is Paying the Navy Collaborator with Small Business Innovation Research (SBIR) Funds**;
- I - 3f A Non-Navy **Collaborator is Foreign Owned, Controlled or Influenced (FOCI)**;
- I - 3g A **Multiple Party CRADA** in Which Non-Navy Collaborator (A) is a U.S. Commercial Entity and Non-Navy Collaborator (B) is Foreign Owned, Controlled or Influenced (FOCI);
- I - 3h **Funding is Being Provided** to the Navy Collaborator **by Another Federal Entity** that is not the Non-Navy Collaborator;
- I - 3i **A Single Individual** Who is not a Business.

I - 3a The Collaborative Work Involves Unclassified Militarily Critical Technology:

Unclassified Militarily Critical Technology CRADAs are to be considered Non-Standard.

Article 3.3 is to be altered if the Collaborative Work involves unclassified Militarily Critical Technology. Also, per the instruction paragraph associated with this Article, an appropriate DD 2354 must be attached to the CRADA as an appendix.

[Note: the instructions for Article 3.3 given below in bold italics are modified from that in the current NSCRADA.]

Article 3.3 Security Regulations and Directives

Each Collaborator will abide by the safety and security regulations and directives of the host facility in which the Cooperative Work is being performed.

[This is the place to add any special security requirements for personnel doing Cooperative Work at the Collaborators' facilities.]

[If the Cooperative Work covers unclassified Military Critical Technology (MCT) the non-government Collaborator must be certified to handle MCT data in accordance with DoDD 5230.25. MCT data may also be export controlled in accordance with the International Trade in Arms Regulations (ITAR). MCT certification is established using DD Form 2345, called a "Military Critical Technical Data Agreement". A list of MCT can be found at <http://www.dtic.mil/mctl>. Items that are export controlled can be found in the ITAR Part 121 The United States Munitions List.

[If a DD Form 2345 is required, insert a copy as an Appendix to the CRADA.]

[If needed, sample statements to be added include the following:]

Part of the work on this Agreement will involve access to and work on Militarily Critical Technology (MCT) that must be controlled in accordance with the International Trade in Arms Regulations (ITAR). Prior to obtaining access or working on MCT technology under this Agreement, **[Non-Navy Collaborator]** must have a current MCT certification and a copy of its Export-Controlled DoD Technical Data Agreement, DD Form 2345, must be submitted to **[Navy Collaborator]**.

[Non-Navy Collaborator]'s work on this Agreement requires access to information that requires a security clearance. **[Non-Navy Collaborator]** must have an approved DoD Contract Security Classification Specification, DD Form 254, approved and in place before any classified work is initiated under this Agreement.

I - 3b The Non-Navy Collaborator is a State or Local Government Entity:

PREAMBLE

It is necessary to modify the first sentence of the Preamble. This sentence makes reference to the “corporate headquarters” address for the Non-Navy Collaborator.

For a **State or local government entity**, substitute “government offices” as illustrated below.

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), **[Navy Collaborator]** located at **[supply appropriate address]**, and **[Non-Navy Collaborator]**, whose **government offices** are located at **[supply appropriate address]**, enter into this Cooperative Research and Development Agreement (CRADA), which shall be binding upon the Collaborators and their assignees according to the clauses and conditions hereof and for the term and duration set forth.

Article 4.2.1

The NSCRADA template Article 4.2.1 reads as follows:

“**[Non-Navy Collaborator]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a corporation duly organized, validly existing, and in good standing under the laws of **[indicate State or Commonwealth]**.”

For a **State or local government entity**, substitute the following:

“**[Non-Navy Collaborator]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a **[State or local]** government entity duly organized, validly existing, and in good standing under the Constitution laws of the **[State of (name) or Commonwealth of (name)]**.”

Article 4.2.3

The NSCRADA template Article 4.2.3 reads as follows:

“The Board of Directors and stockholders of **[Non-Navy Collaborator]** have taken all actions required by law, its Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.”

For a **State or local government entity**, substitute the following:

“The government officials of **[Non-Navy Collaborator]** have taken all actions required by law in the **[State of (name) or Commonwealth of (name)]** to authorize the execution and delivery of agreements, such as this Agreement.”

I - 3c The Non-Navy Collaborator is a Public or Private Foundation that is not a Corporation:

PREAMBLE

It is necessary to modify the first sentence of the Preamble. This sentence makes reference to the “corporate headquarters” address for the Non-Navy Collaborator.

For a **public or private foundation that is not a corporation**, substitute “administrative headquarters” as illustrated below.

“Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), **[Navy Collaborator]** located at **[supply appropriate address]**, and **[Non-Navy Collaborator]**, whose **administrative offices** are located at **[supply appropriate address]**, enter into this Cooperative Research and Development Agreement (CRADA), which shall be binding upon the Collaborators and their assignees according to the clauses and conditions hereof and for the term and duration set forth.”

Article 4.2.1

The NSCRADA template Article 4.2.1 reads as follows:

“**[Non-Navy Collaborator]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a corporation duly organized, validly existing, and in good standing under the laws of **[indicate State or Commonwealth]**.”

For a **U.S. public or private foundation that is not a corporation**, substitute the following:

“**[Non-Navy Collaborator]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is an organization duly registered, validly existing, and in good standing under the laws of **[State of (name) or Commonwealth of (name)]**.”

Article 4.2.3

The NSCRADA template Article 4.2.3 reads as follows:

“The Board of Directors and stockholders of **[Non-Navy Collaborator]** have taken all actions required by law, its Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.”

For a **U.S. public or private foundation that is not a corporation**, substitute the following:

“The **[Board of Directors or equivalent]** of **[Non-Navy Collaborator]** have taken all actions required by law, its Charter, its bylaws, or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.”

I - 3d The Non-Navy Collaborator is a U.S. College or University:

PREAMBLE

It is necessary to modify the first sentence of the Preamble. This sentence makes reference to the “corporate headquarters” address for the Non-Navy Collaborator.

For a **college or university**, substitute “administrative offices” as illustrated below.

“Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), **[Navy Collaborator]** located at **[supply appropriate address]**, and **[Non-Navy Collaborator]**, whose **administrative offices** are located at **[supply appropriate address]**, enter into this Cooperative Research and Development Agreement (CRADA), which shall be binding upon the Collaborators and their assignees according to the clauses and conditions hereof and for the term and duration set forth.”

Article 4.2.1

The NSCRADA template Article 4.2.1 reads as follows:

“**[Non-Navy Collaborator]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a corporation duly organized, validly existing, and in good standing under the laws of **[indicate State or Commonwealth]**.”

For a **U.S. college or university**, substitute the following:

“**[Non-Navy Collaborator]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a **[college or university]** duly organized, validly existing, and in good standing under the laws of **[indicate State or Commonwealth]**.”

Article 4.2.3

The NSCRADA template Article 4.2.3 reads as follows:

“The Board of Directors and stockholders of **[Non-Navy Collaborator]** have taken all actions required by law, its Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.”

For a **U.S. college or university**, substitute the following:

“The **[Board of Regents or equivalent]** of **[Non-Navy Collaborator]** have taken all actions required by law or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.”

I - 3e The Non-Navy Collaborator is Paying the Navy Collaborator with Small Business Innovation Research (SBIR) Funds:

The alternative language and instructions below pertain to a CRADA in which funds are directly received from a Small Business Innovation Research (SBIR) award winner for cooperative work in support of a Phase I or Phase II SBIR contract or grant. For further information on SBIRs and CRADAs see Section V - 8 of this document.

This type of CRADA must be reported as Non-Standard.

TITLE PAGE

Insert NON-STANDARD at the beginning of Title Page to read as follows:

NON-STANDARD

NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

BETWEEN

[NAVY COLLABORATOR]
[Acronym]

AND

[USE FULL NAME OF NON-NAVY COLLABORATOR]
[Acronym, if used]

FOOTERS

Change footer to read as follows:

Based on the 5th Edition, Revision 1
Navy Standard CRADA 1 May 2002

TABLE OF CONTENTS

Insert new definitions “1.23 ‘SBIR Contract Data’” and “1.24 ‘Small Business Innovation Research (SBIR) Contractor’”. It is then necessary to renumber all subsequent definitions.

.....
.....

1.22	“Restricted Access Information”
1.23	“Small Business Innovation Research (SBIR) Contract Data”
1.24	“Small Business Innovation Research (SBIR) Contractor”
1.25	“Subject Data”
1.26	“Subject Invention”
1.27	“Tangible Property”
1.28	“Unlimited Rights”

Change title of Article 7.1.1.3.2 in the Table of Contents and in the body of the Agreement to read as follows:

“Data that are Proprietary Information, Restricted Access Information, or SBIR Contract Data”

APPENDICES

The following is to be included in the Table of Contents and part of the entire Agreement (see new Instructions to ORTA below):

Appendix [XXX] SBIR Waiver

PREAMBLE

The Phrase “Cooperative Research and Development Agreement (CRADA)” is to be replaced with “Non-Standard Cooperative Research and Development Agreement (CRADA)” as indicated in bold type below.

“Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), **[Navy Collaborator] [acronym]**, whose address is **[address]** and **[Non-Navy Collaborator]**, whose corporate headquarters are located at **[supply appropriate address]**, enter into this **Non-Standard Cooperative Research and Development Agreement (CRADA)**, which shall be binding upon the Collaborators and their assignees according to the clauses and conditions hereof and for the term and duration set forth.”

Instructions to ORTA (when Non-Navy Collaborator is supplying funds resulting from an SBIR award):

[ORTA, the previous two paragraphs should be expanded as appropriate to include specific background information. Explicitly state that [Non-Navy Collaborator] is an SBIR contractor and list the SBIR Contract Number and the branch of the Federal Government that awarded the contract. On funded CRADAs with SBIR Contractors, before the Agreement is executed and before Navy Collaborator can receive funding from an SBIR Contractor, a waiver must be granted by the Small Business Administration (SBA) that specifically authorizes Navy Collaborator to receive the funded amount. All waivers must be requested and received before the CRADA is executed or any funding is accepted. The request for this waiver must be submitted to the Navy SBIR Program Office, which, in turn, will forward the application to SBA in the required format. The Navy SBIR Program Office will notify the requestor of the SBA decision. Explicitly state the date that a waiver was granted by the SBIR Program Office that authorized Navy Collaborator to receive SBIR funding from [Non-Navy Collaborator. Maintain a record of any waivers in your records. For further information on this section, please contact Dr. Peter Majumdar at peter.majumdar@navy.mil.]

Article 1. Definitions

Add the following definitions to Article 1:

1.23 “SBIR Contract Data” means any data developed by a Non-Government Collaborator under a contract that is funded under the U.S. Federal Small Business Innovation Research Program authorized under 15 USC 638.

1.24 “Small Business Innovation Research (SBIR) Contractor” means any contractor working under a contract that is funded under the U.S. Federal Small Business Innovation Research Program authorized under 15 USC 638. On funded CRADAs, before the Agreement is executed and before **[Navy Collaborator]** can receive funding from an SBIR Contractor, a waiver must be granted by the Navy SBIR Program Office that specifically authorizes **[Navy Collaborator]** to receive the funding. If the SBIR Contract was awarded by a Non-Navy organization, then an additional waiver is required from the SBIR Program Office for that government organization. These waivers are required even if the funds will not come from the SBIR contract.

Article 5. Funding

[IF PAYMENTS ARE TO BE MADE directly from Non-Navy Collaborator to [Navy Collaborator], use the following Articles:]

5.1 Payment Schedule

[Non-Navy Collaborator] agrees to pay **[Navy Collaborator]** the following fees/costs in accordance with the payment schedule below. **[Navy Collaborator]** received a waiver from the Navy SBIR Program Office on [insert date] to permit **[Navy Collaborator]** to receive \$[insert entire approved funding amount under the waiver] from **[Non-Navy Collaborator]** under SBIR Contract Number [insert SBIR contract number] for work conducted by **[Navy Collaborator]** under this Agreement.

7.1.1.3.2 Data that are Proprietary Information, Restricted Access Information, or SBIR Contract Data.

[Non-Navy Collaborator] shall place a proper proprietary marking on each medium used for recording Data that **[Non-Navy Collaborator]** delivers to **[Navy Collaborator]** under this Agreement that **[Non-Navy Collaborator]** asserts is Proprietary Information. **[Non-Navy Collaborator]** shall request in writing if it wishes Subject Data generated by **[Navy Collaborator]** to be marked as Restricted Access Information. **[Non-Navy Collaborator]** shall place a proper marking on each medium used for recording Data that **[Non-Navy Collaborator]** delivers to **[Navy Collaborator]** under this Agreement that **[Non-Navy Collaborator]** asserts is SBIR Contract Data. The Collaborators together shall confer to determine if such marking is appropriate, with reference to the Definitions of Article 1. If the Collaborators mutually agree to the marking then:

(d) For Non-Subject Data and Subject Data that are SBIR Contract Data, the marking shall read:

“SBIR CONTRACT DATA OF [Full Name of Non-Navy Collaborator] – GOVERNMENT RIGHTS LIMITED AS PROVIDED IN SBIR CONTRACT NUMBER [Insert SBIR Contract Number]”.

7.1.2.2 Rights in Subject Data

Except as represented in Article 4.3.2, the Collaborators shall have Unlimited Rights in all Subject Data that are not Proprietary Information, Restricted Access Information, **or SBIR Contract Data**. Notwithstanding 15 USC 3710a, **[Non-Navy Collaborator]** grants Government Purpose Rights in any Subject Data furnished by **[Non-Navy Collaborator]** to **[Navy Collaborator]** under this Agreement that are properly marked as Proprietary Information. The Government has Government Purpose Rights in Subject Data that are Restricted Access Information. **Government rights to [Non-Navy Collaborator] Subject Data originated under an SBIR contract will be in accordance with the SBIR contract.**

I - 3f The Non-Navy Collaborator is Foreign Owned, Controlled or Influenced (FOCI):

This CRADA is Non-Standard.

If the Non-Navy Collaborator is directly or indirectly owned or controlled by a foreign company or government (FOCI), the CRADA is considered Non-Standard. There are many categories of FOCI entities, such as universities, companies, and U.S. subsidiaries of foreign companies. Article 4.2.1 must be revised appropriately for each case. For further information on FOCI see Section V - 4 of this document.

PREAMBLE

The first sentence refers to the “corporate headquarters” address for the Non-Navy Collaborator. The following may be used as a substitute phrase:

The Non-Navy Collaborator is a FOCI;

Article 4.2.1

The following are suggested alternatives for Article 4.2.1 that may be used in the case of a CRADA with a foreign company or university:

- (a) For a **foreign owned, controlled, or influenced corporation**, substitute the following:

“**[Non-Navy Collaborator]** is directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a corporation duly organized, validly existing, and in good standing under the laws of **[indicate country]**.”

- (b) For a **foreign owned or controlled college or university**, substitute the following:

“**[Non-Navy Collaborator]** is directly or indirectly controlled by a foreign government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a **[college or university]** duly organized, validly existing, and in good standing under the laws of **[indicate country]**.”

Article 10.2.3.3

The original article reads as follows:

10.2.3.3 FOCI Successor or Assignee

If **[Non-Navy Collaborator]** or its successor or assignee is a U.S. company, and becomes, during the term of this Agreement or thereafter, directly or indirectly owned, controlled, or influenced by a foreign company or government (FOCI), then **[Non-Navy Collaborator]** or its successor or assignee shall promptly notify **[Navy Collaborator]** to that effect.

The allowed paragraph when the Non-Navy Collaborator is a FOCI is as follows:

10.2.3.3 FOCI Successor or Assignee

If **[Non-Navy Collaborator]** or its successor or assignee becomes, during the term of this Agreement or thereafter, directly or indirectly owned, controlled, or influenced by a different foreign company or government (FOCI), then **[Non-Navy Collaborator]** or its successor or assignee shall promptly notify **[Navy Collaborator]** to that effect.

I - 3g A Multiple Party CRADA in Which Non-Navy Collaborator (A) is a U.S. Commercial Entity and Non-Navy Collaborator (B) is Foreign Owned, Controlled or Influenced (FOCI):

This CRADA is Non-Standard.

The following article is approved for use. For further information on CRADAs with multiple parties and FOCIs please see Section III - 3 and Section V - 4, respectively.

7.4.8.1 Exclusive Licenses and Exclusive License Option

[Navy Collaborator] may terminate any Exclusive License or cancel any option for an Exclusive License to a Subject Invention granted **[Non-Navy Collaborator (A)]** under this Agreement in the event that:

- (a) **[Non-Navy Collaborator (A)]** is in default for failure to make payment as agreed in Article 5; or
- (b) the Agreement is terminated unilaterally by **[Non-Navy Collaborator (A)]**; or,
- (c) **[Non-Navy-Collaborator (A)]** fails to perform according to the Statement of Work (Appendix A); or
- (d) **[Non-Navy Collaborator (A)]** becomes a foreign owned, controlled, or influenced (FOCI) organization that does not qualify under the requirements of Executive Order 12591, Section 4(a).

[Navy Collaborator] may terminate any Exclusive License or cancel any option for an Exclusive License to a Subject Invention granted **[Non-Navy Collaborator (B)]** under this Agreement in the event that:

- (a) **[Non-Navy Collaborator (B)]** is in default for failure to make payment as agreed in Article 5; or
- (b) the Agreement is terminated unilaterally by **[Non-Navy Collaborator (B)]**; or,
- (c) **[Non-Navy-Collaborator (B)]** fails to perform according to the Statement of Work (Appendix A); or
- (d) **[Non-Navy Collaborator (B)]** becomes a different foreign owned, controlled, or influenced (FOCI) organization that does not qualify under the requirements of Executive Order 12591, Section 4(a).

I - 3h Funding is Being Provided to the Navy Collaborator by Another Federal Entity that is not the Non-Navy Collaborator:

The following article is approved for use:

Article 5

If the Navy Collaborator or both Collaborators will be funded by another Government agency (e.g. DARPA), use the following alternative for Article 5:

5.1 Funding source

Each Collaborator will fund its own efforts.

[Navy Collaborator]'s participation in this Agreement is contingent upon its receipt of funds from **[Government sponsoring agency]** via *Military Interdepartmental Procurement Request (MIPR) number XXXXX (italicized text is optional or may be modified for the specific CRADA)* in accordance with Article 5.2.

5.2 Related Payments

Funding to support **[Navy Collaborator]**'s effort as described in the Statement of Work (Appendix A) will be provided directly by **[Government sponsoring agency]** in accordance with the payment schedule below:

[Government sponsoring agency] shall provide one (1) payment of X thousand dollars (\$X,000) to **[Navy Collaborator]** within fifteen (15) days after this Agreement has been signed by both Collaborators.

[Insert additional payments, if appropriate.]

The total funded amount shall be X thousand dollars (\$X,000).

If **[Government sponsoring agency]** fails to provide payment with fifteen (15) days after its due date, then **[Navy Collaborator]** may proceed to terminate the Agreement under the terms of Article 11.2."

I - 3i A Single Individual Who is not a Business:
--

Replace all labels **[Non-Navy Collaborator]** with the full name of the Non-Navy Collaborator or shortened form of name if desired.

Article 3.1 [Navy Collaborator] Personnel and Facilities

Insert the following as the second paragraph of this Article:

When **[Non-Navy Collaborator]** performs Cooperative Work at **[Navy Collaborator]** facilities, **[Non-Navy Collaborator]** will be self-supervised and will coordinate all work with the **[Navy Collaborator]** PI.

Article 3.2 [Non-Navy Collaborator] Personnel and Facilities

Insert the following as the second paragraph of this Article:

[Non-Navy Collaborator] shall perform all Cooperative Work done on **[his/her]** behalf, except as permitted by Article 10.2.3. **[Non-Navy Collaborator]** has the responsibility for the scientific and technical conduct of the Cooperative Work performed by **[Non-Navy Collaborator]** or done on behalf of **[Non-Navy Collaborator]** by third parties in support of this Agreement.

Article 4.2.1

Replace the original Article with the following:

[Non-Navy Collaborator] is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a citizen of the United States and a resident of **[indicate State or Commonwealth]**.

Article 4.2.2

Insert the following Article:

4.2.2 **[Non-Navy Collaborator]** has the requisite power and authority to enter into this Agreement and to perform according to the terms of this Agreement.

[Note, the original Article 4.2.3 has been deleted for this single individual Non-Navy Collaborator Model Agreement.]

Article 7.3.2

Replace Article 7.3.2 with the following:

Employees of **[Navy Collaborator]** shall report the adoption of a trademark or service mark associated with the Cooperative Work to **[Navy Collaborator]** within thirty (30) days of the first use of the mark. Use includes internal use of any product or service of the Cooperative Work.

Article 7.3.3

Replace Article 7.3.3 with the following:

[Navy Collaborator] shall notify **[Non-Navy Collaborator]** within thirty (30) days of its employee's report of the first use of a trademark or service mark. **[Non-Navy Collaborator]** shall notify **[Navy Collaborator]** within thirty (30) days of **[his/her]** first use of a trademark or service mark.

Article 7.4.1.1 Collaborator's Instructions to Employees

Replace Article 7.4.1.1 with the following:

[Navy Collaborator] shall instruct its employees to submit an Invention Disclosure to **[Navy Collaborator]** for all innovations, solutions to technical problems, or unique increases to the general body of knowledge resulting from the Cooperative Work. For the purposes of this Article, these innovations, solutions, and increases to knowledge shall be deemed Inventions.

Article 7.4.1.2 Timely Invention Disclosure by Inventors

Replace Article 7.4.1.2 with the following:

Within ninety (90) days of Making an Invention resulting from the Cooperative Work, unless a shorter time period is required by circumstances, **[Navy Collaborator]** inventor(s) shall submit an Invention Disclosure to **[Navy Collaborator]**.

In the case of an Invention Made jointly by inventors from both Collaborators, the inventors shall submit an Invention Disclosure with both Collaborators.

Article 7.4.1.3 Obligation to Provide Invention Disclosures to the Other Collaborator

Replace Article 7.4.1.3 with the following:

[Navy Collaborator] shall provide **[Non-Navy Collaborator]** with a copy of each Invention Disclosure reporting a Subject Invention within sixty (60) days of receiving the Invention Disclosure from its inventor(s).

[Non-Navy Collaborator] shall provide **[Navy Collaborator]** with an Invention Disclosure for all innovations, solutions to technical problems, or unique increases to the general body of knowledge resulting from the Cooperative Work within sixty (60) days of making such an Invention.

Article 7.4.3 Title to Ownership of Subject Inventions

Replace Article 7.4.3 with the following:

[Navy Collaborator] shall be entitled to own the Subject Inventions of its employees. **[Non-Navy Collaborator]** shall be entitled to own **[his/her]** Subject Inventions. Each Collaborator shall cooperate with the other Collaborator to obtain inventor signatures on Patent Applications,

assignments or other documents required to secure Intellectual Property protection. For any Invention Made jointly by **[Non-Navy Collaborator]** and employees of **[Navy Collaborator]**, each Collaborator shall have ownership of the Subject Invention in the form of an undivided interest.

Article 7.4.4.1 Filing of Patent Applications on Solely Made Inventions

Insert the following as the first paragraph of Article 7.4.4.1:

[Navy Collaborator] has primary responsibility for filing Patent Applications on the Subject Inventions of its employee(s). **[Non-Navy Collaborator]** has primary responsibility for filing Patent Applications on **[his/her]** Subject Inventions.

Article 7.4.4.2 Filing of Patent Applications on Jointly Made Inventions

Replace Article 7.4.4.2 with the following:

In the case of an Invention jointly Made by employees of **[Navy Collaborator]** and **[Non-Navy Collaborator]**, the Collaborators shall confer and agree as to which Collaborator will file any Patent Application. Officers of the non-filing Collaborator shall cooperate with the filing Collaborator to obtain signatures on documents that are needed to file a Patent Application.

Article 7.4.4.6 second paragraph:

In the event both Collaborators decline to file a Patent Application on a Subject Invention, **[Non-Navy Collaborator]** may, at **[his/her]** sole discretion, renounce **[his/her]** entitlement and leave **[his/her]** rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on **[his/her]** behalf.

Section I - 4

Amendments

Amendments to the CRADA are allowed under the Article 11.1. Amendments must be signed prior to the latest expiration date of the CRADA. A CRADA cannot be amended once it has expired.

The Office of Naval Research approved format for Amendments follows:

[INSERT AMENDMENT NUMBER, i.e., FIRST, SECOND, etc.]
AMENDMENT OF
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
BETWEEN
[INSERT COMMAND NAME OF NAVY COLLABORATOR]
AND
[INSERT FULL NAME OF NON-NAVY COLLABORATOR]

The **[Navy Collaborator]** (**Abbreviation of Command Name**) and **FULL NAME OF [Non-Navy Collaborator]** (**Abbreviation of Non-Navy Collaborator**), agree to amend the Cooperative Research and Development Agreement (CRADA) entitled "**[INSERT SUBJECT OF CRADA FROM COVER PAGE]**", NCRADA Number **[USE NUMBER FROM CRADA COVER PAGE]** by **[DESCRIBE HOW YOU ARE CHANGING THE CRADA]**.

1. **[Navy Collaborator]** and **[Non-Navy Collaborator]** agree to amend Article _____ to read as follows:

[INSERT THE ENTIRE TEXT OF THE AMENDED ARTICLE]
[LIST EACH AMENDED ARTICLE SEPARATELY]

2. All other terms and conditions of the Agreement remain in effect.

For the **[Non-Navy Collaborator]**:

I, the undersigned, am duly authorized to bind **[Non-Navy Collaborator]** to the Amendment(s) of this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of 20__.

By:
Title:

For the Department of the Navy:

I, the undersigned, by 15 USC 3710a and Navy regulations, am duly authorized to bind the U.S. Navy to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of 20__.

By:
Title:

Navy Organization:

SECTION II
CRADA PROCESSES

TABLE OF CONTENTS:

- II - 1 Choosing the Appropriate Partnership Mechanism
- II - 2 Ways of Doing Business (Chart)
- II - 3 Justification Prior to Negotiating CRADA or Work With Private Parties (WWPP) Agreements
- II - 4 Sample CRADA Application Templates
 - II - 4a CRADA Application Template - Example 1 Worksheet Form A
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- II - 5 CRADA Creation Process
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Section II - 1

Choosing the Appropriate Partnership Mechanism

Within the Department of Defense there are many non-contractual means of forming an agreement for the purpose of doing work either with, or for, a Non-Federal Collaborator. In many instances, more than one type of agreement will be available, given the statutory restrictions on each type of agreement. For instance, a particular effort may fit either a Work for Private Parties (Testing) agreement or a CRADA. DoDI 5535.8 states that "CRADAs should be used wherever possible" to expand capabilities for R&D and to transfer technology. Accordingly, in situations where both a CRADA and another type of agreement are statutorily authorized, a CRADA should be used.

The following table, Section II - 2 from Naval Undersea Warfare Center, lists many of the appropriate partnership mechanisms between Non-Navy Collaborators and the Navy. Further details of each mechanism may be determined by consulting the statute of interest. Currently, other than the Navy CRADA, there may be different processes and formats for the agreement used depending on which Navy laboratory is your place of work. Consult your local authorizations and guidelines.

When approached by a Non-Federal Collaborator about possible work with your laboratory, you as the ORTA manager and your local Navy attorney need to advise the potential partner as to what mechanism your laboratory may use to perform the proposed effort. Prior to any negotiation, if the Non-Federal party is a FOCl, you must first determine through your local security office and the Federal Trade Representative any restrictions that may exist on the technology and the foreign countries involved.

General guidelines for a Navy CRADA include the following:

1. The proposed work must be within the mission of your laboratory.
2. There must be an exchange of intellectual property among all Collaborators.
3. Each Collaborator must have a well defined role in the Statement of Work.
4. Special consideration will be given to U.S. small businesses.
5. There should be a goal to commercialize a product resulting from the successful completion of the CRADA. Commercialization includes sale of items to the Government.
6. The work is research and/or development including the test and evaluation of materials.

CRADAs should not be used for the following:

1. The work involves no exchange of intellectual property among the Collaborators.
2. The proposed work only involves the sale of the use of a test facility or range.
3. The Navy is providing only the sale of services to the Non-Navy Collaborator based on a task request.

NAVSEA has introduced a Community of Practice for dealing with CRADAs and Work for Other Agreements under the broad title Work With Private Parties (WWPP). The decision of which mechanisms to use is discussed in the NAVSEA manuals for WWPP. An example of a form used in the mechanism selection from NSWC - Indian Head follows (Section II - 3, Justification Prior to Negotiating CRADA or WWPP Agreements).

Section II - 2 Ways of Doing Business						
Type of Agreement (Authority)	Parties	Effect	Advantages	Restrictions	Authorized Signatories	Process Manager
Partnering Agreements						
CRADA (15 U.S.C. §3710a)	Federal lab and any other entity including other federal activities.	CRADA allows exchange of personnel, property and intellectual property between Government and educational or private entity. Data developed by the Government can be protected from release. Provides commercial exposure for technology.	Low cost; CRADA allows shared resources between Government and private industry. FAR and DFARS do not apply. Government may receive funds.	No funding can be provided by the Government. Must have cooperative elements, but not necessarily cooperative tasks. May have problems if CRADA exists for non-dual use technology. Does not overcome necessary funding for contingencies.	Commander, NUWCDIVNPT	Code 01TPEO
Cooperative Agreement (10 USC §2371, 31 U.S.C. §6305, DoDGARs)	Lab and another non-federal entity, other federal entities may be involved	Principal purpose is to transfer something of value to carry out a public purpose of support authorized by a United States law, and the transaction requires substantial lab involvement.	Encourages basic and advanced research in areas of interest. Allows some supervision.	Government involvement and control is substantial. Must help fulfill agency's goals. Funding must be for support and stimulation or be authorized by statute. Primary purpose has no direct Federal Government Benefit.	Delegated to NUWCDIVNPT Contracting	Code 59
Other Transactions (10 U.S.C. §2371, NUWCDIVNPTINST 4000.4)	Lab and another non-federal entity; other federal entities may be involved	Purpose is to provide a flexible method that doesn't fit into a contract, grant or cooperative agreement. Well suited for Consortium Oversight. Intended for dual use products and technology.	Very flexible. Can be used to avoid the imposition of Government accounting on partners. The Government may receive funds.	Cannot be used if standard grants or contracts are available. Must explain special needs. Can only use for R&D. Cannot transfer IP rights.	Delegated to NUWCDIVNPT Contracting	Code 59
Other Transactions for Prototyping (§845, 10 U.S.C. 2371 note. P.L. 106-398 Sec. 803 Expires 9/30/04)	Lab and another non-federal entity; other federal entities may be involved	Purpose is to provide a flexible method that doesn't fit into a contract, grant or cooperative agreement. Well suited for Consortium Oversight. Intended for military products and technology.	Very flexible. Can be used to avoid the imposition of Government accounting on partners. The Government may receive funds.	Cannot be used if standard grants or contracts are available. Non-traditional contractor, cost matching or innovative agreement required. Competitive award for procurements unless justified.	NAVSEA 02	Code 59

Section II - 2 Ways of Doing Business						
Type of Agreement (Authority)	Parties	Effect	Advantages	Restrictions	Authorized Signatories	Process Manager
Partnering Agreements						
Educational Partnership (10 U.S.C. §2194)	Defense lab and educational institution	Allows use of institutional faculty and students in lab projects, instruction by lab personnel, provision of career and academic advice to students, loan of lab equipment to institution, and transfer of surplus equipment.	Can use graduate students from educational institution for Division projects. Aids the institutions and DoD in attracting qualified students and future employees. Allows easy path for donation of center equipment.	Partnership must be for the purpose of encouraging and enhancing study in the scientific disciplines. Other party must be a non-profit educational institution.	Commander, NUWCDIVNPT	Code 01TPEO
Personal Excellence Partnership		Allows encouragement of participation of Governmental personnel with private organizations	Informal. Allows contribution of no cost resources.	Cannot donate equipment. Difficult to guard against liability	Commander, NUWCDIVNPT	
MOU (Memorandum of Understanding, 10 U.S.C. §2350a)	Defense lab and allied foreign government	Allows a cooperative research and development program between a lab and a NATO or allied foreign country for the purpose of improving conventional defense capabilities.	Allows establishment of cooperative research between nations.	MOU must be rigidly monitored to avoid violation of treaties with other countries. Requires high level approval.	Secretary of Defense (limited ability to delegate)	
MOU or MOA (Memorandum of Understanding)	Lab and another Government agency	Formalized agreement between two federal agencies	Allows agencies to share resources in areas where they have a common interest	Not enforceable in court. Merely a formalization of mutual interest.	Commander and authorized party from other entity	
MOU or MOA	Lab and commercial entity	Formalized agreement providing order to relationship without allocating resources. Can include non-disclosure.	Allows agencies sharing of information in areas with a common interest	Legal review should ensure no enforceable promises or allocation of resources. Merely a formalization of mutual interest.	Commander and authorized party from other entity	
IPA (Intergovernmental Personnel Assignment, 5 U.S.C. §3371)	Lab and Federal, State or Local government or a qualified non-profit entity	Allows the lab or the governmental unit to transfer employees to work on projects.	Increases agency flexibility in cooperation with educational institutions and qualified non-profit entity.		HRO Director with Commander's approval	Code 01?

Section II - 2 Ways of Doing Business						
Type of Agreement (Authority)	Parties	Effect	Advantages	Restrictions	Authorized Signatories	Process Manager
Non-Partnering Agreements						
Contract (31 U.S.C. §6303, FAR, DFARS)	Lab and another non-federal entity	Principle purpose of the instrument is to acquire goods or services for the lab.	Closely fulfills needs in carrying out mission.	FAR and DFARS control formation and performance. CICA applies.	Contracting officer and other party	Code 59
Grant (31 U.S.C. §6304, DoDGARs)	Lab and another non-federal entity; other federal entities may be involved	Principle purpose is to transfer something of value to carry out a public purpose of support authorized by a United States law, and the transaction does not require substantial lab involvement.	Allows support of worthy groups by transfer of resources. Encourages basic and advanced research in areas of interest.	Government involvement and control is minimal. Grant must help fulfill agency's goals. Primary purpose has no direct Federal Government Benefit.	Delegated to NUWCDIVNPT Contracting	Code 59
Work With Private Parties (Goods & Services) (10 USC §2563, NUWCDIVNPTINST 4000.4)	Working capital funded activity and private party	The lab can provide its unique services or equipment in the marketplace when excess resources are available.	Allows lab to receive payments from a commercial entity to perform work for that entity	This transaction requires legal review. Commercial competition is prohibited. Indemnification is negotiable. Requires risk analysis.	Commander, NUWC	Code 59
Work With Private Parties (Testing) (10 USC §2539b, NUWCDIVNPTINST 4000.4)	Working capital funded activity and private party	The lab can provide its unique equipment and facilities for use in the marketplace when excess resources are available. Allows commercial entities to use lab facilities.	Allows lab to receive payments from a commercial entity to perform work for that entity	Can create significant problems if lab personnel make an invention during performance. Available only for specialized items. Easier to use than 10 USC §2553. Commercial competition is prohibited to the extent economically practical. Private party must indemnify the Government.	Commander, NUWC, Division Newport	Code 59

Section II - 2 Ways of Doing Business						
Type of Agreement (Authority)	Parties	Effect	Advantages	Restrictions	Authorized Signatories	Process Manager
Non-Partnering Agreements						
Range Test Agreement (10 USC §2681)	DoD and Commercial entity	Services of a major range and test facility may be provided. Facility must be designated as such by DoD.	Cost reimbursement of direct costs is authorized to the appropriation accounts incurring the costs. Appropriate indirect costs can also be billed. Specific required construction can be a cost.	Testing must be at the designated facility. Contract is terminable upon writing with specified determinations. Must have indemnification. Non-competition is not required when work is being performed for a Government end-user.	Commander, NUWC, Division Newport	Code 00
Economy Act Order (31 U.S.C. §1535)	Two governmental units	Lab can order goods and services from or provide goods and services to another Government agency		Must be cheaper than privately available. Cannot use to circumvent FAR, DFARS without high level approval.	Outside DoD - Commander, NUWC but ASN(RD&A) if non-FAR	Code 57
Tech. Transfer (15 U.S.C. §3710)	Lab and others needing technology	Establishes an Office of Research and Technology Applications at each lab to assess technology which may have commercial applications and disseminate such information.	Exposes marketable technology which may be presented to industry for licensing.	Provisions are somewhat free form.	Implemented	Code 01TPEO
Bailment Agreement or No cost Contract (31 U.S.C. §6303, FAR, DFARS)	Lab and another non-federal entity	Principle purpose of the instrument is testing of contractor provided good to determine if it meets needs.	No cost; however, contingencies must be covered by available funding.	Potential unfunded liability if transferred item is lost. Replacement funding must be available. FAR and DFARS control formation and performance. CICA applies.	Contracting officer and other party	Code 59
Non-disclosure Agreement (Type of no-cost contract)	Lab and Entity having proprietary information	Encourages entity to share proprietary information with Lab personnel having need to know for Government purposes.	No cost.	Use of agreement is often unnecessary. Agreement requires legal review. Individuals cannot sign.	Contracting officer.	Code 59

Section II - 3

Example for NAVSEA Laboratories

Justification Prior to Negotiating CRADA or Work With Private Parties (WWPP) Agreements

(Check One)

WWPP: 2563 or 2539b CRADA: 3710a

Name of Partner or Private Party: _____

[Navy Lab]: Technical POC: _____ Code: _____ Ext. _____

1. What **[Navy Laboratory]** Core Equity(s) does this effort support?

2. Describe how the work that will be performed is consistent with the selected Core Equity(s).

3. What is the benefit to the Navy if **[Navy Laboratory]** does this work? (Does the work result in knowledge or capability that the Navy needs and will not gain otherwise, or does the work enable the sustainment of a critical technical capability that will otherwise be lost or continue to erode, support dual-use/technology transfer opportunity, etc.?)

4. Is **[Navy Laboratory]** recovering the true cost of doing the work? (Consider the cost to process the documents, labor, materials, wear and tear on equipment, etc.)

Technical POC Signature

Date

Section II - 4

Sample CRADA Application Templates

Within this section are three examples of templates that you may use or modify as part of developing your CRADA. The examples in Sections II - 4a and II - 4b constitute a single application package. The templates are to be filled out by you, your principal investigator and the authorized representative of the Non-Navy Collaborator. Once completed, most of the information that you need to answer to populate the Standard CRADA template should be available.

Section II - 4a

CRADA Application Template - Example 1

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT PROPOSAL FORM A	Date Received	File Number
---	---------------	-------------

Instructions: Employees of the Naval Surface Warfare Center, Panama City Division are to use this form when proposing a Cooperative Research and Development Agreement (CRADA). Where space on the form is inadequate, enter "see attached page," and use plain pages as needed. This form should be printed and signed by both the Navy employee and the Non-Navy employee proposing the CRADA, and submitted via the Navy employee's chain of command to the Office of Research and Technology Applications, Code T06, NSWC PCD. Non-Navy employees should provide a copy of this form to their employer for their cognizance.

Part I. COLLABORATORS

1. NAVY COLLABORATOR

Name:

Location:

Code:

Phone:

E-Mail:

2. NON-NAVY COLLABORATOR

Name:

Location (Address):

Part II. PURPOSE OF COOPERATIVE RESEARCH

Describe the nature and intent of this proposed transfer of technology:

Part III. CONTACTS

1. NAVY TECHNICAL CONTACT

Name:

Location (Department):

Phone and Facsimile Numbers:

2. NON-NAVY TECHNICAL CONTACT

Name:

Location (Department):

Phone and Facsimile Numbers:

3. NON-NAVY LEGAL CONTACT

Name:

Location (Department):

Phone and Facsimile Numbers:

E-mail:

Part IV. SIGNATURES

I am proposing the CRADA describe above and detailed in Form B

Navy Employee

I am aware of the proposed CRADA

Navy Branch Head

(Comments may be attached to this form)

Section II - 4b

CRADA Application Template - Example 2

Naval Surface Warfare Center, Panama City Division

Cooperative Research and Development Agreement (CRADA)

Worksheet Form B

This document is used by the Naval Surface Warfare Center, Panama City Division (NSWC PCD), Office of Research and Technology Applications (ORTA), in drafting a Cooperative Research and Development Agreement with a single Non-Navy Collaborator. If you have any comments or questions, please contact the following: ORTA Manager, Mr. Edward C. Linsenmeyer at Panama City--Code T06, telephone (850) 234-4161 or facsimile (850) 235-5374.

Instructions: Electronic versions are requested when the CRADA application is submitted. Navy Technical Contact and Non-Navy Technical Contact should work together and consolidate their respective information to complete and submit one questionnaire. Fill in each section with the requested information. You are not limited by the space provided below. The most important item for both collaborators to develop before the CRADA document is prepared is a good Statement of Work. Upon completion, the questionnaire should be submitted to the NSWC PCD ORTA Manager.

1. PROPOSED AGREEMENT TITLE:

Provide a short title for the proposed collaborative work:

2. NAVY TECHNICAL PRINCIPAL INVESTIGATOR

Name:
Address:
Office Code:
Phone:
Fax:
Cell:
E-mail:

3. NON-NAVY PREFERRED POINT-OF-CONTACT

Name:
Address:
Phone:
Fax:
E-mail:

4. NON-NAVY TECHNICAL PRINCIPAL INVESTIGATOR

Name:
Address:
Phone:
Fax:
E-mail:

5. NON-NAVY LEGAL POINT OF CONTACT (OPTIONAL)

Name:
Address:
Phone:
Fax:
E-mail:

6. NON-NAVY CORPORATE HEADQUARTERS ADDRESS

Official Organization Name:
Official Organization Acronym (if any):
Address:

7. BACKGROUND INFORMATION ON NON-NAVY COLLABORATOR

Provide a short paragraph describing the nature of the non-Federal Collaborator: what are the areas of its business, research, or educational interest.

8. PUBLIC RELEASE SUMMARY

Write a brief description, preferably in layman's terms of the intent and nature of the work to be done and how the Collaborators will participate and benefit. Discuss why the Collaborators are getting together and define what unique capabilities, expertise, and facilities that are forming a basis for the Cooperative Research that is to be done.

The Summary is not to be used as a binding requirement of the Agreement. This summary will be used: (1) in internal documents and public releases from the Office of Naval Research; and (2) in internal documents and public releases from both the Navy and Non-Navy Collaborators. This section will be available for public release, even if the identity of the Non-Navy Collaborator is protected from disclosure.

9. OBJECTIVES OF THE COLLABORATION

Describe the specific, realizable results or benefits to be gained by each Collaborator at the conclusion of this Agreement. State the desired final outcome by each Collaborator, including any intentions of commercialization, if appropriate. Describe, if appropriate, any benefits to the war-fighter. Will this support any existing Department of Defense acquisition program? If so, please state program and sponsor.

FOR NAVY COLLABORATOR:

FOR NON-NAVY COLLABORATOR:

10. REQUIREMENT BY NAVY COLLABORATOR FOR SERVICE OR SUPPORT CONTRACTOR PERSONNEL

Will the Navy Collaborator use service or support contractor personnel in the performance of the work under this Agreement?

If yes, specify contractor(s) name, address, and existing contract agreement number.

11. REQUIREMENT BY NON-NAVY COLLABORATOR FOR SERVICE OR SUPPORT CONTRACTOR PERSONNEL

Will the Non-Navy Collaborator use service or support contractor personnel in the performance of the work under this Agreement?

If yes, specify contractor(s) name, address.

12. REQUIREMENT FOR USE OF NAVY FACILITIES AND OR TEST RANGES

Will the Navy use at NSWC PCD any specialized facilities or test ranges for which there is a charge or fee for use?

If yes, specify item and provide the point of contact name and phone number.

Will the Navy use any other Navy specialized facilities or test ranges for which there is a charge or fee for use?

If yes, specify item and provide the point of contact name and phone number.

Will the Navy use any other Department of Defense specialized facilities or test ranges for which there is a charge or fee for use?

If yes, specify item and provide the point of contact name and phone number.

13. SECURITY REQUIREMENTS

FOR THE NAVY:

Is the collaborative work classified?

If yes, specify the required classification guidelines appropriate to this work.

If yes, provide the names of all NSWC PCD personnel, service or contractor personnel who will have access to data resulting from this Agreement.

Does the collaborative work include unclassified Military Critical Technology (MCT)?

Is the data being generated under this agreement Controlled Unclassified Information?

Has a Non-Disclosure Agreement been established with the Non-Navy Collaborator?

FOR THE NON-NAVY COLLABORATOR:

If the collaborative work includes unclassified Military Critical Technology (MCT), the Non-Navy Collaborator must be certified to handle MCT data. This data is controlled by the International Trade in Arms Regulation (ITAR). **The Non-Navy Collaborator must provide proof of certification to the NSWC PCD ORTA by submitting a copy of the form DD 2345 “Export-Controlled DoD Technical Data Agreement”.**

If this collaborative work is classified, please provide the following information for your Security Office:

Name:

Address:

Phone:

E-mail:

14. NAVY MISSION AREA

What is the NSWC PCD mission area for the work to be performed by this collaborative effort?

15. REPRESENTATIONS OF NON-NAVY COLLABORATOR

a. Non-Navy Collaborator is (select one from the following):

- (1) a U. S. commercial business whose Standard Industrial Classification (SIC) Code is **{specify}** for the commercial product **{identify}** to be developed as a result of this Collaborative Research;
- (2) a non-profit or not-for profit entity under U. S. law;
- (3) a U. S. public or private educational institution;
- (4) a state or local government entity of the U. S.;
- (5) a foreign owned or controlled institution (if so, state nature of organization, identify the country and Non-Navy Collaborator’s type of organization, e.g., *corporation, partnership, University, etc.*).

- b. State/Country under which Non-Navy Collaborator is organized, exists, or is “incorporated”:
- c. Non-Navy Collaborator’s type of leadership (e.g., *Board of Directors, owner, president, etc.*):
- d. Non-Navy Collaborator **is** or **is not** a Small Business as defined by the U. S. Small Business Administration’s Guidelines. SPECIFY:

16. FUNDING

- a. Will NSWC PCD receive funding from the Non-Navy Collaborator for the work proposed under this Agreement?
- b. If yes, list all amounts, schedules, and any specific items for the current Fiscal Year (FY) and two (2) additional Fiscal Years if applicable.
- c. If no, what is the source of funds for the work being done by the Navy Collaborator?

17. REPORTS AND PUBLICATIONS

Enter the number or frequency of written reports each Collaborator will submit to the other during this Agreement on its work and the results being obtained (*only the Collaborator producing data is required to provide reports; however, both Collaborators may provide reports*). All Collaborators will provide annual reporting and status updates upon request of the Navy Collaborator’s ORTA Manager.

- a. Navy Collaborator will provide _____ report(s) according to the following schedule:
- b. Non-Navy Collaborator will provide _____report(s) according to the following schedule:

18. OPTION FOR ACQUIRING AN EXCLUSIVE LICENSE - FIELD OF USE

The Navy Collaborator gives the Non-Navy Collaborator the option of acquiring an Exclusive License for a specific field of use in the Government’s rights to any Subject Invention Made in whole or in part by a Navy employee.

NON-NAVY COLLABORATOR specify the field of use:

19. INTELLECTUAL PROPERTY

Does this CRADA involve the licensing of (an) existing Navy patent(s)?
_____ Yes _____ No

If yes, list patent title(s), date(s) of issue, author(s), and patent number(s):

Has a license application been filed? _____ Yes _____ No

If yes, enclose a copy of the licensing agreement.

FOR NAVY COLLABORATOR:

List all Non-Subject Inventions Made prior to the Effective Date of this Agreement that pertain to the proposed Collaborative Work. Provide Invention Title, inventor name(s), patent number or Navy case number if an Invention Disclosure, or Patent Application Serial Number, and date of issue (for patents only).

FOR NON-NAVY COLLABORATOR:

List all Non-Subject Inventions Made prior to the Effective Date of this Agreement that pertain to the proposed Collaborative Work. Provide Invention Title, inventor name(s), patent number or Navy case number if an Invention Disclosure, or Patent Application Serial Number, and date of issue (for patents only).

20. NOTICES

Name and express mail usable mailing address - no P.O. boxes - for Non-Navy Collaborator's receipt of any notices pertaining to or required by this Agreement (*this may be the same person signing the Agreement*):

Name:
Address:
Phone:
Fax:
E-mail:

21. DURATION

A Standard Navy CRADA may be for up to three (3) years and may be renewed. Specify length of effectiveness, or expiration date, of Agreement (*e.g., one year, two years, 31 May 2009, etc.*).

The duration of this CRADA will be _____ (specify months/years).

22. STATEMENT OF WORK

List the division of responsibilities, what each Collaborator is doing or providing, and the schedule. You **MUST** state any actual, or the possibility of, animal or human testing under the Collaborator responsible for those clearances.

Navy Collaborator will:

Non-Navy Collaborator will:

The Collaborators will jointly:

Section II - 4c

CRADA Application Template - Example 3

AGREEMENT TITLE:

[Navy Lab] Points of Contact:

Primary POC

Name: Code:
Phone:

Alternate POC

Name: Code:
Phone:

CRADA Non-Navy Collaborator (NNC) Information (PREAMBLE)

Company/University Name:
Address:

Administrative POC (Preferred Contact)

Name:
Email:
Phone:

Technical POC (Principal Investigator)

Name:
Email:
Phone:

Signature Authority (Name and Title): (ARTICLE 14)
(person who can legally bind the NNC)

State of Incorporation (may not be where company is located) (ARTICLE 4.2):

- o Categorized as Small Business? Yes or No
- o Foreign Owned? Indicate Yes or No
 - If YES, which country?

Note: Articles referenced are from the Standard CRADA. Language provided will be targeted for the article noted.

CRADA Topic (ARTICLE 2)

Provide a **public releasable summary** of the objectives of the work to be performed under the agreement and the benefits to the Division, Navy and the Non-Navy Collaborator. In detail, describe the specific, realizable results or benefits to be gained by each Collaborator at the conclusion of this Agreement. State the desired outcome by each Collaborator, including any intentions for commercialization, if appropriate. This Article and the Statement of Work, Appendix A, are the defining articles for the Cooperative Work to be done by the Collaborators.

Ensure there is no company proprietary or business sensitive information in the summary.

[Navy Lab] Personnel and Facilities (ARTICLE 3.1)

Are service/support contractor personnel being used by Navy Collaborator? Yes or No?

- If YES, provide company name.

Classification (ARTICLE 3.3)

Will classified data/information be shared and/or generated through this partnership? Yes or No?

- If YES, provide NNC security POC for DD254 receipt:

Funding (ARTICLE 5)

Are funds being provided from NNC to [Navy Lab]? Yes or No?

- If YES, provide level of funding and payment schedule.

- Are funds originating from a MILITARY/GOVERNMENT Sponsor? Yes or No?

Preexisting Intellectual Property (ARTICLE 7.5.4, if applicable)

List issued patents, filed patent applications, invention disclosures submitted to [00OC] and software related to the CRADA effort.

- o [Navy Lab] Patents/Cases
- o Non-Navy Collaborator Patents (if known)

Length of CRADA (ARTICLE 13)

Use timeline estimates to determine the length of the CRADA (remember to add in time for documentation/final reports). Future work associated with this agreement can be detailed in an amendment as the project matures. Total length of a Standard CRADA cannot exceed 5 years.

Statement of Work (Appendix A – is *NOT* releasable to the public)

Summary of effort (can contain Proprietary or business sensitive information).

Navy Pls are cautioned that discussions with potential Non-Navy Collaborators may include information that is proprietary to the Non-Navy Collaborator. Therefore, these discussions should be treated as business sensitive. Details should not be shared with others who are not involved with the proposed CRADA in accordance with 18 U.S.C. 1905.

Indicate what is to be done, where, and how for each:

- o List of Joint [Navy Lab]/Non-Navy Collaborator Tasks:
- o List of [Navy Lab] Tasks:

- List of Non-Navy Collaborator Tasks:

Provide a timeline for all tasks noted above. See sample timelines below.

SAMPLE 6 month project broken down into weeks - Due Date indicated (weeks from receipt of funds)

1 2 3 4 6 8 10 12 13 20 26

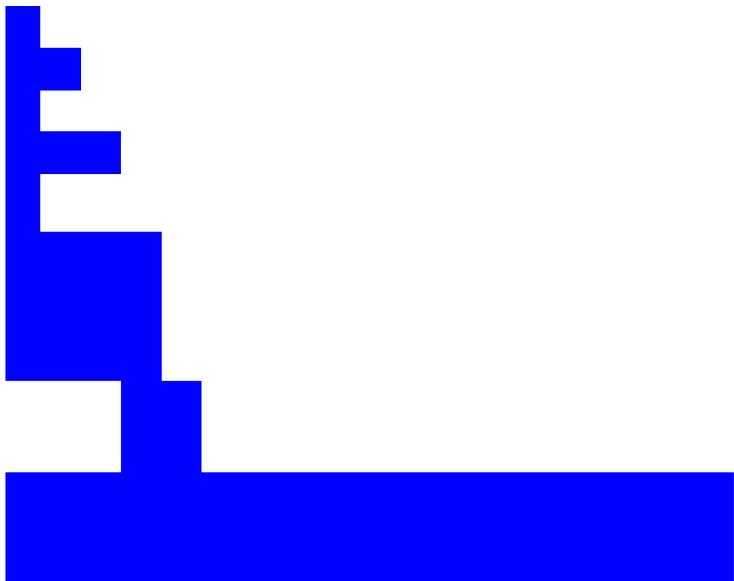
[Navy Lab] and [Non-Navy Collaborator] Tasks

1. Develop xyz and 123 interface for ABC system demonstration and test
2. Perform post- analysis and reporting



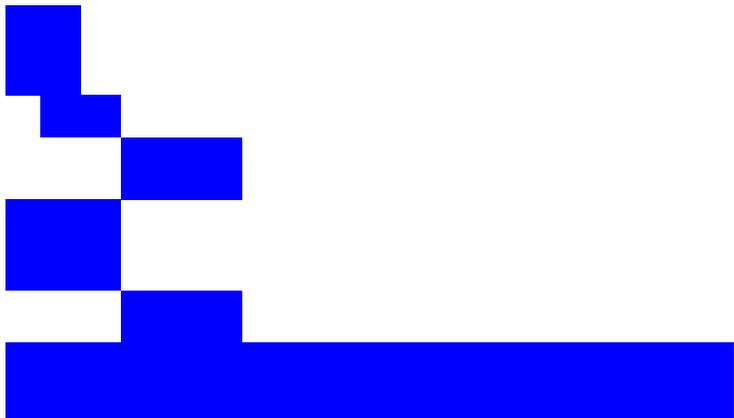
[Navy Lab] TASKS

1. Provide latest ABC source code
2. Provide ABC system data
3. Provide xyz software
4. Provide 123 hardware and software
5. Provide 3 systems of xyz laptop and peripherals
6. Provide assistance in developing test documentation
7. Provide user time and technical assistance on LBITs shipboard systems
8. Provide engineering support to operate the [Navy Lab] developed ABC source code
9. Provide telephone question answering support to [Non-Navy Collaborators]



[Non-Navy Collaborator] TASKS

1. Provide 123 hardware and software
2. Provide 123 hardware, peripherals, and software
3. Install and configure ABC and xyz
4. Develop, integrate, and test 123 software to interface
5. Initiate, develop, and submit Certification and Accreditation documentation
6. Provide engineering support for 123
7. Provide telephone question answering support to [Navy Lab]



Section II - 4d

CRADA Application Template - Example 4 - Security Questionnaire

CRADA Number: TBD
 Date Submitted: _____
 Due Date: _____
 *Revision Number (see attached): _____
 Submission Date: _____
 Due Date: _____

**NAWCWD Cooperative Research and Development Agreement
 Security Questionnaire**

GENERAL	
What is the Agreement start date?	
What is the anticipated duration?	5 yrs
Is the customer industry, academia, or other? (if other, then identify)	
What is the customer's complete name/address/CAGE Code?	
Is the company foreign owned, controlled, or influenced (Y/N/NA)?	
Does the company have a special security agreement with DoD?	
Will subcontractors be used (Y/N)?	
What is the sub's name/address?	
Is this a classified agreement (Y/N)?	
If yes, provide copy of DD254.	
Is the agreement with a command other than NAWCWD (Y/N)?	
If yes, who is it with (list activity name/address)?	
What product, service, or weapon system is involved?	
What type of test(s) is being performed?	
Who is the NAWCWD Technical POC?	
What is the POC's competency code and phone number?	
Where (CL/Pt. Mugu) will the work take place?	
What is the complete activity name and address?	
What is the building and/or lab/room number(s)?	

INFORMATION CLASSIFICATION	
Will the CRADA involve access to, and work on, Militarily Critical Technology (Y/N)?	
Who (government, customer, other) has the overall security cognizance in security matters? (if other, identify)	
Will performance include access to U.S. classified information (Y/N)?	
What is the highest level required? (confidential, secret, top secret, SAP/SCI)	
Where does the classified information reside (activity name, building/room number)?	
Is there a current classification guide (Y/N/NA)?	
Provide guide number, title, and/or other type of guidance.	
Will performance include access to U.S. Sensitive but Unclassified information (Y/N)?	
Where does the sensitive information reside (activity name, building/room number)?	
Does the CRADA Statement of Work explain what performance is classified (Y/N/NA)?	
What is the paragraph number?	
Is there a requirement to store classified at the customer's facility (Y/N/NA)?	
Does the contractor have a Facility Security Clearance (Y/N)?	
Who (government, customer, other) owns the data that will be processed? (if other, identify)	
Is access to intelligence information required (Y/N)?	
Does NAWCWD need to provide safeguarding capability (Y/N)?	
What resources are needed (i.e., security containers, locks, etc.)?	
Will performance include access to Foreign Government Information (Y/N)?	
What country?	
Will FOUO or sensitive unclassified information be involved (Y/N)?	
How will information be protected?	Information will be marked FOUO and protected IAW DoD 5400.7-R, Ch. 3 & 4.
Is there a customer requirement for data encryption (Y/N/NA)?	
Does the customer have an OPSEC plan (Y/N/NA)? Provide copy.	

COMPUTER USAGE	
>>>>Automated Information Systems are computers<<<<	
Will government-owned Non-NMCI Automated Information Systems (AIS) be used in support of the Agreement (Y/N/NA)?	
Have they been accredited or has an Interim Authority to Operate been issued (Y/N/NA)? <i>*see note below</i>	
Have all users signed a User Awareness Agreement (Y/N/NA)?	
<p>*Provided is the definition of what is considered an Automated Information System (AIS) that requires accreditation:</p> <ul style="list-style-type: none"> • Per DoD Directive 5200.28, AIS includes stand-alone systems, analog or hybrid; associated peripheral devices and software; process control computers; embedded computer systems; communications switching computers; personal computers; intelligent terminals; word processors; office automation systems; application and operating system software; firmware; and other AIS technologies, as may be developed. • Per NSTISSI No. 4009, AIS is described as “The entire infrastructure, organization, personnel, and components for the collection, processing, storage, transmission, display, dissemination, and disposition of information. 	
Will customer require access to government-owned AIS (Y/N)?	
Will customer-owned unclassified AIS be brought onto a government site in support of the Agreement (Y/N)?	
Provide a letter from the company’s Facility Security Officer (FSO) that authorizes the AIS to be used on site. The letter should include purpose, location, government POC, equipment specifications, and assurances that the AIS being used are at the unclassified level.	
Will customer-owned classified AIS be used (Y/N)?	
Have they been accredited by Defense Security Services (DSS) (Y/N)?	
Will foreign national AIS be used in support of the Agreement (Y/N)?	
Will foreign nationals be required to use AIS in support of the Agreement (Y/N)?	
Will they be government-owned, customer-owned, or foreign-owned AIS resources? (if foreign, identify)	

FOREIGN NATIONALS/FOREIGN DISCLOSURE	
Are there foreign nationals (FN) involved (Y/N)?	
Does the FN have Lawful Permanent Residency (green card) (Y/N)?	
Are they a foreign company, foreign government, or U.S. citizen working for a foreign-owned company, or a foreign citizen working for a U.S. company?	
What country(ies) do they represent?	
Will foreign nationals need to be on station (Y/N/NA)?	
How many foreign nationals will need to be on station?	
What is start date of the FN visit?	
What is the duration of the FN visit?	
Will foreign nationals require access to NAWCWD or NAWCWD contractor facilities prior to the FN visit start date (Y/N)?	
Where will they require access (<i>activity name/building/room numbers</i>)?	
To which recreational areas will they require access?	
Will they require after hours or weekend access (Y/N)?	
Will the foreign nationals have customers or family visitors (Y/N)?	
Is a Foreign National Visit Request required (Y/N)?	
Has the Visit Request been approved and scheduled (Y/N)?	
Has AIR 7.4.1 been contacted for release issues/approvals (Y/N/NA)?	
Who is AIR 7.4.1 point of contact (<i>name/phone number</i>)?	
Provide correspondence.	
Is there a requirement for technical discussions prior to the FN visit start date (Y/N/NA)?	
Will performance require FN access to classified information (Y/N/NA)?	
What type of information?	
Where does the information reside?	
Does the information need to be physically released (Y/N)?	
Who owns the information?	
Who is responsible for the release of the information?	
Has AIR 7.4.1 Foreign Disclosure been contacted for release approval (Y/N)?	
Will performance require FN access to unclassified technical information (Y/N/NA)?	
What type of information?	
Where does the information reside?	
Who owns the information?	
Does the information need to be physically released (Y/N)?	
Who is responsible for the release of the information?	
Has AIR 7.4.1 Foreign Disclosure been contacted for release approval (Y/N)?	
Is a Technical Assistance Agreement required (Y/N/NA)?	
Has the POC reviewed it (Y/N)?	
Include a copy.	

Is an export license required (Y/N/NA)?	
Has the POC reviewed it (Y/N)?	
Provide copy.	
Have escort requirements been determined (Y/N)?	
What are restrictions?	
Who are the escorts?	
Are the escorts civil service, military or certified contractor?	
Has an escort brief been received (Y/N)?	
Will additional guards/escorts be required (Y/N)?	
Is a threat brief requested/required (Y/N/NA)?	

PROGRAM PROTECTION	
Has the OPSEC checklist been received and reviewed (Y/N/NA)?	
Is there a requirement to conduct photography (Y/N)?	
What kind of camera (digital, still, video) will be used?	
Has an OPSEC brief for the photography pass been obtained (Y/N)?	
Has a photography pass been applied for (Y/N)?	
Is the photographer a U.S. citizen (Y/N)?	
Will foreign nationals have access to local telephone junction boxes serving sensitive programs/projects (Y/N/NA)?	
Will foreign nationals possess/use radio frequency (RF) test equipment that would allow interception/analysis/exploitation of other programs/project's emissions (Y/N/NA)?	
Are there PBX vulnerabilities (Y/N/NA)?	
Who will ensure sensors associated with a foreign national project are only used for their intended purpose?	
Will there be any restrictions concerning the possession of:	
Vision enhancing devices (<i>binoculars</i>) (Y/N)? If yes, describe.	
Audio enhancing devices (<i>bionic ears</i>) (Y/N)? If yes, describe.	
Audio/still/video recorders (<i>i.e. cassette/MP3 recorders, camcorders, cameras, VCRs, audio/video surveillance devices</i>) (Y/N)? If yes, describe.	
RF receiving/scanning devices (Y/N)? If yes, describe.	

COMSEC ISSUES	
Is there COMSEC involved (Y/N)?	
Has the EKMS/COMSEC Custodian reviewed the CRADA (Y/N)?	
Who owns the crypto?	
Who is the POC for crypto matters for this CRADA?	
What are their activity name, location and phone number?	

Where will the crypto be used (<i>activity name and building/room number</i>)?	
What will be the highest level of data encrypted by the crypto? (unclassified, confidential, secret, top secret, sensitive but unclassified)	
What crypto devices will be used?	
Will the COMSEC be transferred to the customer (Y/N)?	

PUBLIC RELEASE	
Is the end product intended for public release (Y/N)?	
Has the Security Policy Review process been initiated through Public Affairs (Y/N/NA)?	

POINTS OF CONTACT	
General CRADA security questions	[local lab POC/phone]
General CRADA questions	[local lab POC/phone]

CRADA Number: **TBD**
 Date Submitted: _____
 *Revision Number (see attached): _____
 Date: _____

Section II - 5

CRADA Creation Process

This outline describes a typical process for the creation of a CRADA. A separate outline will address CRADA Monitoring.

1. Choosing the mechanism
 - a. Approached by laboratory scientist/engineer
 - i. Identify what is the desired work to be done
 1. Is CRADA appropriate?
 2. Is 10 USC the appropriate statute?
 - ii. Check with your local Navy legal counsel
 - b. Approached by external customer
 - i. Identify what is the desired work to be done
 1. Is CRADA appropriate?
 2. Is 10 USC the appropriate statute?
 - ii. Is this in your mission area?
 - iii. Identify what is the desired work to be done
 1. Is CRADA appropriate?
 2. Is 10 USC the appropriate statute?
 - iv. Identify potential laboratory team
 1. Are personnel available?
 2. Identify other resources needed
 - v. Check with your local Navy legal counsel
 - vi. Notify relevant local authorities of intent
2. Non-Navy Collaborator Identification
 - a. FOCI
 - i. Notify local Security Office
 - ii. Notify relevant System Command
 - iii. Notify US Trade Representative
 - iv. Identify any ITAR's issues
 - b. Non-FOCI
 - i. Check Corporate Status
 1. Registered in which state?
 2. Large or small business
 3. Identify any federal restraints
 - c. Identify Non-Navy Collaborator Authority
 - i. Who is authorized to negotiate?
 - ii. Who is authorized to sign?
3. CRADA application
 - a. Provide application to all parties
 - b. Each party identify Principal Investigators
 - c. Identify non-subject data relevant to proposed work
 - d. Identify funding mechanism
 - i. Non-Navy Collaborator funds Navy
 1. Incremental Payment
 - a. Annual
 - b. Milestone

- 2. Fully funded
 - ii. Third party payment
 - 1. Navy Sponsor
 - a. Annual
 - b. Milestone
 - c. Other
 - 2. Other Federal Source
 - a. Annual
 - b. Milestone
 - c. Other
 - 3. Other Non-Federal Source
 - a. Annual
 - b. Milestone
 - c. Other
 - e. Collaborators prepare SOW
- 4. Review and Negotiate SOW
 - a. Provide copy to local Navy legal counsel
 - b. Local review
 - i. PI
 - ii. PI supervisor
 - iii. ORTA
 - iv. Local Navy legal counsel
 - c. Submit reviewed SOW to Non-Navy Collaborator

(Iterate Steps a - c as necessary)
- 5. Review Funding Plan
 - a. Local Review
 - i. PI
 - ii. PI supervisor
 - iii. ORTA Manager
 - iv. Laboratory Comptroller
 - b. Submit reviewed Funding Profile to Non-Navy Collaborator
- 6. ORTA Prepares CRADA
 - a. Two originals
 - b. Local review before mailing
 - i. Local Navy legal counsel
 - ii. Principal Investigator
 - iii. ORTA Manager
 - c. Mail to Non-Navy Partner for Signature
- 7. Further Negotiation
 - a. Authorization
 - i. ORTA Manager
 - ii. Local Navy legal counsel
 - iii. Non-Navy Collaborator's authorized negotiator
 - b. Conflict resolution
 - i. What can and cannot be changed
 - ii. Do it in writing

- c. ORTA drafts revised CRADA as necessary
- 8. Signatures and Registration
 - a. ORTA receives two signed copies from Non-Navy Collaborator
 - b. Local routing by ORTA Manager
 - i. Internal memos/summaries
 - ii. Include local Navy legal counsel review
 - iii. Commanding Officer Signs
 - c. Correspondence with Non-Navy Collaborator
 - i. Cover letter
 - ii. Original signed copy enclosed
 - d. Other copies
 - i. Local Security Office
 - ii. Local Navy legal counsel office
 - iii. Principal Investigator with Oral Review
 - iv. Others (USTR, SYSCOM, ONR)

Section II - 6

Due Diligence for CRADAs

The following discussion may be helpful for you in determining the details about your potential non-federal partner. The questions posed are ones that will help you build your own process for determining who may be a successful partner.

- 1. Your potential partner, ABC Company, claims to be registered in the United States in the State of XYZ.**
 - Have you checked that ABC is registered and in good standing in the state XYZ?
 - Have you checked that ABC is a small/large business?
 - Is ABC a subsidiary of a larger company?

- 2. Your first point of contact within ABC Company claims that he represents the company and can close the deal.**
 - Who is the head of ABC Company?
 - Who is your technical POC within the company?
 - Where does he/she fit within the organization?
 - Who is the legal POC for ABC Company?
 - Is the legal POC a full-time employee of ABC Company?
 - Does the legal POC have experience with Federal Government CRADAs?
 - Does the legal POC have experience with Navy CRADAs?
 - Who has the authority to bind ABC Company to the deal?
 - Is he/she aware of this negotiation?
 - Who has the authority to negotiate the deal?

- 3. Your point of contact with ABC Company claims that they are willing to pay for the proposed work with your laboratory.**
 - Have you checked the ABC Company financial history?
 - Have you checked the ABC Company product line?
 - Is the proposed product part of ABC's current product line?
 - What have been the sales of current product line?

- 4. Your point of contact claims that ABC Company has technical competence in the area of the proposed work.**
 - Has the company demonstrated the ability to do R&D in this technical area?
 - Have patents been issued to ABC in the technical area of interest?
 - Do the PIs have demonstrated experience in this technical area?
 - If special facilities are required, does ABC have the necessary resources or can they demonstrate that they have access to the resources needed?

5. Has ABC Company entered into similar Agreements with a federal laboratory?

- If yes, have you contacted the federal partner(s) to determine success of relationship?
- What technical areas were involved?
- Was a successful product created?
- Were there difficulties in the administration of the Agreement?

6. Is ABC Company performing the proposed work under any federal grant, contract, agreement, or other transaction?

- If yes, has the federal funding sponsor been identified?
 - Determine the contract number.
 - Determine funding to ABC.
 - Determine the contracting officer's name, organization, address, phone, e-mail.
 - Determine the contracting officer's representatives (COR) name, organization address, phone number.
- If yes, determine clauses in the federal award regarding performance standards such as time, schedule, and quality that may affect your ability to perform such work for ABC.
- If yes, determine clauses in the federal award that affect the ownership of generated intellectual property.
- If yes, are there restrictions for working with a federal laboratory? (See SBIR/STTR)
 - Are waivers permitted?
 - If yes, who grants the waiver?
 - What is the waiver process?
- If yes, are ONLY these funds being used to fund the federal party?
 - Are these funds to be sent directly from the company or from the federal sponsor?

How to answer the above questions?

Answering the questions above will depend on the resources available to you at your laboratory. Many of these questions can be answered by using the Internet.

For instance, registration of a company as a corporation in a state can be checked by using the state's Department of Commerce, or small business administration offices. Using the web, you can also check the company's advertised profile - links there may help determine organization, product line, personnel, patents and publications. Data on patents can be determined by a search at the U.S. Patent and Trademark Office website. The Defense Technical Information Center (DTIC) can provide you with information on DoD contracted research that has been performed by ABC Company. Also DTIC can provide you with information on ABC Company's internal research and development (IR&D) efforts. Checking information in DTTIS can provide you data on what other CRADAs that they may have started or completed.

You may find the use of your local Navy Investigation Office as a means of checking a company's affiliations and corporate status, i.e., who owns them, are they really not a FOCI.

Your legal office may subscribe to a financial service that can provide company financial profiles.

Networking with other Navy ORTA managers may also be a good resource of information on ABC Company.

Section II - 7

Pricing Your CRADA

Article 5 of the Navy Standard CRADA addresses funding. There are four basic ways in which the work performed by the Navy Collaborator may be paid for performing the work that supports the CRADA.

1. Each partner funds its own effort.
2. The Non-Navy Collaborator fully pays for all services performed by the Navy Collaborator.
3. The Non-Navy Collaborator makes partial payment for services performed by the Navy Collaborator.
4. The Navy Collaborator is paid fully or in part by a Non-Navy federal source.

The Anti-Deficiency Act requires that no work may be performed by a federal employee for which funds have not been received in order to cover the costs associated with that effort. ORTA managers are encouraged to remind Navy CRADA Principal Investigators of this requirement. The ORTA manager and Navy Principal Investigator should mutually agree on the internal process within the laboratory for the management, monitoring and reporting of funds received from Non-Navy sources to support the CRADA effort.

This section of the CRADA Handbook addresses allowable charges to the Non-Navy Collaborator or a Non-Navy Federal source.

What is permitted and required?

By federal law, the Non-Navy Collaborator may be charged for work that is to be accomplished through the use of a CRADA.

- 15 USC 3710a

“the term cooperative research and development agreement” means any agreement between one or more Federal laboratories and one or more non-federal parties under which the Government, through its laboratories provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement...”

If funds are collected from the Non-Navy Collaborator, the Navy is required to maintain accounting records and maintain records of all funds received and expended. This is explicitly stated in the Navy Standard CRADA Article 5.4 “Accounting Records”.

“Navy Collaborator shall maintain current accounts, records, and other evidence supporting all expenditures against funding provided by Non-Navy Collaborator under this Agreement and shall retain such records for at least twelve (12) months after the completion, expiration, or termination of this Agreement. Navy Collaborator shall provide Non-Navy Collaborator a financial report within four (4) months after completion, expiration, or termination of this Agreement.” (Underlined for emphasis.)

What are allowable reimbursable charges?

The Office of Naval Research has not issued a formal template for determining allowable charges nor has it issued a template for the final financial report. NAVSEA laboratories that engage in Work With Private Parties are provided guidelines for charging customers for services performed under those Agreements.

The following paragraphs describe items that are allowable as reimbursable charges to support the CRADA. Consult with your local comptroller to establish what algorithm is to be used in charges for the CRADA and format for the financial report. The financial report should be reviewed by the Principle Investigator and the ORTA manager before distribution to the Non-Navy Collaborator.

1. Labor - All labor charges associated with establishing, performing, monitoring, and closing the CRADA may be charged. These charges are to be made according to the laboratory's laboratory rates for billing for external customers. This may include Navy Marine Corps Internet charges that are added to basic labor rates.
 - a. Direct labor hours, including credit hours, compensatory time, and overtime are allowable charges for all scientists, engineers, and technicians. Management support costs are also allowable.
 - b. Administrative support by secretaries, budget office personnel, and contracting support personnel are also allowable charges. In some laboratories, these functions are required to be paid by direct labor charge codes, while others may be paid through general laboratory overhead.
 - c. Labor hours also may be charged by legal and security personnel for basic CRADA review, review of CRADA amendments and time spent in CRADA negotiation. Again, in some laboratories this may be an overhead function not requiring a direct labor hour payment.
 - i. ORTA management may be an allowable charge. Again this depends on how the laboratory has established the funding the ORTA office. Possible algorithms for charging for ORTA services include a fixed fee for service, and a threshold or percentage fee based upon the estimated in-house labor costs for externally funded CRADAs.
 - d. A laboratory may also issue a surcharge to the labor rate to cover the Navy's portion of the employee benefit package (i.e., retirement, social security). Depending on your laboratory, there may be a fixed percentage fee to cover these latter expenses when funds are received from non-federal sources. Check with your comptroller.
2. Travel - Travel costs for federal employees may be paid for by third parties when associated with a CRADA. All travel costs allowed by the Joint Travel Regulations to perform the work under the CRADA are allowable. This includes compensatory travel time.
3. Materials - All costs associate with disposable and non-disposable material in support of work performed under the CRADA are allowable. This includes shipping, inventory control, storage, and disposal.

4. Facilities - The costs associated with operating a laboratory facility is an allowable charge. This cost may include the labor associated with operating personnel, any security charges that may be associated with maintaining the facility, and any depreciation costs for the facility.
5. Permits - Any costs associated with special permits that may be required for the Navy Collaborator to perform its work under the CRADA are allowable charges.
6. Intellectual Property - Costs associated with copyrights, trademarks, invention disclosures, patent application and maintenance fees, are allowable charges. The process for determining these costs are determined through negotiation in accordance with the terms of Articles 7.2 -7.4 of the Standard Navy CRADA.

Section II - 8

CRADA Monitoring

As the ORTA manager, you need to monitor the administrative activities of the signed CRADA. After you have registered your CRADA with the ONR Technology Transfer Office and had a meeting with your local Principal Investigator to remind him of his responsibilities, you need to develop your individual process for monitoring the CRADA during its duration. The following two sections provide you with activities that you may use in the ORTA. What you will do will depend on the specific nature of your CRADA and on the resources available to you.

Section II - 8a

CRADA Monitoring

Part 1 - Outline

This outline describes a process for monitoring a signed CRADA. What you do will depend upon the resources available to you. Milestone and quad charts are not required by ONR. These are to be used in developing best practices. If any of these ideas work well for you, please consider reporting your success to others in the Navy community annual meetings.

- (1) Review Signed CRADA
 - (a) Prepare milestone chart
 - (i) Use SOW
 - (ii) Use reporting Schedule
 - (iii) Use funding profile
 - (b) Prepare Quad Chart (see sample that follows)
 - (c) Meet with PI
 - (i) Upon final signature
 - (ii) Clarify lines of responsibility
 - 1. Changes in SOW
 - 2. Changes in funding
 - 3. Activity Reporting
 - (iii) Provide copy of milestone chart
 - (iv) Provide copy of Quad Chart
 - (v) Meet quarterly
- (2) Activity Reporting
 - (a) Reports and Publications
 - (i) Interim reports
 - 1. Know the schedule
 - 2. Local PI reports receipt to ORTA
 - (ii) Publications
 - 1. Review prior to Publication
 - a. Navy PI
 - b. ORTA Manager
 - c. Cleared for Public Release by Navy
 - 2. Copy of Publication
 - a. PI
 - b. ORTA Manager
 - i. Place in CRADA file
 - (iii) Classified Information
 - 1. Review local process with local Security Office
 - 2. Review local process with Navy PI
 - a. ORTA Manager on Routing
 - b. Maintain a log in CRADA file
 - (b) Intellectual Property
 - (i) Marking of Data
 - 1. Establish process for marking data
 - a. Navy PI
 - b. ORTA Manager

- c. Navy Attorney
 - d. Navy Security Office
 - 2. PI reports to ORTA Manager
 - a. Data delivered to Non-Navy Collaborator
 - b. Data received by Non-Navy Collaborator
 - (ii) Copyrights applied/issued
 - 1. Reported by Non-Navy Collaborator
 - 2. Record copyright license to the Government
 - (iii) Trademark and Service Marks applied/issued
 - 1. Obligation to report Trademarks and Service Marks
 - a. Navy Collaborator
 - b. Non-Navy Collaborator
 - 2. Responsibility to Report Filing
 - 3. issue/Report License to Use
 - (iv) Subject Inventions
 - 1. Obligation to Report
 - a. By Navy
 - i. Report by PI
 - ii. Report to ORTA Manager
 - iii. Report to Navy Patent Attorney
 - b. By Non-Navy Collaborator
 - i. Report to PI
 - ii. Report to ORTA Manager
 - c. By both Navy and Collaborator
 - i. Report by PI
 - ii. Report to ORTA Manager
 - iii. Report to Navy Patent Attorney
 - iv. Report to Non-Navy Attorney
 - 2. Determine/Record Title and Ownership
 - a. Report by PI
 - b. Report to ORTA Manager
 - c. Report to Navy Patent Attorney
 - 3. Determine/Record Filing of Invention Disclosures
 - a. Report by PI
 - b. Report to ORTA Manager
 - c. Report to Navy Patent Attorney
 - d. Report to Non-Navy Attorney
 - (v) Nonexclusive License to Subject Inventions
 - 1. Report from Navy Attorney
 - 2. ORTA Manager Records in CRADA File
- (3) Amendments to SOW
 - (a) Use authorized Navy and Non-Navy negotiators
 - (b) Signatures
 - (i) From Non-Navy Collaborator
 - (ii) By local Commanding Officer
 - (c) Notifications and Correspondence
 - (i) Signed copy to Non-Navy Collaborator
 - (ii) Signed copy to Navy PI

- (4) Amendments to Funding
 - (a) Use authorized Navy and Non-Navy negotiators
 - (b) Signatures
 - (i) From Non-Navy Collaborator
 - (ii) By local Commanding Officer
 - (c) Notifications and Correspondence
 - (i) Signed copy to Non-Navy Collaborator
 - (ii) Signed copy to Navy PI
 - (iii) Signed copy to local Navy Comptroller

- (5) Final Reports
 - (a) From Non-Navy Collaborator
 - (b) From Navy PI
 - (i) Use Navy Form
 - (ii) Prepare final Quad Chart
 - (iii) Submit to ONR

CRADA TITLE

<p style="color: blue; margin: 0;">Name of Non-NAVY Collaborator</p> <p style="color: blue; margin: 0;">CRADA: Insert CRADA number</p> <p style="color: blue; margin: 0;">FUNDS – IN: yes or no</p> <p style="color: blue; margin: 0;">Date and duration: date (duration)</p>	<p style="margin: 0;">INTENT:</p> <p style="color: blue; margin: 0;">One sentence summary.</p>
<p style="margin: 0;">S&T Focus Area:</p> <p style="color: blue; margin: 0;">Choose from Naval S&T Strategic Plan</p> <p style="margin: 0;">Objective Categories:</p> <p style="color: blue; margin: 0;">Choose from Naval S&T Strategic Plan</p> <p style="margin: 0;">S&T Research Areas:</p> <p style="color: blue; margin: 0;">Choose from Naval S&T Strategic Plan</p>	<p style="color: blue; margin: 0;">Laboratory Name</p> <p style="margin: 0;">ORTA: name</p> <p style="margin: 0;">Phone: xxx xxx-xxxx</p> <p style="margin: 0;">E-mail: who@where</p>

DRAFT NOT FOR RELEASE

Section II - 8b

CRADA Monitoring

Part 2 - ORTA Checklist

TASK	TIME REFERENCE
ONR ADMINISTRATIVE	
Prepare ONR Summary Document Send CRADA electronically & hard copy to ONR	Within 10 days of signature
The Navy T2 Program Office reports agreements through the Navy DTTIS database.	Within 30 days of signature
FUNDING	
Monitor and follow payment schedule, if applicable	
Send notice of default to NNC	15 days after default
Termination of Agreement	
Cancel option for exclusive license	
Terminate any exclusive license	
Return excess funds	After completion, expiration, or termination of CRADA
Issue financial report to Collaborator	Within 4 months of completion, expiration, or termination of CRADA
REPORTS AMONG COLLABORATORS	
Submission of Interim reports to Collaborator	As required by Article 6.1
Submit a final report to Collaborator that contains results obtained a list of all Subject Inventions	Within four months of completion, expiration, or termination of Agreement
PUBLICATIONS or PUBLIC DISCLOSURE of SUBJECT DATA	
Confer and consult prior to publication or public disclosure of Subject Data	
Review any proposed abstract, publication, presentation, or other document	Not less than 15 days and not to exceed 30 days, unless mutually agreed, prior to publication or disclosure (note "disclosure" includes peer review prior to publication)
Notification of objection to a proposed disclosure	Within 30 days of the date of notice to disclose
Notification of objection that patent rights may be compromised by a proposed disclosure	Patent Application must be filed by responsible Collaborator within 90 days of date of notification of intent to disclose
Notification of objection that public disclosure may release Controlled Unclassified Information, Proprietary Information, Restricted Access Information, or Information restricted by US security laws or regulations	Disclosure is to be postponed until Information no longer meets definition; for Proprietary Information, RAI Collaborators may agree to release
MARKING OF DATA	
Marking of Restricted Access Information	Mark only if Collaborators have determined such marking is appropriate.
Marking Data that are Subject to 35 USC 205	Mark at time of delivery.

TASK	TIME REFERENCE
MARKING OF DATA (con't.)	
Marking Data that are Classified Information, CUI, MCT, or other wise restricted.	Mark at time of delivery
Determine duration period of protection of RAI.	During negotiation of CRADA
Mark each RAI approved item with the correct expiration date.	Mark at date of approval. Negotiated date not to exceed 5 years from creation date.
FOIA REQUESTS	
Notify Collaborator of any FOIA requests for Data under the Agreement.	Promptly
REQUEST FOR SUBJECT DATA	
Deliver Subject Data to requesting Collaborator	Within fifteen (15) days of request
REQUESTS FOR NON-SUBJECT DATA	
Deliver marked Non-Subject Data and defined limited rights	After completion of a separate non-disclosure agreement
TRADEMARKS and SERVICE MARKS	
Report to Collaborator the first use of a trademark or service mark	Within thirty (30) days of employees report of use
File application for trademark or service mark	
SUBJECT INVENTIONS (IP Attorney)	
Provide Collaborator with a copy of each Invention Disclosure	Within sixty (60) days of receiving the Invention Disclosure from employee
PATENT APPLICATIONS (IP Attorney)	
File Patent Application on Subject Inventions of Navy employees	At least sixty (60) days prior to any bar date or one year from the date the Invention Disclosure was received.
Confer and consult on who should file a Patent Application on any Subject Invention	
Confer and consult on who should file a Patent Application on any Invention jointly Made	
If responsible, file a Patent Application of any Subject Invention	At least sixty (60) days prior to any bar date or one year from the date the Invention Disclosure was received.
Notify other Collaborator of intent to assume filing because Collaborator failed to file	Ten (10) days written notification
Notify other Collaborator of all filing deadlines for prosecution of a Patent Application of a Subject Invention	
Notify other Collaborator of all filing deadlines for maintenance of a Patent on a Subject Invention	
Notification of intent to respond to a filing deadline.	Sixty (60) days prior to deadline.
Provide Collaborator with copies of prosecution papers of a Patent Application of a Subject Invention	Within thirty days of receipt of such communication
Notify inventors of intention not to file a Patent Application	
Identify Preexisting Non-Subject Inventions Pertinent to the Cooperative Work	During CRADA negotiation

TASK	TIME REFERENCE
CONFIRMATORY LICENSE	
Each Collaborator has the obligation to provide a Confirmatory License Agreement to the other Collaborator for each nonexclusive license	Within ninety (90) days of filing
EXCLUSIVE LICENSE	
Navy Collaborator gives Non-Navy Collaborator the option to acquiring an exclusive license in a Subject Invention Made by Navy Collaborator employee	Non-Navy must notify Navy Collaborator within 180 days of filing the Patent Application Collaborator in order to exercise the option
	Non-Navy Collaborator must exercise an exclusive license to the Subject Invention within 180 days of election.
NNC BECOMES A FOCI	
Navy may terminate any exclusive license or cancel any option for an exclusive license to a Subject invention under this Agreement.	Non-Navy Collaborator becomes a FOCI that does not qualify under Executive Orders 12591, Section 4(a)
FORCE MAJEURE EVENT	
Notify the other Collaborator of inability to perform under a <i>Force Majeure event</i>	Prompt notification; work may be suspended
THIRD PARTIES	
Request written permission of other Collaborator to for use of third parties to perform any part of Cooperative Work	
UNILATERAL TERMINATION	
Either Collaborator may unilaterally terminate the Agreement	Not less than thirty (30) days prior to desired termination date

Section II - 9

Principal Investigator Responsibilities

MEMORANDUM

Date:

From: [ORTA or Technology Transfer Office Manager]
(Office Code, Name)

To: PI Code Number (PI Name)

Subject: CRADA Principal Investigator Responsibilities

Congratulations! The Cooperative Research and Development Agreement (CRADA) between **[Navy Collaborator] (NAVY COLLABORATOR Acronym)** and **[Non-Navy Collaborator] (NCRADA-CRADA Number)**, was fully executed on **CRADA start date**. This memorandum is forwarded for information as it serves as a reminder of the specific terms of this Agreement as well as your responsibilities as CRADA Principal Investigator (PI). Please read this entire memo carefully and keep it in your files for future reference.

[Use the following paragraph if funds are received from the Non-Navy Collaborator to perform this Agreement.]

If **[Non-Navy Collaborator]** has agreed to provide funding for work to be done by **[Navy Collaborator Acronym]** under the CRADA, you are responsible for monitoring the expenditure of funds received from **[Non-Navy Collaborator]**. Because **[Navy Collaborator Acronym]** is a Navy Working Capital Fund organization, **[Navy Collaborator Acronym]** cannot provide any goods or services until funds have been received, nor can you continue **[Non-Navy Collaborator]** funded work after current received funds have been expended. You are to notify the **[Navy Collaborator Acronym]** ORTA when you are nearing the completion of the expenditure of funds received. The **[Navy Collaborator Acronym]** ORTA will send official notification to the **[Non-Navy Collaborator]** regarding any need for continued funding.

The CRADA PI is responsible for the following, either explicitly or as the representative of **[Navy Collaborator Acronym]** for the purposes of the CRADA:

- Conduct the scientific and technical aspects of the project within **[Navy Collaborator Acronym]** facilities or supervise aspects performed on behalf of **[Navy Collaborator Acronym]** by third parties. (Article 3.1 and Appendix A Statement of Work)
- Supervise **[Navy Collaborator Acronym]** representatives who perform cooperative work at **[Non-Navy Collaborator]**'s facilities. (Article 3.2)
- Provide interim report(s) of results to the undersigned (**state periodicity**) and, within four months of the termination or expiration of the CRADA, a final report. (Article 6; see Section III - 2b CRADA Final Report)

- Confer and consult with the **[Non-Navy Collaborator]** prior to any publication or public disclosure of Subject Data to ensure that no Proprietary Information, Restricted Access Information, Government Classified Information, Controlled Unclassified Information, or Militarily Critical Technology is released and that patent rights are not compromised. (Article 6.3)
- Ensure proper handling and marking of all data generated or shared. (Article 7.1.1.3)
- Ensure the Protection of Data including Classified Information, Controlled Unclassified Information, Militarily Critical Technologies or otherwise restricted Information. (Article 7.1.1.4)
- Confer with **[Non-Navy Collaborator]** on the Delivery and Rights of Subject Data. (Article 7.1.2)
- Report to the **[Navy Collaborator Acronym]** ORTA and the Office of Counsel for Intellectual Property (**Organization Code**) any Copyrights by the **[Non-Navy Collaborator]** resulting from the CRADA. (Article 7.2)
- Report to the **[Navy Collaborator Acronym]** ORTA and the Office of Counsel for Intellectual Property (**Organization Code**) any Trademarks and Service Marks resulting from this CRADA. (Article 7.3)
- Report to the **[Navy Collaborator Acronym]** ORTA and the Office of Counsel for Intellectual Property (**Organization Code**) any Subject Invention within 90 days from the date the Subject Invention was made. (Article 7.4.1.2)
- Return any property, equipment, or other resources purchased or provided by **[Non-Navy Collaborator]** upon expiration or termination of the Agreement. (Article 8.1).

Questions regarding these responsibilities may be forwarded to the undersigned at ***phone number***.

**[Technology Transfer Office or ORTA
Manager Name]**

Copy to:
ORTA if not TTO Manager
PI First Line Supervisor
Legal Office
Security Office

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Section III - 1

Template Introduction

This section contains the approved template for the Navy Standard CRADA and approved templates for three non-standard CRADAs. The use of the Navy Standard CRADA is subject to the terms and conditions described in Section 1.2 of this Handbook.

Changes made to these CRADA using any of the approved alternative language clauses are to be made in accordance with the Instructions, Section 1.2 of this handbook.

The Supplemental Appendix to the Standard CRADA, Final Report, is not currently a requirement to be included in the CRADA. If you choose to include it in your Standard CRADA or the any of the approved non-Standard CRADAs, you will need to modify Article 6.2 to reflect that the final report will use that format.

Each of the templates for Non-Standard CRADAs included in this section is preceded by an explanation of the scope of that particular CRADA.

STANDARD
NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
BETWEEN
[NAVY COLLABORATOR]
AND
[NON-NAVY COLLABORATOR]

AGREEMENT TITLE:

AGREEMENT NUMBER: NCRADA- **[Navy Org.] - [last two digits of CY] - [serial number]**

AGREEMENT ADMINISTRATORS:

[NAVY COLLABORATOR]

Technology Transfer Office: **[insert name, organization code, telephone number, e-mail address]**

Legal Counsel: **[insert name, organization code, telephone number, e-mail address]**

Principal Investigator: **[insert name, organization code, telephone number, e-mail address]**

[NON-NAVY COLLABORATOR]

Preferred Contact: **[insert name, telephone number, e-mail address]**

Legal Counsel [OPTIONAL]: **[insert name, telephone number, e-mail address]**

Principal Investigator: **[insert name, telephone number, e-mail address]**

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STANDARD
NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
BETWEEN
[Navy Collaborator]
AND
[Non-Navy Collaborator]

PREAMBLE

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), **[Navy Collaborator]**, located at **[supply appropriate address]**, and **[Non-Navy Collaborator]**, whose corporate headquarters are located at **[supply appropriate address]**, enter into this Cooperative Research and Development Agreement (CRADA), which shall be binding upon the Collaborators and their assignees according to the clauses and conditions hereof and for the term and duration set forth.

The U.S. Federal Technology Transfer Act of 1986, as amended, provides for making the expertise, capabilities, and technologies of U.S. Federal laboratories accessible to other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons in order to improve the economic, environmental, and social well-being of the United States by stimulating utilization of U.S. federally funded technology developments and/or capabilities.

[Navy Collaborator] has extensive expertise, capabilities, and information in **[technology area]**, and, in accordance with the U.S. Federal Technology Transfer Act, desires to make this expertise and technology available for use in the public and private sectors.

[Non-Navy Collaborator] has the interest, resources, capabilities, and technical expertise to transition the results of Naval research and development for public use.

[ORTA, the previous two paragraphs should be expanded as appropriate to include specific background information.]

NOW THEREFORE, the Collaborators agree as follows:

Article 1. DEFINITIONS

[Note: Specialized definitions required for this Agreement may be added alphabetically within the DEFINITIONS. If specialized definitions are added, they must be included in the Table of Contents.]

As used in this Agreement, the following terms shall have the meanings defined below, which are equally applicable to both the singular and plural forms of nouns or any tense of verbs.

1.1 “Agreement” means this Cooperative Research and Development Agreement (CRADA) with its Appendices.

1.2 “Classified Information” means all Data classified in accordance with the national security laws of the United States.

1.3 “Collaborator” means the Navy participant or the Non-Navy participant represented and bound by the signatories of this Agreement.

1.4 “Controlled Unclassified Information (CUI)” means Government Data, Information, or materials provided to or resulting from this Agreement that may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation.

1.5 “Cooperative Work” means research, development, engineering, or other tasks performed under this Agreement by **[Navy Collaborator]** or **[Non-Navy Collaborator]** working individually or together, pursuant to the Objectives (Article 2) and the Statement of Work (Appendix A).

1.6 “Data” means recorded information of any kind regardless of the form or method of the recording, including computer software.

1.7 “Effective Date” means the date of the last signature of the Collaborators executing this Agreement.

1.8 “Exclusive License” means the grant by the owner of Intellectual Property of the exclusive right to make, use, or sell a patented invention.

1.9 “Government” means the Government of the United States of America.

1.10 “Government Purpose Rights” means the right of the Government 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. Government Purpose Rights includes competitive procurement, but does not include the right to have or permit others to use Data for commercial purposes.

1.11 “Information” means all data, trade secrets, and commercial and financial information. (Chapter 5 Subsection II of Title 5 USC)

1.12 “Intellectual Property” means the property of ideas, examples of which include, but are not limited to, patents, trademarks, copyrights, and trade secrets.

1.13 “Invention” means any invention or discovery that is or may be patentable or otherwise protected under Title 35, United States Code, or any novel variety of plant that is or may be patentable under the Plant Variety Protection Act. (15 USC 3703(9))

1.14 “Invention Disclosure” means the document identifying and describing to organizational management the Making of an Invention.

1.15 “Made” when used in conjunction with any Invention means the conception or first actual reduction to practice of such Invention. (15 USC 3703(10))

1.16 “Militarily Critical Technologies (MCT)” means those technologies identified in the Militarily Critical Technologies List and under the Export Administration Act of 1979, as amended.

1.17 “Non-Subject Data” means any Data that are not Subject Data.

1.18 “Non-Subject Invention” means any Invention that is not a Subject Invention.

1.19 “Patent Application” means an application for patent protection for an Invention with any domestic or foreign patent-issuing authority.

1.20 “Principal Investigator (PI)” means that person having the responsibility for the performance of the Cooperative Work on behalf of a Collaborator.

1.21 “Proprietary Information” means information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information:

is not known or available from other sources without obligations concerning its confidentiality;

has not been made available by the owners to others without obligation concerning its confidentiality;

is not already available to the Government without obligation concerning its confidentiality; and

has not been developed independently by persons who have had no access to the information. (FAR/DFARS Definition)

1.22 “Restricted Access Information” means Subject Data generated by **[Navy Collaborator]** that would be Proprietary Information if the Information had been obtained from a non-Federal Collaborator participating in a CRADA (15 USC 3710a). Under 15 USC 3710a(c)(7)(B), the Collaborators mutually may agree to provide appropriate protection to Subject Data generated by **[Navy Collaborator]** (Restricted Access Information) against public dissemination or release under the Freedom of Information Act (FOIA) for a period of up to five (5) years after development of the Information.

1.23 “Subject Data” means that Data first recorded in the performance of the Cooperative Work.

1.24 “Subject Invention” means any Invention Made in the performance of the Cooperative Work.

1.25 “Tangible Property” means personal or real property that can be physically touched or held.

1.26 “Unlimited Rights” means the right to use, modify, reproduce, release, disclose, perform, or display Data or Computer Programs in whole or in part, in any manner and for any purpose whatsoever, and to have or permit others to do so.

Article 2. OBJECTIVES

[Describe the specific, realizable results or benefits to be gained by each Collaborator at the conclusion of this Agreement. State the desired outcome by each Collaborator, including any intentions for commercialization, if appropriate. This Article and the Statement of Work, Appendix A, are the defining articles for the Cooperative Work to be done by the Collaborators.]

Article 3. RESPONSIBILITIES

The Collaborators shall provide personnel, facilities, and equipment necessary for, and shall perform, the Cooperative Work.

3.1 **[Navy Collaborator]** Personnel and Facilities

The Cooperative Work done by **[Navy Collaborator]** will be performed under the program guidance of **[name]**, PI, **[Navy Collaborator]** Code **[supply organizational code identification]**, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within the facilities of **[Navy Collaborator]** or done on behalf of **[Navy Collaborator]** by third parties in support of this Agreement.

[Note to ORTA: If service or support contractor personnel are being used by Navy Collaborator, refer to the Navy CRADA Handbook (Handbook).]

[Non-Navy Collaborator] personnel who perform Cooperative Work at **[Navy Collaborator]** facilities will be supervised by the **[Non-Navy Collaborator]** PI.

3.2 **[Non-Navy Collaborator]** Personnel and Facilities

The Cooperative Work done by **[Non-Navy Collaborator]** will be performed under the program guidance of **[name]**, **[Non-Navy Collaborator]** PI, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within the facilities of **[Non-Navy Collaborator]** or done on behalf of **[Non-Navy Collaborator]** by third parties in support of this Agreement.

[Navy Collaborator] personnel who perform Cooperative Work at **[Non-Navy Collaborator]** facilities will be supervised by the **[Navy Collaborator]** PI.

3.3 Security Regulations and Directives

Each Collaborator will abide by the safety and security regulations and directives of the host facility in which the Cooperative Work is being performed.

[This is the place to add any special security requirements for personnel doing Cooperative Work at the Collaborators' facilities. If the Cooperative Work covers unclassified Military Critical Technology (MCT), the non-Government Collaborator must be certified to handle MCT data. MCT data must be controlled in accordance with the International Trade in Arms Regulations (ITAR). MCT certification is established using DD Form 2345, called an "Export-Controlled DoD Technical Data Agreement". If the Cooperative Work covers classified topics, a security clearance must be put in place for the Non-Navy Collaborator's facilities]

and personnel using a DoD Contract Security Classification Specification, DD Form 254, completed through [Navy Collaborator]'s Security Office. Refer to the CRADA Handbook.]

Article 4. REPRESENTATIONS AND WARRANTIES

4.1 [Navy Collaborator]'s Representations and Warranties

[Navy Collaborator] hereby warrants and represents to [Non-Navy Collaborator] as follows:

4.1.1 [Navy Collaborator] is a Federal laboratory of the U.S. Department of the Navy (Navy) as defined by 15 USC 3710a (d)(2)(A) and Department of Defense Instruction 5535.8, dated May 14, 1999.

4.1.2 The performance of the activities specified by this Agreement is consistent with the [specify the appropriate mission area] and technology transfer missions of [Navy Collaborator] (15 USC 3710a).

4.1.3 The Department of the Navy official executing this Agreement for [Navy Collaborator] has the requisite power and authority to enter into this Agreement and to bind [Navy Collaborator] to perform according to the terms of this Agreement.

4.2 [Non-Navy Collaborator]'s Representations and Warranties

[Non-Navy Collaborator] hereby warrants and represents to [Navy Collaborator] as follows:

[The following Article 4.2.1 is for a single commercial entity. Choose the appropriate alternatives to Article 4.2.1 from those listed in the Handbook according to the nature of the Non-Navy Collaborator: a university, nonprofit entity, State or local government, directly or indirectly foreign owned, controlled, or influenced (FOCI) entity, multiple Collaborators, and their respective means of organization and/or State laws.]

4.2.1 [Non-Navy Collaborator] is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). [Non-Navy Collaborator], as of the Effective Date of this Agreement, is a corporation duly organized, validly existing, and in good standing under the laws of [indicate State or Commonwealth].

4.2.2 The official executing this Agreement for [Non-Navy Collaborator] has the requisite power and authority to enter into this Agreement and to bind [Non-Navy Collaborator] to perform according to the terms of this Agreement.

[The following Article 4.2.3 is for a single commercial entity. Choose the appropriate alternatives to Article 4.2.3 from those listed in the Handbook according to the nature of the organization as private industry, university, or nonprofit entity, State or local government, or FOCI and their respective means of organization and/or State laws.]

4.2.3 The Board of Directors and stockholders of [Non-Navy Collaborator] have taken all actions required by law, its Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.

4.2.4 The execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any agreement binding on **[Non-Navy Collaborator]**. Furthermore, the execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any valid order of any court, or any regulatory agency or other body having authority to which **[Non-Navy Collaborator]** is subject.

4.2.5 **[Non-Navy Collaborator]** is not presently subject to debarment or suspension by any agency of the Government. Should **[Non-Navy Collaborator]** be debarred or suspended during the term of this Agreement or thereafter, **[Non-Navy Collaborator]** will notify **[Navy Collaborator]** within thirty (30) days of receipt of a final notice. **[Navy Collaborator]** may then elect to terminate this Agreement and any licenses and options granted under this Agreement.

4.2.6 **[Non-Navy Collaborator]** **[is/is not]** a small business as defined in 15 USC 632 and implementing regulations (13 CFR 121.101 et seq.) of the Administrator of the Small Business Administration.

4.3 Joint Representations

The Collaborators make the following representations.

4.3.1 There is no express or implied warranty as to any research, Invention, or product, whether tangible or intangible. In particular, the Collaborators make no express or implied warranty as to the merchantability or fitness for a particular purpose of any research, Invention, or product, whether tangible or intangible. Likewise, the Collaborators make no express or implied warranty as to any Cooperative Work, Subject Invention, Subject Data, or other product resulting from the Cooperative Work.

4.3.2 The use and dissemination of Information and materials exchanged under this Agreement will be in accordance with all U.S. laws and regulations, including those pertaining to national security and export control. Nothing in this Agreement shall be construed as a license to export Information or to permit any disclosure in violation of law, regulation, or Department of Defense policy. The exporting Collaborator is responsible for obtaining any export licenses that may be required by U.S. Federal law.

Article 5. FUNDING

[IF PAYMENTS ARE TO BE MADE directly from Non-Navy Collaborator to Navy Collaborator, use the following Articles.]

5.1 Payment Schedule

[Non-Navy Collaborator] agrees to pay **[Navy Collaborator]** the following fees/costs in accordance with the payment schedule below:

[Insert amount to be paid, identify the task for which payment is made, the schedule of the tasks, and date of payment or, if preferred, the date and amount of each scheduled payment.]

Checks will be payable to:

[Specify endorsement. Do not specify an individual by name but rather an organization (or job title or function) that has the requisite authority to receive funds for the Navy.]

Each check and its cover correspondence shall refer to Navy CRADA number "NCRADA-[Navy Collaborator]-[last two digits of CY]-[lab CRADA sequence number]."

Checks will be mailed to:

[Specify address, including the name of the authorized recipient, title, and appropriate organizational code.]

5.2 Insufficient and Excess Funds

[Navy Collaborator] may discontinue performance under this Agreement if the funds provided by **[Non-Navy Collaborator]** for performance by **[Navy Collaborator]** are insufficient or are not provided as specified in Article 5.1. In the event **[Non-Navy Collaborator]** fails to tender the Government the required payment within fifteen (15) days after its respective due date, **[Non-Navy Collaborator]** shall be in default under this Agreement for failure to make payments. If **[Non-Navy Collaborator]** is in default for this reason, **[Navy Collaborator]** shall notify **[Non-Navy Collaborator]**. If **[Non-Navy Collaborator]** does not cure the default within fifteen (15) days of mailing date of notice, **[Navy Collaborator]** may proceed to terminate the Agreement in accordance with Article 11.2.2, may cancel any option for an Exclusive License to a Subject Invention, and may terminate any Exclusive License granted pursuant to this Agreement.

Funds that **[Non-Navy Collaborator]** paid under Article 5.1 and that **[Navy Collaborator]** has not obligated or expended at the time of completion, expiration, or termination of this Agreement shall be returned to **[Non-Navy Collaborator]** after **[Navy Collaborator]**'s submission of a final fiscal report to **[Non-Navy Collaborator]**.

5.3 No New Commitments

[Navy Collaborator] shall make no new commitments concerning this Agreement after receipt of a written termination notice from **[Non-Navy Collaborator]** in accordance with Article 11.2 and shall, to the extent practicable, cancel all outstanding commitments by the termination date. Should such cancellation result in any costs incurred by **[Navy Collaborator]**, **[Non-Navy Collaborator]** agrees that such costs shall be chargeable against any funding that it provided to **[Navy Collaborator]**.

5.4 Accounting Records

[Navy Collaborator] shall maintain current accounts, records, and other evidence supporting all its expenditures against funding provided by **[Non-Navy Collaborator]** under this Agreement and shall retain such records for at least twelve (12) months after the completion, expiration, or termination of this Agreement. **[Navy Collaborator]** shall provide **[Non-Navy Collaborator]** a financial report within four (4) months after completion, expiration, or termination of this Agreement.

[IF NO PAYMENTS ARE TO BE MADE by Non-Navy Collaborator to Navy Collaborator, or Navy Collaborator is using in-house funding or Government funds already received, use ONLY the following phrase and remove Article Titles 5.1 through 5.4 from the Table of Contents]

Each Collaborator will fund its own efforts.

[Consult the Handbook for the situations in which payments are made only after the completion of a critical milestone in the Cooperative Work or in the case where Navy Collaborator's participation is contingent upon receipt of funds from another Government Organization.]

Article 6. REPORTS AND PUBLICATIONS

6.1 Interim Reports

The Collaborators shall submit **[optional: insert number or frequency for each interim written report]** interim written reports to each other on the progress of the Cooperative Work as mutually agreed.

6.2 Final Reports

The Collaborators shall submit to each other a final report within four (4) months of the completion, termination, or expiration of this Agreement that includes the results obtained and a list of all Subject Inventions Made.

6.3 Agreement to Confer Prior to Publication or Public Disclosure

The Collaborators agree to confer and consult prior to any publication or public disclosure of Subject Data to ensure that no Proprietary Information, Restricted Access Information, Government Classified Information, CUI, or MCT Information is released and that patent rights are not compromised. Prior to any such publication or public disclosure of Subject Data, each Collaborator shall be offered a period not less than fifteen (15) days and not to exceed thirty (30) days, unless otherwise mutually agreed in writing by the Collaborators, to review any proposed abstract, publication, presentation, or other document for public disclosure that contains Subject Data. For the purposes of this Article, the term "disclosure" shall include, but not be limited to, submission of any manuscript for peer review prior to publication. It is the responsibility of the Collaborator intending to make public disclosure of Subject Data to notify the other Collaborator of such intent.

If a Collaborator objects to a proposed public disclosure, that Collaborator must so notify the other Collaborator within thirty (30) days of the date of notice of intent to disclose publicly.

If no objection is received by the Collaborator intending to make public disclosure, concurrence is assumed. If a Collaborator objects on the grounds that patent rights may be compromised, a Patent Application must be filed by the responsible Collaborator within ninety (90) days of the date of notification of intent to make public disclosure, or by another date mutually agreed to by the Collaborators. If a Collaborator objects to the release of Information on the grounds that the Information is Proprietary Information, Restricted Access Information, or Information whose dissemination is restricted by U.S. security laws or regulations, the disclosure shall be postponed until the Information no longer meets the definitions of Proprietary Information, Restricted Access Information, or is no longer covered by U.S. security laws or regulations.

6.4 Classified Information

Any presentation that includes Subject Data that are Classified Information or otherwise restricted Data must have prior review and approval by **[Navy Collaborator]** pursuant to the pertinent security laws, regulations, and directives.

Article 7. INTELLECTUAL PROPERTY

7.1 Data

7.1.1 General Provisions Applying to All Data

7.1.1.1 Ownership

Each Collaborator shall have title to all Data generated by that Collaborator.

7.1.1.2 No Implied License

Unless otherwise specifically provided, the Collaborators agree that the exchange of Data of any kind does not confer a license to any Invention claimed in any patent or Patent Application or to the subject matter of any copyright, trademark/service mark, or other form of Intellectual Property protection.

7.1.1.3 Marking of Data

7.1.1.3.1 Data Provided With Less Than Unlimited Rights

Each Collaborator shall mark all Data that it provides with less than Unlimited Rights with a marking that clearly identifies the limited rights.

7.1.1.3.2 Data That are Proprietary Information or Restricted Access Information

[Non-Navy Collaborator] shall place a proper proprietary marking on each medium used for recording Data that **[Non-Navy Collaborator]** delivers to **[Navy Collaborator]** under this Agreement that **[Non-Navy Collaborator]** asserts is Proprietary Information. **[Non-Navy Collaborator]** shall request in writing if it wishes Subject Data generated by **[Navy Collaborator]** to be marked as Restricted Access Information. The Collaborators together shall confer to determine if such marking is appropriate, with reference to the Definitions of Article 1. If the Collaborators mutually agree to the marking then:

(a) For Non-Subject Data that are Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[Non-Navy Collaborator]** - **[Navy Collaborator]** MAY USE ONLY FOR PURPOSE OF CRADA NUMBER “NCRADA-**[Navy Collaborator]** - **[last two digits of CY]**-**[lab CRADA sequence number]**”;

(b) For Subject Data that are Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[Non-Navy Collaborator]** - GOVERNMENT HAS GOVERNMENT PURPOSE RIGHTS UNDER CRADA NUMBER “NCRADA-**[Navy Collaborator]**-[last two digits of CY]-[lab CRADA sequence number]”;

(c) For Data that are Restricted Access Information, the marking shall read:

“RESTRICTED ACCESS INFORMATION - PROTECT IN ACCORDANCE WITH CRADA NUMBER “NCRADA-**[Navy Collaborator]**-[last two digits of CY]-[lab CRADA sequence number]” UNTIL [INSERT DATE: Insert negotiated date not to exceed five (5) years from the generation of a Restricted Access Information document]”.

[ORTA, insert full name of Non-Navy Collaborator in the statements above and see Handbook regarding date for Restricted Access Information.]

7.1.1.3.3 Data that are Subject to 35 USC 205

[Navy Collaborator] shall mark Data it provides under this Agreement that disclose one or more Inventions in which the Government owns or may own a right, title or interest, and that are subject to confidentiality under 35 USC 205. Such Data shall be marked:

“**[Navy Collaborator]** DATA PROTECTED FROM RELEASE OR DISCLOSURE UNDER 35 USC 205.”

[Note to ORTA: Insert full name of Navy Collaborator in the above marking.]

7.1.1.3.4 Data that are Classified Information, CUI, MCT, or Otherwise Restricted

Each Collaborator shall mark all Data that are Classified Information, CUI, MCT, or otherwise restricted by U.S. security or export control laws or regulations that it provides under this Agreement.

[Note to ORTA: No standard marking is provided. Marking will vary according to the type of Data provided and should be consistent with Navy Collaborator’s marking regulations and policies.]

7.1.1.4 Protection of Data

Except for the rights granted in Article 7.1.2.2, Data shall be protected in accordance with the proper markings of its owner and as provided by, at a minimum, the requirements of 15 USC 3710a. Proprietary Information will be protected only if it is properly marked as such. Information provided in intangible form that is Proprietary Information must be designated Proprietary Information at the time it is delivered, followed within fifteen (15) days by a writing summarizing the exact Information to be protected. The Collaborator receiving Information in an intangible form that is designated as Proprietary Information shall be responsible for protecting the Information as Proprietary Information during the fifteen (15) day notification period. After the

fifteen (15) day period, if no written summary has been received, the receiving Collaborator need not continue to protect the Information received in intangible form.

Restricted Access Information shall be protected from public dissemination for up to five (5) years, as mutually agreed.

Classified Information, CUI, MCT, or otherwise restricted Information shall be protected in accordance with the security laws of the United States.

7.1.1.5 Release of Data Under the Freedom of Information Act

Data in the possession of **[Navy Collaborator]** that are not marked CUI, Proprietary Information of **[Non-Navy Collaborator]** or Restricted Access Information must be released by **[Navy Collaborator]** where such release is required pursuant to a request under the Freedom of Information Act (FOIA) (5 USC 552). **[Navy Collaborator]** shall protect Data that are properly marked CUI, Proprietary Information of **[Non-Navy Collaborator]** or Restricted Access Information from release under the FOIA for as long as the marked Data meet the definition of CUI, Proprietary Information or Restricted Access Information. Prior to release of any such Data, **[Navy Collaborator]** shall promptly notify **[Non-Navy Collaborator]** of any request for Data of **[Non-Navy Collaborator]** regardless of whether the requested Data are marked Proprietary Information.

7.1.2 Subject Data

7.1.2.1 Delivery of Requested Subject Data

Each Collaborator shall have the right to review and receive delivery of all Subject Data generated by the other Collaborator. Requested Subject Data shall be delivered to the requesting Collaborator within fifteen (15) days of the request.

7.1.2.2 Rights in Subject Data

Except as represented in Article 4.3.2, the Collaborators shall have Unlimited Rights in all Subject Data that are not Proprietary Information or Restricted Access Information. Notwithstanding 15 USC 3710a, **[Non-Navy Collaborator]** grants Government Purpose Rights in any Subject Data furnished by **[Non-Navy Collaborator]** to **[Navy Collaborator]** under this Agreement that are properly marked as Proprietary Information. The Government has Government Purpose Rights in Subject Data that are Restricted Access Information.

7.1.3 Rights in Non-Subject Data

The Collaborators shall have Unlimited Rights in any Non-Subject Data delivered under this Agreement that are not Proprietary Information.

[Navy Collaborator] has a limited right to use, reproduce, and disclose only to Government employees for use in support of the Cooperative Work any Non-Subject Data that are properly marked as Proprietary Information and are provided by **[Non-Navy Collaborator]** under this Agreement. Such Proprietary Information can be used only for the purpose of performing the Cooperative Work unless consent to other use or disclosure is obtained from **[Non-Navy Collaborator]** in writing.

[Non-Navy Collaborator] shall have a limited right to use, reproduce, or disclose Non-Subject Data that may describe one or more Inventions in which the Government owns or may own a right, title or interest, if such Non-Subject Data are provided by **[Navy Collaborator]** under this Agreement. In accordance with 35 USC 205, such Non-Subject Data are to be held in confidence. Such Non-Subject Data shall be properly marked by **[Navy Collaborator]** and the limited rights of **[Non-Navy Collaborator]** shall be defined by a separate non-disclosure agreement.

7.2 Copyrights

7.2.1 Copyright by **[Non-Navy Collaborator]**

[Non-Navy Collaborator] may copyright works of authorship prepared pursuant to this Agreement if eligible for copyright protection under Title 17 USC.

7.2.2 Copyright License to the Government

[Non-Navy Collaborator] grants to the Government a nonexclusive, irrevocable, paid-up license in copyrighted works of authorship, including software (17 USC 106) prepared pursuant to this Agreement for any purpose, consistent with the rights in Data described in Article 7.1.

7.2.3 Copyright Statement

[Non-Navy Collaborator] shall include the following statement on any text, drawing, mask work or other work of authorship, that may be copyrighted under 17 USC, that is created in the performance of this Agreement:

“The U.S. Government has a copyright license in this work pursuant to a Cooperative Research and Development Agreement with **[Navy Collaborator]**.”

[ORTA: Insert the full name of Navy Collaborator in the statement above.]

7.3 Trademarks and Service Marks

This section only applies to marks created under, or as a result of, this Agreement and does not effect any Collaborator’s pre-existing marks or marks created outside the scope of this work.

7.3.1 Ownership of Trademarks and Service Marks

The Collaborator first establishing a trademark or service mark for goods or services with which the mark is used shall be considered the owner of the mark.

7.3.2 Obligation of Employees to Report Trademarks and Service Marks

Employees of both Collaborators shall report the adoption of a trademark or service mark associated with the Cooperative Work to their employer within thirty (30) days of the first use of the mark. Use includes internal use of any product or service of the Cooperative Work.

7.3.3 Obligation of Collaborators to Notify Each Other

Each Collaborator shall notify the other Collaborator within thirty (30) days of their employee's report of the first use of a trademark or service mark.

7.3.4 Responsibility for Filing an Application for Trademark or Service Mark

The Collaborator owning a trademark or service mark shall establish the use of the mark in intra- and interstate commerce and shall be responsible for filing all applications for trademark or service mark registration as appropriate.

7.3.5 License to Use Trademark or Service Mark

The Collaborator owning the trademark or service mark as defined in Article 7.3.1, shall grant a paid-up, irrevocable, nonexclusive license to the other Collaborator for use of the trademark or service mark on the goods or services for which the mark is intended to be used.

7.4 Subject Inventions

7.4.1 Obligation to Report Subject Inventions

7.4.1.1 Collaborators' Instructions to Employees

Each Collaborator shall instruct its employees to submit an Invention Disclosure to that Collaborator for all innovations, solutions to technical problems, or unique increases to the general body of knowledge resulting from the Cooperative Work. For the purposes of this Article, these innovations, solutions, and increases to knowledge shall be deemed Inventions.

7.4.1.2 Timely Invention Disclosure by Inventors

Within ninety (90) days of Making an Invention resulting from the Cooperative Work, unless a shorter time period is required by circumstances, the inventor(s) shall submit an Invention Disclosure to their employer.

In the case of an Invention Made jointly by inventors from both Collaborators, the inventors shall submit an Invention Disclosure with their respective employer.

7.4.1.3 Obligation to Provide Invention Disclosures to the Other Collaborator

Each Collaborator shall provide the other Collaborator with a copy of each Invention Disclosure reporting a Subject Invention within sixty (60) days of receiving the Invention Disclosure from its inventor(s).

7.4.2 Determination of Subject Inventions

The Collaborators shall review each Invention Disclosure resulting from the Cooperative Work and shall confer and consult to determine whether an Invention Disclosure represents a Subject Invention.

7.4.3 Title to and Ownership of Subject Inventions

Each Collaborator shall be entitled to own the Subject Inventions of its employees. Each Collaborator shall cooperate with the other Collaborator to obtain inventor signatures on Patent Applications, assignments or other documents required to secure Intellectual Property protection. For any Invention Made jointly by employees of the Collaborators, each Collaborator shall have ownership of the Subject Invention in the form of an undivided interest.

7.4.4 Filing of Patent Applications

7.4.4.1 Filing of Patent Applications on Solely Made Inventions

Each Collaborator has primary responsibility for filing Patent Applications on the Subject Inventions of its employee(s).

Notwithstanding such primary responsibility, by mutual agreement, the Collaborators may identify which Collaborator shall file a Patent Application on any Subject Invention.

7.4.4.2 Filing of Patent Applications on Jointly Made Inventions

In the case of an Invention jointly Made by employees of both Collaborators, the Collaborators shall confer and agree as to which Collaborator will file any Patent Application. Officers of the non-filing Collaborator shall cooperate with the filing Collaborator to obtain signatures on documents that are needed to file a Patent Application.

7.4.4.3 Preserving Intellectual Property Rights

The Collaborator responsible for filing of a Patent Application on any Subject Invention shall file such Patent Application at least sixty (60) days prior to any bar date or one year from the date the Invention Disclosure was received, whichever comes first. If no Patent Application is filed within the specified time period, the other Collaborator may assume control of filing the Patent Application and take title to the Subject Invention on ten (10) days written notification. The Collaborator that relinquished the responsibility to file shall retain a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Subject Invention practiced throughout the world by or on its behalf.

7.4.4.4 Filing Deadlines

The Collaborator responsible for filing any Patent Application for a Subject Invention shall notify the other Collaborator of all filing deadlines for prosecution of any Patent Application and maintenance of any patents on the Subject Invention. Notwithstanding the primary responsibility defined in Article 7.4.4.1, sixty (60) days prior to any filing deadline, the Collaborators shall confer to determine if the filing Collaborator intends to respond to the filing deadline. The non-filing Collaborator will be permitted to take action if the filing Collaborator declines.

7.4.4.5 Copies and Inspection

7.4.4.5.1 Copies of Prosecution Papers

Each Collaborator filing a Patent Application on a Subject Invention shall provide the other Collaborator with a copy of any communication relating to prosecution of said Patent Application within thirty (30) days of receipt of such communication.

7.4.4.5.2 Access to Patent Application File and Right to Make Copies

Upon written request, the filing Collaborator shall give the other Collaborator an Associate Power of Attorney, with authorization to access the Patent Application, make copies, and, in the event the filing Collaborator fails or declines to take action, do all that is necessary to secure Intellectual Property protection for the Subject Invention.

7.4.4.6 Rights of Inventors if the Collaborators Decline to File a Patent Application

In the event both Collaborators decline to file a Patent Application on a Subject Invention, the Government will renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

In the event both Collaborators decline to file a Patent Application on a Subject Invention, **[Non-Navy Collaborator]** may, at its sole discretion, renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

7.4.5 Nonexclusive License to Subject Inventions

7.4.5.1 Nonexclusive License Grant

Each Collaborator grants to the other Collaborator a nonexclusive, irrevocable, paid-up license to practice a Subject Invention Made by employees of the granting Collaborator or have the Subject Invention practiced throughout the world by or on behalf of the other Collaborator. No nonexclusive license granted under this Agreement shall permit licensee to grant sublicenses.

7.4.5.2 Confirmatory Nonexclusive License Agreement

Each Collaborator has the obligation to provide a Confirmatory License Agreement (Appendix B) to the other Collaborator for each nonexclusive license within ninety (90) days of the date of filing.

7.4.6 Option for Exclusive License to Subject Inventions

[Navy Collaborator] gives **[Non-Navy Collaborator]** the option of acquiring an Exclusive License for the field of use **[state field of use]** in the Government's rights in any Subject Invention Made in whole or in part by a **[Navy Collaborator]** employee. The license shall be for reasonable consideration. In order to exercise this option, **[Non-Navy Collaborator]** must notify **[Navy Collaborator]** in writing within one hundred and eighty (180) days of the filing of a Patent Application. Unless another time period is mutually agreed upon between the Collaborators,

[Non-Navy Collaborator] must execute an Exclusive License to the Subject Invention within one hundred and eighty (180) days of election to exercise the option, or the Invention shall be made available for licensing by the public in accordance with 37 CFR Part 404.

Any Exclusive License granted by the Government in a Subject Invention is subject to the statutorily required reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have that Subject Invention practiced throughout the world by or on behalf of the Government (15 USC 3710a).

7.4.7 Limitation on Assignment of Licenses Granted Under This Agreement

No license granted under this Agreement shall be assigned, licensed or otherwise disposed of except to the successor in interest of that part of **[Non-Navy Collaborator]**'s business to which such license pertains.

[The following Article 7.4.8 is to be used for a Non-Navy Collaborator that is “not” directly or indirectly foreign owned, controlled, or influenced (FOCI). For FOCI organizations identified as such in Article 4.2.1, use the appropriate alternative to Article 7.4.8 listed in the CRADA Handbook under “MODIFICATIONS FOR CRADAs WITH A FOCI ENTITY”.]

7.4.8 Termination of License Granted and Cancellation of Exclusive License Option to Subject Inventions

7.4.8.1 Exclusive Licenses and Exclusive License Option

[Navy Collaborator] may terminate any Exclusive License or cancel any option for an Exclusive License to a Subject Invention granted under this Agreement in the event that:

(a) **[Non-Navy Collaborator]** is in default for failure to make payment as agreed in Article 5; or

(b) The Agreement is terminated unilaterally by **[Non-Navy Collaborator]**; or

(c) **[Non-Navy Collaborator]** fails to perform according to the Statement of Work (Appendix A); or

(d) **[Non-Navy Collaborator]** becomes a foreign owned, controlled, or influenced (FOCI) organization that does not qualify under the requirements of Executive Order 12591, Section 4(a).

7.4.8.2 Nonexclusive Licenses

[Navy Collaborator] shall terminate any nonexclusive license to a Subject Invention granted under this Agreement if **[Non-Navy Collaborator]** becomes a FOCI organization that does not qualify under the requirements of Executive Order 12591, Section 4(a).

7.5 Non-Subject Inventions

7.5.1 Ownership of Non-Subject Inventions

Each Collaborator owns its Non-Subject Inventions.

7.5.2 Rights Under Other Agreements

Nothing in this Agreement is intended to change the rights in Intellectual Property acquired by the Collaborators in any other contract or agreement between the **[Non-Navy Collaborator]** and the Government.

7.5.3 No License to Non-Subject Inventions

This Agreement does not grant any Collaborator a license, express or implied, to any Non-Subject Invention.

[Each paragraph in the following Article 7.5.4 is optional.]

7.5.4 Preexisting Non-Subject Inventions Pertinent to the Cooperative Work

Non-Subject Inventions Made prior to the Effective Date and pertinent to the Cooperative Work that are specifically identified as property of **[Navy Collaborator]** include but are not limited to the following:

[List Invention Title, inventor name(s), patent number, or Navy case number if an Invention disclosure, or Patent Application Serial Number, and date of issue (for patents only).]

Non-Subject Inventions Made prior to the Effective Date and pertinent to the Cooperative Work that are specifically identified as property of **[Non-Navy Collaborator]** include but are not limited to the following:

[List Invention Title, inventor name(s), patent number, or attorney's docket number if an Invention disclosure or Patent Application Serial Number, and date of issue (for patents only).]

7.6 Research License

Each Collaborator shall allow the other Collaborator to practice any of its Non-Subject Inventions for the purpose of performing the Cooperative Work.

No license, express or implied, for commercial application(s) is granted to either Collaborator in Non-Subject Inventions by performing the Cooperative Work.

For commercial application(s) of Non-Subject Inventions, a license must be obtained from the owner.

Article 8. TANGIBLE PROPERTY

8.1 Title to Preexisting Tangible Property

Each Collaborator shall retain title to all Tangible Property to which it had title prior to the Effective Date of this Agreement.

8.2 Tangible Property Purchased by Collaborators to Perform the Cooperative Work

Each Collaborator shall retain title to all Tangible Property that it purchases during the period of this Agreement. **[Non-Navy Collaborator]** cannot take title to any Government Tangible Property under this Agreement. Collaborator consumables to be used in the Cooperative Work of this Agreement are the property of the purchasing Collaborator until consumed.

8.3 Title to Developed Tangible Property

All Tangible Property developed under this Agreement with all components purchased by one Collaborator shall be the property of that Collaborator. Tangible Property having any component purchased by **[Navy Collaborator]** shall be the property of the Government, unless such Tangible Property can reasonably be separated without damage to the other individual components. After this Agreement is completed, expired, or terminated, if separation of components can be made without damage, the Collaborators may, by mutual agreement, separate the Tangible Property into its components and the separated components shall remain the property of the Collaborator that purchased them.

8.4 Tangible Property Operational and Disposition Costs

During the period of and upon completion, expiration, or termination of this Agreement, each Collaborator shall be responsible for all costs of maintenance, removal, storage, repair, disposal, and shipping of all Tangible Property to which it has title.

8.5 Disposal of Tangible Property

Disposal of Tangible Property shall be in accordance with applicable U.S. Federal, State, and local property disposal laws, environmental laws, and regulations.

Article 9. LIABILITY

9.1 Extent of Government Liability

The Government shall be solely liable for the negligent or wrongful acts of its officers and employees to the extent provided for in the Federal Tort Claims Act (28 USC 2671 et. Seq.) and in other applicable laws and regulations of the United States that specifically waive sovereign immunity. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the United States.

9.2 Extent of **[Non-Navy Collaborator]** Liability

[Non-Navy Collaborator] is solely responsible for its actions and the actions of those acting for **[Non-Navy Collaborator]** in the performance of this Agreement and for any damages that may arise from any suit, action, or claim, and for any costs from or incidental to any suit, action, or claim, including but not limited to settlement and defense costs. Further, **[Non-Navy Collaborator]** agrees that in any suit, action or claim brought by anyone not a party to this Agreement based on actions of **[Non-Navy Collaborator]**, **[Non-Navy Collaborator]** shall not pursue any actions to enter the Government as a party in such suit, action or claim unless the Government has some liability under the Federal Tort Claims Act.

9.3 *Force Majeure*

No Collaborator shall be liable for the consequences of any *force majeure* that (1) is beyond its reasonable control; (2) is not caused by the fault or negligence of such Collaborator; (3) causes such Collaborator to be unable to perform its obligations under this Agreement; and (4) cannot be overcome by the exercise of due diligence. In the event of the occurrence of a *force majeure*, the Collaborator unable to perform shall promptly notify the other Collaborator. The Collaborators shall suspend performance only for such period of time as is necessary to overcome the result(s) of the *force majeure* and shall use their best efforts to resume performance as quickly as possible.

Article 10. GENERAL PROVISIONS

10.1 Characteristics of the Agreement

10.1.1 Entire Agreement

This Agreement constitutes the entire agreement between the Collaborators concerning the Cooperative Work and supersedes any prior understanding or written or oral agreement relative to the Cooperative Work.

10.1.2 Severability

The illegality or invalidity of any Article of this Agreement shall not impair, affect, or invalidate any other Article of this Agreement.

10.1.3 Interpretation of Headings

Headings of the Articles of this Agreement are for convenience of reference only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

10.2 Agreements Between Collaborators

10.2.1 Governing Laws

United States Federal Laws shall govern this Agreement for all purposes.

10.2.2 Independent Parties/Entities

The relationship of the Collaborators to this Agreement is that of independent parties and not as agents of each other, partners, or participants in a joint venture. Each Collaborator shall maintain sole and exclusive control over its personnel and operations.

10.2.3 Assignment/Subcontracting

[Note to ORTAs: Refer to the Handbook for a discussion on issues related to the use of contractors during the execution of a CRADA.]

10.2.3.1 Neither Collaborator may allow third parties to perform any part of the Cooperative Work under this Agreement without express written consent of the other Collaborator. If consent is obtained, the Collaborator requesting such consent shall remain fully responsible for the portion of the Cooperative Work to be accomplished under a third-party agreement, and the third party is not a Collaborator of this Agreement. Any third-party agreement to perform a portion of the Cooperative Work shall contain terms consistent with this Agreement.

10.2.3.2 This Agreement shall not be assigned or otherwise transferred by either Collaborator without the prior written consent of the other Collaborator, except to the successor of that part of **[Non-Navy Collaborator]**'s business to which this Agreement pertains.

10.2.3.3 If **[Non-Navy Collaborator]** or its successor or assignee is a U.S. company, and becomes, during the term of this Agreement or thereafter, directly or indirectly owned, controlled, or influenced by a foreign company or government (FOCI), then **[Non-Navy Collaborator]** or its successor or assignee shall promptly notify **[Navy Collaborator]** to that effect.

10.2.4 Disputes

10.2.4.1 Settlement and Resolution

[Navy Collaborator] and **[Non-Navy Collaborator]** agree to use reasonable efforts to reach a fair settlement of any dispute. If such efforts are unsuccessful, remaining issues in dispute will be referred to the signatories or their successors for resolution. If a dispute continues, the remaining issues may be submitted to the Chief of Naval Research (CNR), or the CNR designee, for resolution. This Agreement does not prevent any Collaborator from pursuing disputes in a U.S. Federal court of competent jurisdiction. No Collaborator will pursue litigation in a U.S. Federal court until after the CNR, or the CNR designee, decides the dispute, or until sixty (60) days after the dispute was first submitted to the CNR, or the CNR designee, whichever comes first.

10.2.4.2 Continuation of Cooperative Work

If payments or installment payments are to be made as stated under Article 5, **[Navy Collaborator]** will not start or continue cooperative work until payments or installment payments are received.

10.2.5 Waivers

None of the provisions of this Agreement shall be considered waived by either Collaborator unless such waiver is given in writing to the other Collaborator, signed by the executing official of this Agreement or the official's successor having the authority to bind the Collaborator making the waiver. The failure of either Collaborator to insist upon strict performance of any of the terms and conditions herein, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any right of either Collaborator under this Agreement.

10.2.6 Use of Name or Endorsements

Except as provided for in Article 7.2.3, **[Non-Navy Collaborator]** shall not use the name of **[Navy Collaborator]** or any other Government entity on any product or service that is directly or indirectly related to either this Agreement or any patent license or assignment associated with this Agreement without the prior approval of **[Navy Collaborator]**. By entering into this Agreement, **[Navy Collaborator]** does not directly or indirectly endorse any product or service

provided, or to be provided, by **[Non-Navy Collaborator]**, its successors, assignees, or licensees. **[Non-Navy Collaborator]** shall not in any way imply that the Department of the Navy endorses any such product or service.

10.3 Environment, Safety, and Health

Each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste in its custody during the course of this Agreement. At the conclusion of this Agreement, each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste still in its possession. Each Collaborator shall obtain at its own expense all necessary permits and licenses as required by U.S. Federal, State, and local law and shall conduct such handling, control, and disposition in a lawful and environmentally responsible manner. Each Collaborator is responsible for all required environmental, safety, and health compliance, notice, and monitoring related to its facility in accordance with U.S. Federal, State, and local law and regulations. Collaborators shall abide by the environmental, safety, and health directives of the host facility in which the Cooperative Work is being performed, and any U.S. Federal, State, or local laws and regulations pertaining to environment, safety, and health that are applicable to the host facility.

10.4 U.S. Competitiveness

[Non-Navy Collaborator] agrees that any product, process, or service using Intellectual Property arising from the performance of this Agreement shall be manufactured substantially in the United States.

10.5 Public Release of This Agreement

This Agreement, without funding information (Article 5) and Appendices, may be released to the public.

Article 11. MODIFICATIONS AND NOTICES

11.1 Amendments

If a Collaborator wishes to modify this Agreement, the Collaborators shall confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by both executing officials of this Agreement or their successors.

11.2 Termination

11.2.1 Termination by Mutual Consent

The Collaborators may elect to terminate this Agreement at any time by mutual consent. Such termination shall not be effective until a written termination agreement is signed by both executing officials of this Agreement or their successors.

11.2.2 Unilateral Termination

A Collaborator may unilaterally terminate this entire Agreement at any time by giving the other Collaborator written notice signed by the executing official of this Agreement or **[his/her]** successor, not less than thirty (30) days prior to the desired termination date. If **[Non-Navy Collaborator]** unilaterally terminates this Agreement, any option for an Exclusive License to a Subject Invention and any Exclusive License to a Subject Invention granted by or pursuant to this Agreement shall simultaneously be terminated.

11.3 Notices

All notices pertaining to or required by Articles of this Agreement, except those pertaining solely to the prosecution of any patent, trademark, or service mark, shall be in writing and shall be signed by an authorized representative of the Technology Transfer Office for **[Navy Collaborator]** or the preferred contact for **[Non-Navy Collaborator]**, and all such notices shall be delivered by hand, sent by courier with proper registration, or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

If to **[Navy Collaborator]**:

[Use the official Navy Collaborator mailing address for the Technology Transfer Office.]

If to **[Non-Navy Collaborator]**:

[Specify the mailing address for the preferred contact.]

A Collaborator shall notify the other Collaborator of a change of address in the manner set forth above.

Notices pertaining solely to the prosecution of any patent, trademark, or service mark related to this Agreement shall be in writing and shall be signed by and sent to the Collaborator's legal counsel for Intellectual Property. Legal counsel for Intellectual Property for each Collaborator shall send a copy of any such notice to the Technology Transfer Office for **[Navy Collaborator]**. If either Collaborator fails to identify such counsel upon request, then such notices shall be sent to the points of contact specified above.

Article 12. SURVIVING PROVISIONS

The Articles covering Definitions, Representations and Warranties, Funding, Reports and Publications, Intellectual Property, Tangible Property, Liability, General Provisions, Modifications and Notices, and Surviving Provisions shall survive the completion, termination, or expiration of this Agreement.

Article 13. DURATION

This Agreement expires **[specify a time no greater than three (3) years]** after its Effective Date, unless otherwise extended in writing according to the provisions of Article 11.

Article 14. SIGNATURES

For **[Non-Navy Collaborator]**:

I, the undersigned, am duly authorized to bind **[Non-Navy Collaborator]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200 ____.

By:

Title:

For the Department of the Navy:

I, the undersigned, by 15 USC 3710a and Navy regulations, am duly authorized to bind the U.S. Navy to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200 ____.

By:

Title:

Navy Organization:

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APPENDIX A
STATEMENT OF WORK
BETWEEN
[Navy Collaborator]
AND
[Non-Navy Collaborator]

The Collaborators agree to perform the following tasks:

[Navy Collaborator] will be responsible for the following tasks (list as applicable):

- 1.
- 2.
- 3.

[Non-Navy Collaborator] will be responsible for the following tasks (list as applicable):

- 1.
- 2.
- 3.

[Navy Collaborator] and **[Non-Navy Collaborator]** will be responsible for the following joint tasks (if applicable):

- 1.
- 2.
- 3.

APPENDIX B

<p>CONFIRMATORY LICENSE AGREEMENT</p>	<p>1. APPLICATION FOR (Title of Invention)</p>
<p>2. INVENTOR(S) AND AFFILIATION</p>	
<p>3. PATENT APPLICATION SERIAL NO.</p>	<p>4. PATENT APPLICATION FILING DATE</p>
<p>5. NAVY ACTIVITY (Name, address, point of contact)</p>	<p>6. NON-NAVY ACTIVITY (Name, address, point of contact)</p>
<p>7. CRADA AGREEMENT NO.</p>	<p>8. DATE OF THIS AGREEMENT</p>
<p>9. The Invention identified above is a "Subject Invention" under Article 7 Intellectual Property included with the CRADA identified in Box 7 between the Department of the Navy and Non-Navy Activity identified in Box 6.</p> <p><i>This document is confirmatory of the nonexclusive, irrevocable, paid-up license to practice the identified Subject Invention or have that Subject Invention practiced throughout the world by or on behalf of the receiving party, and of all other rights acquired by the receiving party by the referenced clause.</i></p> <p><i>This license is granted to</i></p> <p>_____ <i>the Government</i></p> <p>_____ <i>Non-Navy Activity identified in Box 6</i> (Select one)</p> <p><i>Under this CRADA in the identified Invention, Patent Application and any resulting patent.</i></p> <p><i>The licensee is hereby granted an irrevocable power to inspect and make copies of the above-identified Patent Application.</i></p> <p>_____ <i>ACTIVITY NAME OF LICENSOR</i></p> <p>_____ <i>SIGNATURE</i></p> <p>_____ <i>NAME (Typed or Printed)</i></p> <p>_____ <i>TITLE</i></p> <p>_____ <i>BUSINESS TELEPHONE</i></p>	

Section III - 2

Supplemental Appendices

The following Appendices may be used in your CRADA package.

Template III - 2a is to be used when the Non-Navy Collaborator is using a third party to perform part of the work described in the Statement of Work of the CRADA. Likewise, Template III - 2b is to be used when the Navy Collaborator is using a third party to perform part of the work described in the Statement of Work of the CRADA.

Appendix C is for use with a Standard CRADA only. If a CRADA is with a FOCI, the use of a third party will only be allowed after all other preliminary procedures have been followed according to Non-Standard CRADA instructions. The use of third parties in a FOCI CRADA will also have to be reviewed by local legal counsel and Appendix C language drafted accordingly.

The CRADA Final Report Appendix is not currently a requirement to be included in your CRADA. If you choose to include it in your Standard CRADA or any of the approved Non-Standard CRADAs, you will need to modify Article 6.2 to reflect that the final report will use that format.

Section III - 2a

Appendix C

Third Party Agreement

[Non-Navy Collaborator] Use of Third Party [insert Third Party name]

As provided in paragraph 10.2.3.1 of **[NCRADA-Navy Org-last two digits of FY-serial number]** [hereinafter the CRADA], **[Non-Navy Collaborator]** desires to have **[Third Party]**, a U.S., business entity, located at **[supply address of Third Party]**, perform the following services on **[Non-Navy Collaborator's]** behalf as part of the Cooperative Work listed in Appendix A of the CRADA:

[List Services].

[Non-Navy Collaborator] shall remain fully responsible for the portion of the Cooperative Work to be accomplished by **[Third Party]**, and **[Third Party]** shall not be a Collaborator of the CRADA. **[Third Party]** agrees to perform their Cooperative Work in accordance with the terms of the CRADA.

The **[Third Party]** is aware that the following employee[s] is[are] being assigned to work on tasks assigned to **[Non-Navy Collaborator]** under the CRADA:

[List Third Party Personnel].

The **[Third Party]** has read the terms and conditions of the CRADA. **[Third Party]** and **[Non-Navy Collaborator]** agree that **[Navy Collaborator]** shall have the same rights to any inventions made, or any data recorded by these or any other **[Third Party]** employees in the performance of tasks assigned to **[Non-Navy Collaborator]** as **[Navy Collaborator]** would have had, had these tasks been performed by **[Non-Navy Collaborator]** employees.

SIGNATURES

For **[Non-Navy Collaborator]**:

I, the undersigned, am duly authorized to bind **[Non-Navy Collaborator]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200__.

By:

Title:

For **[Third Party]**:

I, the undersigned, am duly authorized to bind **[Third Party]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200____.

By:

Title:

For the Department of the Navy:

I, the undersigned, on behalf of the Department of the Navy, hereby acknowledge the foregoing agreement between **[Non-Navy Collaborator]** and **[Third Party]**.

Entered into this _____ day of _____ 200____.

By:

Title:

Note: Add the following to Article 1. Definitions and to the "Table of Contents":

"Third Party" means a Non-Navy participant who is not a Collaborator but who works on behalf of a Non-Navy Collaborator and is bound to this Agreement as provided in Appendix C.

Section III - 2b

Appendix C

Third Party Agreement

[Navy Collaborator] Use of Third Party [insert Third Party name]

As provided in paragraph 10.2.3.1 of **[NCRADA-Navy Org-last two digits of FY-serial number]** [hereinafter the CRADA], **[Navy Collaborator]** desires to have **[Third Party]**, a U.S., business entity, located at **[supply address of Third Party]**, perform the following services on **[Navy Collaborator's]** behalf as part of the Cooperative Work listed in Appendix A of the CRADA:

[List Services].

[Navy Collaborator] shall remain fully responsible for the portion of the Cooperative Work to be accomplished by **[Third Party]**, and **[Third Party]** shall not be a Collaborator of the CRADA. **[Third Party]** agrees to perform their Cooperative Work in accordance with the terms of the CRADA.

The **[Third Party]** is aware that the following employee[s] is[are] being assigned to work on tasks assigned to **[Navy Collaborator]** under the CRADA:

[List Third Party Personnel].

The **[Third Party]** has read the terms and conditions of the CRADA. **[Third Party]** and **[Navy Collaborator]** agree that **[Non-Navy Collaborator]** shall have the same rights to any inventions made, or any data recorded by these or any other **[Third Party]** employees in the performance of tasks assigned to **[Navy Collaborator]** as **[Non-Navy Collaborator]** would have had, had these tasks been performed by **[Navy Collaborator]** employees.

For **[Navy Collaborator]**:

I, the undersigned, am duly authorized to bind **[Navy Collaborator]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200_____.

By:

Title:

For **[Third Party]**:

I, the undersigned, am duly authorized to bind **[Third Party]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200____.

By:

Title:

For Non-Navy Collaborator:

I, the undersigned, on behalf of **[Non-Navy Collaborator]**, hereby acknowledge the foregoing agreement between **[Navy Collaborator]** and **[Third Party]**.

Entered into this _____ day of _____ 200____.

By:

Title:

Note: Add the following to Article 1. Definitions and to the "Table of Contents":

"Third Party" means a Non-Navy participant who is not a Collaborator but who works on behalf of a Non-Navy Collaborator and is bound to this Agreement as provided in Appendix C.

Section III - 2c

This appendix is not currently a requirement to be included in your CRADA. If you choose to include it in your Standard CRADA or any of the approved Non-Standard CRADAs, you will need to modify Article 6.2 to reflect that the final report will use that format.

Appendix (XX)

CRADA Final Report

Navy Collaborator:

ORTA:

Name:

Phone:

Fax:

E-Mail:

Non-Navy Collaborator:

CRADA Number:

CRADA Title:

CRADA Objective:

ONR Product Description: (Use Appendix A of ONR Strategic Plan)

Funding Provided by Non-Navy Collaborator to Navy Collaborator:
(Indicate Total Funding to Navy Lab from Non-Navy Collaborator)

CRADA Products

Data that Non-Federal Collaborator Indicated as Proprietary
(Identify Data and Date Submitted; if None, State 'None')

Data Marked Restricted Access Information
(Identify Data and Date or Request; if None, State 'None')

Reports Exchanged:
(Number and Dates; if None, State 'None')

Invention Disclosures Made:
(Who Invented, Title, When; if None, State 'None')

Patent Applications:
(Who, Inventors, Title, When, Registration Number; if None, State 'None')

Copyrights Filed:
(Who, Title of Work, Date Filed; if None, State 'None')

Trademarks:
(Who, Mark Filed, Date Filed; if None, State 'None')

Licenses Granted:
(Title, Date Signed; if None, State 'None')

CRADA Outcomes

Describe the Results of the Collaboration.

Were Objectives Met? How?

What was Demonstrated, or Developed?

Will this Result in a Commercial Product by the Non-Navy Collaborator? If So, Describe.

Will this Result in a Product Used by the Department of Defense? If So, Describe.

What was the Value of the Collaboration to Your Lab and the Navy?

Signatures (Principal Investigators)

For Non-Navy Collaborator

_____ Date _____
(Print Name of Non-Navy Principal Investigator)

For Navy Collaborator

_____ DATE _____
(Print Name of Navy Principal Investigator)

Section III - 3

Multiple Party Non-Standard CRADA - Explanation

A multiple party CRADA is Non-Standard; however, many of the articles of the Standard CRADA, when repeated with the names of the different Collaborators, will make the creation of such an agreement easier. There will be many options to consider due to the different relationships among the Collaborators. No single example of a Multi-Party Collaborator will cover all of the many possibilities.

In drafting a multi-party CRADA, much care must be given in the relationship among all Collaborators when addressing the protection of intellectual property, defining the terms and conditions for licenses and patents, funding liability, and dispute resolution.

There are two basic approaches to addressing the structure of this type of agreement. The first is simple repetition of the articles and individual paragraphs of the Standard CRADA for each different Non-Navy Collaborator giving a new heading for each Non-Navy Collaborator. As an example, consider Article 3.2 **[Non-Navy Collaborator]** Personnel and Facilities, of the Standard CRADA. With two Non-Navy Collaborators, this information could be written as a repeated Article: Article 3.2 for Non-Navy Collaborator A, and a new Article 3.3 with the same information for Non-Navy Collaborator B. If this approach is taken, you must be careful to add new headings and their numerical serialization in the Table of Contents and text of the CRADA.

The second approach to addressing this type of agreement is to modify an Article heading and repeat under this new heading the required paragraphs prefacing each section with the phrase “For **[Non-Navy Collaborator A]**” or “For **[Non-Navy Collaborator B]**” as appropriate.

The following is a Non-Standard CRADA with multiple parties. The draft template is for a single Navy Collaborator, and two U.S. commercial entities. The instructions to the ORTA need to be removed from the final signed document. All “blue text” indicates changes from the Navy Standard CRADA; these need to be in “black” in the final signed CRADA.

The draft multiple party CRADA has also attempted to use language that covers all the Non-Navy Collaborators collectively without specific mention of name. Thus there are many phrases used that read as “the Non-Navy Collaborators”, “a Non-Navy Collaborator”, “each Non-Navy Collaborator”, and “all Non-Navy Collaborators”. The intent of the Articles stands out very clearly when this language is used, almost as an instruction.

New definitions and modified articles have been placed in the multiple party CRADA. The new definition, “Co-Exclusive License”, has been added and used in matters dealing with Intellectual Property. There is an expansion of the definition, “exclusive license” to reflect that multiple Collaborators are involved. A new article on Shared Data, now Article 7.1.1.5, is included in the draft CRADA. By using this Article, many simplifications are made in the subsequent articles dealing with notification of each Collaborator when information is exchanged among the Collaborators.

Legal Review

Legal review is obtained at the laboratory to ensure compliance with the laboratory's mission, statutes, regulations, instructions and executive directives. If the model multiple party CRADA is changed, the modification is noted and a written explanation of its necessity is to be provided by local legal counsel and is included with the Agreement when it is forwarded to ONR.

Signature Process

As with any Navy CRADA, the signature process is in accordance with SECNAVINST 5700.16A dated 7 March 2000. Specifically, the laboratory commanding officer has the authority to enter into a CRADA and sign such Agreements for the DON provided that the requirements of SECNAVINST 5700.16A are met.

Actions After Signature

An electronic copy of the signed Multiple Party Non-Standard CRADA, along with any other supporting documents, should be forwarded to ONR at the following address:

Office of Naval Research
Technology Transfer Program, Code 03TSB
875 North Randolph Street
Arlington, VA 22203-1995
dorothy.vincent@navy.mil

DRAFT

NON-STANDARD

NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

BETWEEN

[NAVY COLLABORATOR]

AND

[NON-NAVY COLLABORATOR]

AND

[NON-NAVY COLLABORATOR]

AGREEMENT TITLE:

AGREEMENT NUMBER: NCRADA-[Navy Org.]-[last two digits of CY]-[serial number]

AGREEMENT ADMINISTRATORS:

[NAVY COLLABORATOR]

Technology Transfer Office: **[insert name, organization code, telephone number, e-mail address]**

Legal Counsel [OPTIONAL]: **[insert name, organization code, telephone number, e-mail address]**

Principal Investigator: **[insert name, organization code, telephone number, e-mail address]**

[ORTA: Repeat the following for each Non-Navy Collaborator]

[NON-NAVY COLLABORATOR]

Preferred Contact: **[insert name, organization code, telephone number, e-mail address]**

Legal Counsel [OPTIONAL]: **[insert name, organization code, telephone number, e-mail address]**

Principal Investigator: **[insert name, organization code, telephone number, e-mail address]**

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Appendix A Statement of Work

Appendix B Confirmatory License Agreement

[Insert other Appendices with title as necessary for this Agreement]

NON-STANDARD

NAVY COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

BETWEEN

[NAVY COLLABORATOR]

AND

[NON-NAVY COLLABORATOR]

AND

[NON-NAVY COLLABORATOR]

PREAMBLE

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), **[Navy Collaborator]**, located at **[supply appropriate address]**, and **[Non-Navy Collaborator]**, whose corporate headquarters are located at **[supply appropriate address]**, enter into this Cooperative Research and Development Agreement (CRADA), which shall be binding upon **all** Collaborators and their assignees according to the clauses and conditions hereof and for the term and duration set forth.

[ORTA: Repeat in the PREAMBLE the name and address for each Non-Navy Collaborator.]

The U.S. Federal Technology Transfer Act of 1986, as amended, provides for making the expertise, capabilities, and technologies of U.S. Federal laboratories accessible to other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons in order to improve the economic, environmental, and social well-being of the United States by stimulating utilization of U.S. federally funded technology developments and/or capabilities.

[Navy Collaborator] has extensive expertise, capabilities, and information in **[technology area]**, and, in accordance with the U.S. Federal Technology Transfer Act, desires to make this expertise and technology available for use in the public and private sectors.

The Non-Navy Collaborators each have the interest, resources, capabilities, and technical expertise to transition the results of Naval research and development for public use.

[ORTA, the previous two paragraphs should be expanded as appropriate to include specific background information.]

NOW THEREFORE, the Collaborators agree as follows:

Article 1. DEFINITIONS

[Note: Specialized definitions required for this Agreement may be added alphabetically within the DEFINITIONS. If specialized definitions are added, they must be included in the Table of Contents.]

As used in this Agreement, the following terms shall have the meanings defined below, which are equally applicable to both the singular and plural forms of nouns or any tense of verbs.

1.1 “Agreement” means this Cooperative Research and Development Agreement (CRADA) with its Appendices.

1.2 “Classified Information” means all Data classified in accordance with the national security laws of the United States.

1.3 “Co-Exclusive License” means the grant by the owner of Intellectual Property of an equal joint Exclusive License to two entities.

1.4 “Collaborator” means the Navy participant or a Non-Navy participant represented and bound by the signatories of this Agreement.

1.5 “Controlled Unclassified Information (CUI)” means Government Data, Information, or materials provided to or resulting from this Agreement that may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation.

1.6 “Cooperative Work” means research, development, engineering, or other tasks performed under this Agreement by **[Navy Collaborator]** or **[Non-Navy Collaborator]** working individually or together, pursuant to the Objectives (Article 2) and the Statement of Work (Appendix A).

1.7 “Data” means recorded information of any kind regardless of the form or method of the recording, including computer software.

1.8 “Effective Date” means the date of the last signature of the Collaborators executing this Agreement.

1.9 “Exclusive License” means the grant by the owner of Intellectual Property of the exclusive right to make, use, or sell a patented invention. As used in this Agreement, “Exclusive License” includes both an Exclusive License granted to any one of the Non-Navy Collaborators subject to a non-exclusive license to the other Non-Navy Collaborator and Co-Exclusive License granted to both Non-Navy Collaborators, unless otherwise specified.

1.10 “Government” means the Government of the United States of America.

1.11 “Government Purpose Rights” means the right of the Government 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. Government Purpose Rights includes competitive procurement, but does not include the right to have or permit others to use Data for commercial purposes.

1.12 “Information” means all data, trade secrets, and commercial and financial information. (Chapter 5 Subsection II of Title 5 USC)

1.13 “Intellectual Property” means the property of ideas, examples of which include, but are not limited to, patents, trademarks, copyrights, and trade secrets.

1.14 “Invention” means any invention or discovery that is or may be patentable or otherwise protected under Title 35, United States Code, or any novel variety of plant that is or may be patentable under the Plant Variety Protection Act. (15 USC 3703(9))

1.15 “Invention Disclosure” means the document identifying and describing to organizational management the Making of an Invention.

1.16 “Made” when used in conjunction with any Invention means the conception or first actual reduction to practice of such Invention. (15 USC 3703(10))

1.17 “Militarily Critical Technologies (MCT)” means those technologies identified in the Militarily Critical Technologies List and under the Export Administration Act of 1979, as amended.

1.18 “Non-Subject Data” means any Data that are not Subject Data.

1.19 “Non-Subject Invention” means any Invention that is not a Subject Invention.

1.20 “Patent Application” means an application for patent protection for an Invention with any domestic or foreign patent-issuing authority.

1.21 “Principal Investigator (PI)” means that person having the responsibility for the performance of the Cooperative Work on behalf of a Collaborator.

1.22 “Proprietary Information” means information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information:

is not known or available from other sources without obligations concerning its confidentiality;

has not been made available by the owners to others without obligation concerning its confidentiality;

is not already available to the Government without obligation concerning its confidentiality; and

has not been developed independently by persons who have had no access to the information. (FAR/DFARS Definition)

1.23 “Restricted Access Information” means Subject Data generated by **[Navy Collaborator]** that would be Proprietary Information if the Information had been obtained from a Non-Federal Collaborator participating in a CRADA (15 USC 3710a). Under 15 USC 3710a(c)(7)(B), the Collaborators mutually may agree to provide appropriate protection to Subject Data generated by **[Navy Collaborator]** (Restricted Access Information) against public dissemination or release under the Freedom of Information Act (FOIA) for a period of up to five (5) years after development of the Information.

1.24 “Subject Data” means that Data first recorded in the performance of the Cooperative Work.

1.25 “Subject Invention” means any Invention Made in the performance of the Cooperative Work.

1.26 “Tangible Property” means personal or real property that can be physically touched or held.

1.27 “Unlimited Rights” means the right to use, modify, reproduce, release, disclose, perform, or display Data or Computer Programs in whole or in part, in any manner and for any purpose whatsoever, and to have or permit others to do so.

Article 2. OBJECTIVES

[Describe the specific, realizable results or benefits to be gained by each Collaborator at the conclusion of this Agreement. State the desired outcome by each Collaborator, including any intentions for commercialization, if appropriate. This Article and the Statement of Work, Appendix A, are the defining articles for the Cooperative Work to be done by the Collaborators.]

Article 3. RESPONSIBILITIES

The Collaborators shall provide personnel, facilities, and equipment necessary for, and shall perform, the Cooperative Work.

3.1 **[Navy Collaborator]** Personnel and Facilities

The Cooperative Work done by **[Navy Collaborator]** will be performed under the program guidance of **[name]**, PI, **[Navy Collaborator]** Code **[supply organizational code identification]**, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within the facilities of **[Navy Collaborator]** or done on behalf of **[Navy Collaborator]** by third parties in support of this Agreement.

[Note to ORTA: If service or support contractor personnel are being used by Navy Collaborator, refer to the Navy CRADA Handbook (Handbook).]

[ORTA: Repeat the paragraph below for each Non-Navy Collaborator.]

[Non-Navy Collaborator] personnel who perform Cooperative Work at **[Navy Collaborator]** facilities will be supervised by the **[Non-Navy Collaborator]** PI.

[ORTA: Article 3.2 is a case of one Navy Collaborator and two Non-Navy Collaborators. Further modification has to be made for a CRADA involving three or more Non-Navy Collaborators.]

3.2 [Non-Navy Collaborator] Personnel and Facilities

For Non-Navy Collaborator (A):

The Cooperative Work done by [Non-Navy Collaborator (A)] will be performed under the program guidance of [name], [Non-Navy Collaborator (A)] PI, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within the facilities of [Non-Navy Collaborator (A)] or done on behalf of [Non-Navy Collaborator (A)] by third parties in support of this Agreement.

[Navy Collaborator] personnel who perform Cooperative Work at [Non-Navy Collaborator (A)] facilities will be supervised by the [Navy Collaborator] PI.

[ORTA: If there are two or more Non-Navy Collaborators, the following paragraph needs to be repeated, as appropriate.]

[Non-Navy Collaborator (B)] personnel who perform Cooperative Work at [Non-Navy Collaborator (A)] facilities will be supervised by the [Non-Navy Collaborator (B)] PI.

For Non-Navy Collaborator (B):

The Cooperative Work done by [Non-Navy Collaborator (B)] will be performed under the program guidance of [name], [Non-Navy Collaborator (B)] PI, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within the facilities of [Non-Navy Collaborator (B)] or done on behalf of [Non-Navy Collaborator (B)] by third parties in support of this Agreement.

[Navy Collaborator] personnel who perform Cooperative Work at [Non-Navy Collaborator (B)] facilities will be supervised by the [Navy Collaborator] PI.

[ORTA: If there are two or more Non-Navy Collaborators, the following paragraph needs to be repeated, as appropriate.]

[Non-Navy Collaborator (A)] personnel who perform Cooperative Work at [Non-Navy Collaborator (B)] facilities will be supervised by the [Non-Navy Collaborator (A)] PI.

3.3 Security Regulations and Directives

Each Collaborator will abide by the safety and security regulations and directives of the host facility in which the Cooperative Work is being performed.

[This is the place to add any special security requirements for personnel doing Cooperative Work at the Collaborators' facilities. If the Cooperative Work covers unclassified Military Critical Technology (MCT), the Non-Government Collaborator must be certified to handle MCT data. MCT data must be controlled in accordance with the International Trade in Arms Regulations (ITAR). MCT certification is established using DD Form 2345, called an "Export-

Controlled DoD Technical Data Agreement". If the Cooperative Work covers classified topics, a security clearance must be put in place for the Non-Navy Collaborator's facilities and personnel using a DoD Contract Security Classification Specification, DD Form 254, completed through [Navy Collaborator]'s Security Office. Refer to the CRADA Handbook.]

Article 4. REPRESENTATIONS AND WARRANTIES

4.1 **[Navy Collaborator]**'s Representations and Warranties

[Navy Collaborator] hereby warrants and represents to [all Non-Navy Collaborators under this Agreement](#) as follows:

4.1.1 **[Navy Collaborator]** is a Federal laboratory of the U.S. Department of the Navy (Navy) as defined by 15 USC 3710a (d)(2)(A) and Department of Defense Instruction 5535.8, dated May 14, 1999.

4.1.2 The performance of the activities specified by this Agreement is consistent with the **[specify the appropriate mission area]** and technology transfer missions of **[Navy Collaborator]** (15 USC 3710a).

4.1.3 The Department of the Navy official executing this Agreement for **[Navy Collaborator]** has the requisite power and authority to enter into this Agreement and to bind **[Navy Collaborator]** to perform according to the terms of this Agreement.

[ORTA: Repeat Article 4.2 in its entirety for each Non-Navy Collaborator and renumber, as appropriate.]

4.2 **[Non-Navy Collaborator]**'s Representations and Warranties

[Non-Navy Collaborator] hereby warrants and represents to **[Navy Collaborator]** and [\[insert names of all other Non-Navy Collaborators\]](#) as follows:

[The following Article 4.2.1 is for a single commercial entity. Choose the appropriate alternatives to Article 4.2.1 from those listed in the Handbook according to the nature of the Non-Navy Collaborator: a university, nonprofit entity, State or local government, directly or indirectly foreign owned, controlled, or influenced (FOCI) entity, multiple Collaborators, and their respective means of organization and/or State laws.]

4.2.1 **[Non-Navy Collaborator]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[Non-Navy Collaborator]**, as of the Effective Date of this Agreement, is a corporation duly organized, validly existing, and in good standing under the laws of **[indicate State or Commonwealth]**.

4.2.2 The official executing this Agreement for **[Non-Navy Collaborator]** has the requisite power and authority to enter into this Agreement and to bind **[Non-Navy Collaborator]** to perform according to the terms of this Agreement.

[The following Article 4.2.3 is for a single commercial entity. Choose the appropriate alternatives to Article 4.2.3 from those listed in the Handbook according to the nature of the organization as private industry, university, or nonprofit entity, State or local government, or FOCl and their respective means of organization and/or State laws.]

4.2.3 The Board of Directors and stockholders of **[Non-Navy Collaborator]** have taken all actions required by law, its Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.

4.2.4 The execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any agreement binding on **[Non-Navy Collaborator]**. Furthermore, the execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any valid order of any court, or any regulatory agency or other body having authority to which **[Non-Navy Collaborator]** is subject.

4.2.5 **[Non-Navy Collaborator]** is not presently subject to debarment or suspension by any agency of the Government. Should **[Non-Navy Collaborator]** be debarred or suspended during the term of this Agreement or thereafter, **[Non-Navy Collaborator]** will notify **[Navy Collaborator]** within thirty (30) days of receipt of a final notice. **[Navy Collaborator]** may then elect to terminate this Agreement and any licenses and options granted under this Agreement.

4.2.6 **[Non-Navy Collaborator]** **[is/is not]** a small business as defined in 15 USC 632 and implementing regulations (13 CFR 121.101 et seq.) of the Administrator of the Small Business Administration.

4.3 Joint Representations

The Collaborators make the following representations.

4.3.1 There is no express or implied warranty as to any research, Invention, or product, whether tangible or intangible. In particular, the Collaborators make no express or implied warranty as to the merchantability or fitness for a particular purpose of any research, Invention, or product, whether tangible or intangible. Likewise, the Collaborators make no express or implied warranty as to any Cooperative Work, Subject Invention, Subject Data, or other product resulting from the Cooperative Work.

4.3.2 The use and dissemination of Information and materials exchanged under this Agreement will be in accordance with all U.S. laws and regulations, including those pertaining to national security and export control. Nothing in this Agreement shall be construed as a license to export Information or to permit any disclosure in violation of law, regulation, or Department of Defense policy. **Each exporting Collaborator is** responsible for obtaining any export licenses that may be required by U.S. Federal law.

Article 5. FUNDING

[IF PAYMENTS ARE TO BE MADE directly from Non-Navy Collaborator to Navy Collaborator, use the following Articles.]

5.1 Payment Schedule

[ORTA: Repeat the following paragraph for each Non-Navy Collaborator who is providing funding to the Navy Collaborator.]

[Non-Navy Collaborator] agrees to pay **[Navy Collaborator]** the following fees/costs in accordance with the payment schedule below:

[Insert amount to be paid, identify the task for which payment is made, the schedule of the tasks, and date of payment or, if preferred, the date and amount of each scheduled payment.]

Checks will be payable to:

[Specify endorsement. Do not specify an individual by name but rather an organization (or job title or function) that has the requisite authority to receive funds for the Navy.]

Each check and its cover correspondence shall refer to Navy CRADA number "NCRADA-**[Navy Collaborator]**-**[last two digits of CY]**-**[lab CRADA sequence number]**."

Checks will be mailed to:

[Specify address, including the name of the authorized recipient, title, and appropriate organizational code.]

5.2 Insufficient and Excess Funds

[Navy Collaborator] may discontinue performance under this Agreement if the funds provided by a **Non-Navy Collaborator** for performance by **[Navy Collaborator]** are insufficient or are not provided as specified in Article 5.1. In the event the **Non-Navy Collaborator** fails to tender the Government the required payment within fifteen (15) days after its respective due date, the **Non-Navy Collaborator** shall be in default under this Agreement for failure to make payments. If the **Non-Navy Collaborator** is in default for this reason, **[Navy Collaborator]** shall notify the **Non-Navy Collaborator**. If the **Non-Navy Collaborator** does not cure the default within fifteen (15) days of mailing date of notice, **[Navy Collaborator]** may proceed to terminate the Agreement in accordance with Article 11.2.2, may cancel any option for an Exclusive License to a Subject Invention, and may terminate any Exclusive License granted pursuant to this Agreement.

Funds that the **Non-Navy Collaborators** paid under Article 5.1 and that **[Navy Collaborator]** has not obligated or expended at the time of completion, expiration, or termination of this Agreement shall be returned to the funding **Non-Navy Collaborators** after **[Navy Collaborator]**'s submission of a final fiscal report to the funding **Non-Navy Collaborators**.

5.3 No New Commitments

[Navy Collaborator] shall make no new commitments concerning this Agreement after receipt of a written termination notice from a **Non-Navy Collaborator** in accordance with Article 11.2 and shall, to the extent practicable, cancel all outstanding commitments by the termination date. Should such cancellation result in any costs incurred by **[Navy Collaborator]**, the **Non-Navy Collaborator** agrees that such costs shall be chargeable against any funding that it provided to **[Navy Collaborator]**.

5.4 Accounting Records

[Navy Collaborator] shall maintain current accounts, records, and other evidence supporting all its expenditures against funding provided by **each Non-Navy Collaborator** under this Agreement and shall retain such records for at least twelve (12) months after the completion, expiration, or termination of this Agreement. **[Navy Collaborator]** shall provide **each funding Non-Navy Collaborator** a financial report within four (4) months after completion, expiration, or termination of this Agreement.

[IF NO PAYMENTS ARE TO BE MADE by Non-Navy Collaborators to Navy Collaborator, or Navy Collaborator is using in-house funding or Government funds already received, use ONLY the following phrase and remove Article Titles 5.1 through 5.4 from the Table of Contents]

Each Collaborator will fund its own efforts.

[Consult the Handbook for the situations in which payments are made only after the completion of a critical milestone in the Cooperative Work or in the case where Navy Collaborator's participation is contingent upon receipt of funds from another Government Organization.]

Article 6. REPORTS AND PUBLICATIONS

6.1 Interim Reports

[ORTA: Article 6.1 paragraphs illustrates one Navy Collaborator and two Non-Navy Collaborators. If more than three Collaborators are involved in the CRADA, the distribution and the number or frequency of reports needs to be specified for each Collaborator.]

[Non-Navy Collaborator (A)] shall submit **[optional: insert number or frequency for each interim written report]** interim written reports to **[Navy Collaborator]** and **[Non-Navy Collaborator (B)]** on the progress of the Cooperative Work as mutually agreed.

[Non-Navy Collaborator (B)] shall submit **[optional: insert number or frequency for each interim written report]** interim written reports to **[Navy Collaborator]** and **[Non-Navy Collaborator (A)]** on the progress of the Cooperative Work as mutually agreed.

[Navy Collaborator] shall submit **[optional: insert number or frequency for each interim written report]** interim written reports to **[Non-Navy Collaborator (A)]** and **[Non-Navy Collaborator (B)]** on the progress of the Cooperative Work as mutually agreed.

6.2 Final Reports

[ORTA: Article 6.2 paragraphs illustrates one Navy Collaborator and two Non-Navy Collaborators. If more than three Collaborators are involved in the CRADA, the distribution and the number or frequency of reports needs to be specified for each Collaborator.]

[Non-Navy Collaborator (A)] shall submit a final report to **[Navy Collaborator]** and **[Non-Navy Collaborator (B)]** within four (4) months of the completion, termination, or expiration of this Agreement that includes the results obtained and a list of all Subject Inventions Made.

[Non-Navy Collaborator (B)] shall submit a final report to [Navy Collaborator] and [Non-Navy Collaborator (A)] within four (4) months of the completion, termination, or expiration of this Agreement that includes the results obtained and a list of all Subject Inventions Made.

[Navy Collaborator] shall submit a final report to [Non-Navy Collaborator (A)] and [Non-Navy Collaborator (B)] within four (4) months of the completion, termination, or expiration of this Agreement that includes the results obtained and a list of all Subject Inventions Made.

6.3 Agreement to Confer Prior to Publication or Public Disclosure

The Collaborators agree to confer and consult prior to any publication or public disclosure of Subject Data to ensure that no Proprietary Information, Restricted Access Information, Government Classified Information, CUI, or MCT Information is released and that patent rights are not compromised. Prior to any such publication or public disclosure of Subject Data, each Collaborator shall be offered a period not less than fifteen (15) days and not to exceed thirty (30) days, unless otherwise mutually agreed in writing by the Collaborators, to review any proposed abstract, publication, presentation, or other document for public disclosure that contains Subject Data. For the purposes of this Article, the term “disclosure” shall include, but not be limited to, submission of any manuscript for peer review prior to publication. It is the responsibility of the Collaborator intending to make public disclosure of Subject Data to notify the other Collaborators of such intent.

If a Collaborator objects to a proposed public disclosure, that Collaborator must so notify the disclosing Collaborator(s) within thirty (30) days of the date of notice of intent to disclose publicly. If no objection is received by the Collaborator intending to make public disclosure, concurrence is assumed. If a Collaborator objects on the grounds that patent rights may be compromised, a Patent Application must be filed by the responsible Collaborator within ninety (90) days of the date of notification of intent to make public disclosure, or by another date mutually agreed to by the Collaborators. If a Collaborator objects to the release of information on the grounds that the Information is Proprietary Information, Restricted Access Information, or Information whose dissemination is restricted by U.S. security laws or regulations, disclosure shall be postponed until the Information no longer meets the definitions of Proprietary Information, Restricted Access Information, or is no longer covered by U.S. security laws or regulations.

6.4 Classified Information

Any presentation that includes Subject Data that are Classified Information or otherwise restricted Data must have prior review and approval by **[Navy Collaborator]** pursuant to the pertinent security laws, regulations, and directives.

Article 7. INTELLECTUAL PROPERTY

7.1 Data

7.1.1 General Provisions Applying to All Data

7.1.1.1 Ownership

Each Collaborator shall have title to all Data generated by that Collaborator.

7.1.1.2 No Implied License

Unless otherwise specifically provided, the Collaborators agree that the exchange of Data of any kind does not confer a license to any Invention claimed in any patent or Patent Application or to the subject matter of any copyright, trademark/service mark, or other form of Intellectual Property protection.

7.1.1.3 Marking of Data

7.1.1.3.1 Data Provided With Less Than Unlimited Rights

Each Collaborator shall mark all Data that it provides with less than Unlimited Rights with a marking that clearly identifies the limited rights.

[ORTA: Article 7.1.1.3.2 is a case of one Navy Collaborator and two Non-Navy Collaborators. Further modification has to be made for a CRADA involving three or more Non-Navy Collaborators.]

7.1.1.3.2 **[Non-Navy Collaborator (A)] Data That are Proprietary Information**

[Non-Navy Collaborator (A)] shall place a proper proprietary marking on each medium used for recording Data that **[Non-Navy Collaborator (A)]** delivers to **[Navy Collaborator]** under this Agreement that **[Non-Navy Collaborator (A)]** asserts is Proprietary Information such that:

(a) For Non-Subject Data that are **[Non-Collaborator (A)]** Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[Non-Navy Collaborator (A)]** - **[Navy Collaborator]** AND **[Non-Navy Collaborator (B)]** MAY USE ONLY FOR PURPOSE OF CRADA NUMBER “NCRADA-**[Navy Collaborator]**-**[last two digits of CY]**-lab CRADA sequence number].

(b) For Subject Data that are **[Non-Navy Collaborator (A)]** Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[Non-Navy Collaborator (A)]** - GOVERNMENT HAS GOVERNMENT PURPOSE RIGHTS AND **[Non-Navy Collaborator (B)]** HAS UNLIMITED RIGHTS UNDER CRADA NUMBER “NCRADA-**[Navy Collaborator]**-**[last two digits of CY]**-lab CRADA sequence number”;

(c) All Collaborators together shall confer to determine if such marking is appropriate, with reference to the Definition of Proprietary Information in Article 1.

[ORTA: Article 7.1.1.3.3 is a case of one Navy Collaborator and two Non-Navy Collaborators. Further modification has to be made for a CRADA involving three or more Non-Navy Collaborators.]

7.1.1.3.3 **[Non-Navy Collaborator (B)] Data That are Proprietary Information**

[Non-Navy Collaborator (B)] shall place a proper proprietary marking on each medium used for recording Data that **[Non-Navy Collaborator (B)]** delivers to **[Navy Collaborator]** under this Agreement that **[Non-Navy Collaborator (B)]** asserts is Proprietary Information such that:

(a) For Non-Subject Data that are **[Non-Navy Collaborator (B)]** Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[Non-Navy Collaborator (B)]** - **[Navy Collaborator]** AND **[Non-Navy Collaborator (A)]** MAY USE ONLY FOR PURPOSE OF CRADA NUMBER “NCRADA-**[Navy Collaborator]**-**[last two digits of CY]**-**lab CRADA sequence number]**”;

(b) For Subject Data that are **[Non-Navy Collaborator (B)]** Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[Non-Navy Collaborator (B)]** - GOVERNMENT HAS GOVERNMENT PURPOSE RIGHTS AND **[Non-Navy Collaborator (A)]** HAS UNLIMITED RIGHTS UNDER CRADA NUMBER “NCRADA - **[Navy Collaborator]**-**[last two digits of CY]**-**lab CRADA sequence number]**”;

(c) All Collaborators together shall confer to determine if such marking is appropriate, with reference to the Definition of Proprietary Information in Article 1.

[ORTA, insert full name of each Non-Navy Collaborator in the statements above.]

7.1.1.3.4 Data That Are Restricted Access Information

A **[Non-Navy Collaborator]** shall request in writing if it wishes Subject Data generated by **[Navy Collaborator]** to be marked as Restricted Access Information. All Collaborators together shall confer to determine if such marking is appropriate, with reference to the Definitions of Restricted Access Information in of Article 1. If the Collaborators mutually agree to the marking then **[Navy Collaborator]** shall mark the Restricted Access Information as:

“RESTRICTED ACCESS INFORMATION - PROTECT IN ACCORDANCE WITH CRADA NUMBER “NCRADA-**[Navy Collaborator]**-**[last two digits of CY]**-**[lab CRADA sequence number]**” UNTIL **[INSERT DATE]**: insert negotiated date not to exceed five (5) years from the generation of a Restricted Access Information document]”.

7.1.1.3.5 Data That are Subject to 35 USC 205

[Navy Collaborator] shall mark Data it provides under this Agreement that disclose one or more Inventions in which the Government owns or may own a right, title or interest, and that are subject to confidentiality under 35 USC 205. Such Data shall be marked:

“**[Navy Collaborator]** DATA PROTECTED FROM RELEASE OR DISCLOSURE UNDER 35 USC 205.”

[Note to ORTA: Insert full name of Navy Collaborator in the above marking.]

7.1.1.3.6 Data That are Classified Information, CUI, MCT, or Otherwise Restricted

Each Collaborator shall mark all Data that are Classified Information, CUI, MCT, or otherwise restricted by U.S. security or export control laws or regulations that it provides under this Agreement.

[Note to ORTA: No standard marking is provided. Marking will vary according to the type of Data provided and should be consistent with Navy Collaborator's marking regulations and policies.]

7.1.1.4 Protection of Data

Except for the rights granted in Article 7.1.2.2, Data shall be protected in accordance with the proper markings of its owner and as provided by, at a minimum, the requirements of 15 USC 3710a. Proprietary Information will be protected only if it is properly marked as such. Information provided in intangible form that is Proprietary Information must be designated Proprietary Information at the time it is delivered, followed within fifteen (15) days by a writing summarizing the exact Information to be protected. The Collaborator receiving Information in an intangible form that is designated as Proprietary Information shall be responsible for protecting the Information as Proprietary Information during the fifteen (15) day notification period. After the fifteen (15) day period, if no written summary has been received, the receiving Collaborator need not continue to protect the Information received in intangible form.

Restricted Access Information shall be protected from public dissemination for up to five (5) years, as mutually agreed.

Classified Information, CUI, MCT, or otherwise restricted Information shall be protected in accordance with the security laws of the United States.

7.1.1.5 Shared Data

For performance of the Cooperative Work of this Agreement, Data supplied by any Collaborator to another Collaborator may be disclosed to all Collaborators of the Agreement without notification to the supplying Collaborator. All Collaborators may discuss among each other any shared Data.

7.1.1.6 Release of Data Under the Freedom of Information Act

Data in the possession of **[Navy Collaborator]** that are not marked CUI, Proprietary Information of a **Non-Navy Collaborator** or Restricted Access Information must be released by **[Navy Collaborator]** where such release is required pursuant to a request under the Freedom of Information Act (FOIA) (5 USC 552). **[Navy Collaborator]** shall protect Data that are properly marked CUI, Proprietary Information of a **Non-Navy Collaborator** or Restricted Access Information from release under the FOIA for as long as the marked Data meet the definition of CUI, Proprietary Information or Restricted Access Information.

Except as provided in Article 7.1.1.5, prior to release of any **Non-Navy Collaborator** Data by **[Navy Collaborator]**, **[Navy Collaborator]** shall promptly notify the **Non-Navy Collaborator** of any request for Data of the **Non-Navy Collaborator** regardless of whether the requested Data are marked Proprietary Information.

7.1.2 Subject Data

7.1.2.1 Delivery of Requested Subject Data

Each Collaborator shall have the right to review and receive delivery of all Subject Data generated by the other Collaborators. Requested Subject Data shall be delivered to the requesting Collaborator within fifteen (15) days of the request.

7.1.2.2 Rights in Subject Data

Except as represented in Article 4.4.2, the Collaborators shall have Unlimited Rights in all Subject Data that are not Proprietary Information or Restricted Access Information.

[ORTA: Article 7.1.2.2 is a case of one Navy Collaborator and two Non-Navy Collaborators. Further modification has to be made for a CRADA involving three or more Non-Navy Collaborators.]

Notwithstanding 15 USC 3710a, **[Non-Navy Collaborator (A)]** grants Government Purpose Rights in any **[Non-Navy Collaborator (A)]** Subject Data furnished by Non-Navy Collaborators to **[Navy Collaborator]** under this Agreement that are properly marked as Proprietary Information.

Notwithstanding 15 USC 3710a, **[Non-Navy Collaborator (B)]** grants Government Purpose Rights in any **[Non-Navy Collaborator (B)]** Subject Data furnished by Non-Navy Collaborators to **[Navy Collaborator]** under this Agreement that are properly marked as Proprietary Information.

The Government has Government Purpose Rights in Subject Data that are Restricted Access Information.

7.1.3 Rights in Non-Subject Data

The Collaborators shall have Unlimited Rights in any Non-Subject Data delivered under this Agreement that are not Proprietary Information.

Each Collaborator has a limited right to use, reproduce, and disclose to its employees for use in support of the Cooperative Work any Non-Subject Data that are marked as Proprietary Information in accordance with Article 7.1.1.3 and are provided by the Non-Navy Collaborators under this Agreement. Such Proprietary Information can be used only for the purpose of performing the Cooperative Work unless consent to other use or disclosure is obtained from the Collaborator providing the marking.

The Non-Navy Collaborators shall have a limited right to use, reproduce, or disclose Non-Subject Data that may describe one or more Inventions in which the Government owns or may own a right, title or interest, if such Non-Subject Data are provided by **[Navy Collaborator]** under this Agreement. In accordance with 35 USC 205, such Non-Subject Data are to be held in confidence. Such Non-Subject Data shall be properly marked by **[Navy Collaborator]** and the limited rights of each Non-Navy Collaborator shall be defined by a separate non-disclosure agreement.

7.2 Copyrights

7.2.1 Copyright by [Non-Navy Collaborators](#)

[Each Non-Navy Collaborator](#) may copyright *its own* works of authorship prepared pursuant to this Agreement if eligible for copyright protection under Title 17 USC.

7.2.2 Copyright License to the Government

[Each Non-Navy Collaborator](#) grants to the Government [and all other Non-Navy Collaborators of this Agreement](#), a nonexclusive, irrevocable, paid-up license in copyrighted works of authorship, including software (17 USC 106) prepared pursuant to this Agreement for any purpose, consistent with the rights in Data described in Article 7.1.

7.2.3 Copyright Statement

[A Non-Navy Collaborator](#) shall include the following statement on any text, drawing, mask work or other work of authorship, that may be copyrighted under 17 USC, that is created [by it](#) in the performance of this Agreement:

“The U.S. Government [and \[specify all relevant Non-Navy Collaborators by full name\]](#) have a copyright license in this work pursuant to a Cooperative Research and Development Agreement with the **[Navy Collaborator]**.

7.3 Trademarks and Service Marks

7.3.1 Ownership of Trademarks and Service Marks

The Collaborator first establishing a trademark or service mark for goods or services with which the mark is used shall be considered the owner of the mark.

7.3.2 Obligation of Employees to Report Trademarks and Service Marks

Employees of [all](#) Collaborators shall report the adoption of a trademark or service mark associated with the Cooperative Work to their employer within thirty (30) days of the first use of the mark. Use includes internal use of any product or service of the Cooperative Work.

7.3.3 Obligation of Collaborators to Notify Each Other

Each Collaborator shall notify the other Collaborators [within thirty \(30\) days](#) of their employee’s report of the first use of a trademark or service mark.

7.3.4 Responsibility for Filing an Application for Trademark or Service Mark

The Collaborator owning a trademark or service mark shall establish the use of the mark in intra- and interstate commerce and shall be responsible for filing all applications for trademark or service mark registration as appropriate.

7.3.5 License to Use Trademark or Service Mark

The Collaborator owning the trademark or service mark as defined in Article 7.3.1, shall grant a paid-up, irrevocable, nonexclusive license to the other Collaborators for use of the trademark or service mark on the goods or services for which the mark is intended to be used.

7.4 Subject Inventions

7.4.1 Obligation to Report Subject Inventions

7.4.1.1 Collaborators' Instructions to Employees

Each Collaborator shall instruct its employees to submit an Invention Disclosure to that Collaborator for all innovations, solutions to technical problems, or unique increases to the general body of knowledge resulting from the Cooperative Work. For the purposes of this Article, these innovations, solutions, and increases to knowledge shall be deemed Inventions.

7.4.1.2 Timely Invention Disclosure by Inventors

Within ninety (90) days of Making an Invention resulting from the Cooperative Work, unless a shorter time period is required by circumstances, the inventor(s) shall submit an Invention Disclosure to their employer.

In the case of an Invention Made jointly by inventors from **more than one** Collaborator, the inventors shall submit an Invention Disclosure with their respective employer.

7.4.1.3 Obligation to Provide Invention Disclosures to the Other Collaborators

Each Collaborator shall provide the other Collaborators with a copy of each Invention Disclosure reporting a Subject Invention within sixty (60) days of receiving the Invention Disclosure from its inventor(s).

7.4.2 Determination of Subject Inventions

The Collaborators shall review each Invention Disclosure resulting from the Cooperative Work and shall confer and consult to determine whether an Invention Disclosure represents a Subject Invention.

7.4.3 Title to and Ownership of Subject Inventions

Each Collaborator shall be entitled to own the Subject Inventions of its employees. Each Collaborator shall cooperate with the other Collaborators to obtain inventor signatures on Patent Applications, assignments or other documents required to secure Intellectual Property protection. For any Invention Made jointly by employees of **more than one** Collaborator, each **inventing** Collaborator shall have ownership of the Subject Invention in the form of an undivided interest.

7.4.4 Filing of Patent Applications

7.4.4.1 Filing of Patent Applications on Solely Made Inventions

Each Collaborator has primary responsibility for filing Patent Applications on the Subject Inventions of its employee(s).

Notwithstanding such primary responsibility, by mutual agreement, the Collaborators may identify which Collaborator shall file a Patent Application on any Subject Invention.

7.4.4.2 Filing of Patent Applications on Jointly Made Inventions

In the case of an Invention jointly Made by employees of **more than one** Collaborator, the **inventing** Collaborators shall confer and agree as to which Collaborator will file any Patent Application. Officers of the non-filing Collaborators shall cooperate with the filing Collaborator to obtain signatures on documents that are needed to file a Patent Application.

7.4.4.3 Preserving Intellectual Property Rights

The Collaborator responsible for filing of a Patent Application on any Subject Invention shall file such Patent Application at least sixty (60) days prior to any bar date or one year from the date the Invention Disclosure was received, whichever comes first. If no Patent Application is filed within the specified time period, **any** other Collaborator may assume control of filing the Patent Application and take title to the Subject Invention on ten (10) days written notification. **Any** Collaborators that relinquished the responsibility to file shall retain a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Subject Invention practiced throughout the world by or on its behalf.

7.4.4.4 Filing Deadlines

The Collaborator responsible for filing any Patent Application for a Subject Invention shall notify the other Collaborators of all filing deadlines for prosecution of any Patent Application and maintenance of any patents on the Subject Invention. Notwithstanding the primary responsibility defined in Article 7.4.4.1, sixty (60) days prior to any filing deadline, the Collaborators shall confer to determine if the filing Collaborator intends to respond to the filing deadline. The non-filing Collaborators will be permitted to take action if the filing Collaborator declines.

7.4.4.5 Copies and Inspection

7.4.4.5.1 Copies of Prosecution Papers

Each Collaborator filing a Patent Application on a Subject Invention shall provide the other Collaborators with a copy of any communication relating to prosecution of said Patent Application within thirty (30) days of receipt of such communication.

7.4.4.5.2 Access to Patent Application File and Right to Make Copies

Upon written request, the filing Collaborator shall give the other Collaborators an Associate Power of Attorney, with authorization to access the Patent Application, make copies, and, in the event the filing Collaborator fails or declines to take action, do all that is necessary to secure Intellectual Property protection for the Subject Invention.

7.4.4.6 Rights of Inventors if the Collaborators Decline to File a Patent

Application

In the event all Collaborators decline to file a Patent Application on a Subject Invention, the Government will renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

In the event all Collaborators decline to file a Patent Application on a Subject Invention, a Non-Navy Collaborator may, at its sole discretion, renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

7.4.5 Nonexclusive License to Subject Inventions

7.4.5.1 Nonexclusive License Grant

Each Collaborator grants to the other Collaborators a nonexclusive, irrevocable, paid-up license to practice a Subject Invention Made by employees of the granting Collaborator or have the Subject Invention practiced throughout the world by or on behalf of the other Collaborators. No nonexclusive license granted under this Agreement shall permit licensee to grant sublicenses.

7.4.5.2 Confirmatory Nonexclusive License Agreement

Each Collaborator has the obligation to provide a Confirmatory License Agreement (Appendix B) to the other Collaborators for each nonexclusive license within ninety (90) days of the date of filing.

7.4.6 Option for Exclusive License to Subject Inventions

[ORTA: This paragraph will need to be changed if multiple “fields of use” are used.]

[Navy Collaborator] gives Non-Navy Collaborators each the option of acquiring an Exclusive License for the field of use of **[state field of use]** in the Government’s rights in any Subject Invention Made in whole or in part by a **[Navy Collaborator]** employee subject to the nonexclusive license granted under Article 7.4.5.1 to each Non-Navy Collaborator separately. For the Non-Navy Collaborators who exercise this option the licenses shall be Co-Exclusive. These licenses shall be for reasonable consideration.

In order for a Non-Navy Collaborator to exercise this option, the Non-Navy Collaborator must notify **[Navy Collaborator]** in writing within one hundred and eighty (180) days of the filing of a Patent Application. Should a Non-Navy Collaborator decide to exercise this option, the Non-Navy Collaborator shall notify all other Non-Navy Collaborators of its decision to do so, simultaneously with the notification to **[Navy Collaborator]**. Unless another time period is mutually agreed upon between the Collaborators, the Non-Navy Collaborator must execute an Exclusive License to the Subject Invention within one hundred and eighty (180) days of election to exercise the option, or the Invention shall be made available for licensing by the public in accordance with 37 CFR Part 404.

Any **Exclusive License** granted by the Government in a Subject Invention is subject to the statutorily required reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have that Subject Invention practiced throughout the world by or on behalf of the Government (15 USC 3710a).

7.4.7 Limitation on Assignment of Licenses Granted Under This Agreement

No license granted to a **Non-Navy Collaborator** under this Agreement shall be assigned, licensed or otherwise disposed of except to the successor in interest of that part of **that Non-Navy Collaborator's** business to which such license pertains.

[The following Article 7.4.8 is to be used for a Non-Navy Collaborator that is “not” directly or indirectly foreign owned, controlled, or influenced (FOCI). For FOCI organizations identified as such in Article 4.2.1, use the appropriate alternative to Article 7.4.8 listed in the CRADA Handbook under “MODIFICATIONS FOR CRADAs WITH A FOCI ENTITY”.]

7.4.8 Termination of License Granted and Cancellation of Exclusive License Option to Subject Inventions

7.4.8.1 Exclusive Licenses and Exclusive License Option

[ORTA: Repeat the following paragraphs for each Non-Navy Collaborator]

[Navy Collaborator] may terminate any **Exclusive License** or cancel any option for an **Exclusive License** to a Subject Invention granted **[Non-Navy Collaborator]** under this Agreement in the event that:

(a) **[Non-Navy Collaborator]** is in default for failure to make payment as agreed in Article 5; or

(b) The Agreement is terminated unilaterally by **[Non-Navy Collaborator]**; or

(c) **[Non-Navy Collaborator]** fails to perform according to the Statement of Work (Appendix A); or

(d) **[Non-Navy Collaborator]** becomes a foreign owned, controlled, or influenced (FOCI) organization that does not qualify under the requirements of Executive Order 12591, Section 4(a)

7.4.8.2 Nonexclusive Licenses

[ORTA: Repeat the following paragraphs for each Non-Navy Collaborator.]

[Navy Collaborator] shall terminate any nonexclusive license to a Subject Invention granted to **[Non-Navy Collaborator]** under this Agreement if **[Non-Navy Collaborator]** becomes a FOCI organization that does not qualify under the requirements of Executive Order 12591, Section 4(a).

7.5 Non-Subject Inventions

7.5.1 Ownership of Non-Subject Inventions

Each Collaborator owns its Non-Subject Inventions.

7.5.2 Rights Under Other Agreements

[ORTA: Repeat the following paragraphs for each Non-Navy Collaborator.]

Nothing in this Agreement is intended to change the rights in Intellectual Property acquired by the Collaborators in any other contract or agreement between **[Non-Navy Collaborator]** and the Government.

7.5.3 No License to Non-Subject Inventions

This Agreement does not grant any Collaborator a license, express or implied, to any Non-Subject Invention.

[Each paragraph in the following Article 7.5.4 is optional.]

7.5.4 Preexisting Non-Subject Inventions Pertinent to the Cooperative Work

Non-Subject Inventions Made prior to the Effective Date and pertinent to the Cooperative Work that are specifically identified as property of **[Navy Collaborator]** include but are not limited to the following:

[List Invention Title, inventor name(s), patent number, or Navy case number if an Invention disclosure, or Patent Application Serial Number, and date of issue (for patents only).]

[ORTA: Repeat the following paragraphs for each Non-Navy Collaborator]

Non-Subject Inventions Made prior to the Effective Date and pertinent to the Cooperative Work that are specifically identified as property of **[Non-Navy Collaborator]** include but are not limited to the following:

[List Invention Title, inventor name(s), patent number, or attorney's docket number if an Invention disclosure or Patent Application Serial Number, and date of issue (for patents only).]

7.6 Research License

Each Collaborator shall allow the other Collaborators to practice any of its Non-Subject Inventions for the purpose of performing the Cooperative Work.

No license, express or implied, for commercial application(s) is granted to any Collaborator in Non-Subject Inventions by performing the Cooperative Work.

For commercial application(s) of Non-Subject Inventions, a license must be obtained from the owner.

Article 8. TANGIBLE PROPERTY

8.1 Title to Preexisting Tangible Property

Each Collaborator shall retain title to all Tangible Property to which it had title prior to the Effective Date of this Agreement.

8.2 Tangible Property Purchased by Collaborators to Perform the Cooperative Work

Each Collaborator shall retain title to all Tangible Property that it purchases during the period of this Agreement. A **Non-Navy Collaborator** cannot take title to any Government Tangible Property under this Agreement. Collaborator consumables to be used in the Cooperative Work of this Agreement are the property of the purchasing Collaborator until consumed.

8.3 Title to Developed Tangible Property

All Tangible Property developed under this Agreement with all components purchased by one Collaborator shall be the property of that Collaborator. Tangible Property having any component purchased by **[Navy Collaborator]** shall be the property of the Government, unless such Tangible Property can reasonably be separated without damage to the other individual components. After this Agreement is completed, expired, or terminated, if separation of components can be made without damage, the Collaborators may, by mutual agreement, separate the Tangible Property into its components and the separated components shall remain the property of the Collaborator that purchased them.

8.4 Tangible Property Operational and Disposition Costs

During the period of and upon completion, expiration, or termination of this Agreement, each Collaborator shall be responsible for all costs of maintenance, removal, storage, repair, disposal, and shipping of all Tangible Property to which it has title.

8.5 Disposal of Tangible Property

Disposal of Tangible Property shall be in accordance with applicable U.S. Federal, State, and local property disposal laws, environmental laws, and regulations.

Article 9. LIABILITY

9.1 Extent of Government Liability

The Government shall be solely liable for the negligent or wrongful acts of its officers and employees to the extent provided for in the Federal Tort Claims Act (28 USC 2671 et. seq.) and in other applicable laws and regulations of the United States that specifically waive sovereign immunity. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the United States.

9.2 Extent of **Non-Navy Collaborators** Liability

[ORTA: Repeat the following paragraph for each Non-Navy Collaborator.]

[Non-Navy Collaborator] is solely responsible for its actions and the actions of those acting for **[Non-Navy Collaborator]** in the performance of this Agreement and for any damages that may arise from any suit, action, or claim, and for any costs from or incidental to any suit, action, or claim, including but not limited to settlement and defense costs. Further, **[Non-Navy Collaborator]** agrees that in any suit, action or claim brought by anyone not a party to this Agreement based on actions of **[Non-Navy Collaborator]**, **[Non-Navy Collaborator]** shall not pursue any actions to enter the Government as a party in such suit, action or claim unless the Government has some liability under the Federal Tort Claims Act.

9.3 *Force Majeure*

No Collaborator shall be liable for the consequences of any *force majeure* that (1) is beyond its reasonable control; (2) is not caused by the fault or negligence of such Collaborator; (3) causes such Collaborator to be unable to perform its obligations under this Agreement; and (4) cannot be overcome by the exercise of due diligence. In the event of the occurrence of a *force majeure*, the Collaborator unable to perform shall promptly notify the other Collaborators. The remaining Collaborators may choose to continue performance without the non-performing Collaborator or they may choose to suspend performance only for such period of time as is necessary for the non-performing Collaborator to overcome the result(s) of the *force majeure* and shall use their best efforts to resume performance as quickly as possible.

Article 10. GENERAL PROVISIONS

10.1 Characteristics of the Agreement

10.1.1 Entire Agreement

This Agreement constitutes the entire agreement between the Collaborators concerning the Cooperative Work and supersedes any prior understanding or written or oral agreement relative to the Cooperative Work.

10.1.2 Severability

The illegality or invalidity of any Article of this Agreement shall not impair, affect, or invalidate any other Article of this Agreement.

10.1.3 Interpretation of Headings

Headings of the Articles of this Agreement are for convenience of reference only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

10.2 Agreements Between Collaborators

10.2.1 Governing Laws

United States Federal Laws shall govern this Agreement for all purposes.

10.2.2 Independent Parties/Entities

The relationship of the Collaborators to this Agreement is that of independent parties and not as agents of each other, partners, or participants in a joint venture. Each Collaborator shall maintain sole and exclusive control over its personnel and operations.

10.2.3 Assignment/Subcontracting

[Note to ORTAs: Refer to the Handbook for a discussion on issues related to the use of contractors during the execution of a CRADA.]

10.2.3.1 No Collaborator may allow third parties to perform any part of the Cooperative Work under this Agreement without express written consent of the other Collaborators. If consent is obtained, the Collaborator requesting such consent shall remain fully responsible for the portion of the Cooperative Work to be accomplished under a third-party agreement, and the third party is not a Collaborator of this Agreement. Any third-party agreement to perform a portion of the Cooperative Work shall contain terms consistent with this Agreement.

10.2.3.2 This Agreement shall not be assigned or otherwise transferred by any Collaborator without the prior written consent of the other Collaborators, except to the successor of that part of a Non-Navy Collaborator's business to which this Agreement pertains.

10.2.3.3 If any Non-Navy Collaborator or its successor or assignee is a U.S. company, and becomes, during the term of this Agreement or thereafter, directly or indirectly owned, controlled, or influenced by a foreign company or government (FOCI), then that Non-Navy Collaborator or its successor or assignee shall promptly notify [Navy Collaborator] to that effect.

10.2.4 Disputes

10.2.4.1 Settlement and Resolution

[Navy Collaborator] and each Non-Navy Collaborator agree to use reasonable efforts to reach a fair settlement of any dispute. If such efforts are unsuccessful, remaining issues in dispute will be referred to the signatories of this Agreement or their successors for resolution. If a dispute continues, the remaining issues may be submitted to the Chief of Naval Research (CNR), or the CNR designee, for resolution. This Agreement does not prevent any Collaborator from pursuing disputes in a U.S. Federal court of competent jurisdiction. No Collaborator will pursue litigation in a U.S. Federal court until after the CNR, or the CNR designee, decides the dispute, or until sixty (60) days after the dispute was first submitted to the CNR, or the CNR designee, whichever comes first.

10.2.4.2 Continuation of Cooperative Work

If payments or installment payments are to be made as stated under Article 5, [Navy Collaborator] will not start or continue cooperative work until payments or installment payments are received.

10.2.5 Waivers

None of the provisions of this Agreement shall be considered waived by any Collaborator unless such waiver is given in writing to the other Collaborators, signed by the

executing official of this Agreement or the official's successor having the authority to bind the Collaborator making the waiver. The failure of any Collaborator to insist upon strict performance of any of the terms and conditions herein, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any right of any Collaborator under this Agreement.

10.2.6 Use of Name or Endorsements

Except as provided for in Article 7.2.3, a Non-Navy Collaborator shall not use the name of [Navy Collaborator] or any other Government entity on any product or service that is directly or indirectly related to either this Agreement or any patent license or assignment associated with this Agreement without the prior approval of [Navy Collaborator]. By entering into this Agreement, [Navy Collaborator] does not directly or indirectly endorse any product or service provided, or to be provided, by any Non-Navy Collaborator, or their successors, assignees, or licensees. A Non-Navy Collaborator shall not in any way imply that the Department of the Navy endorses any such product or service.

10.3 Environment, Safety, and Health

Each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste in its custody during the course of this Agreement. At the conclusion of this Agreement, each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste still in its possession. Each Collaborator shall obtain at its own expense all necessary permits and licenses as required by U.S. Federal, State, and local law and shall conduct such handling, control, and disposition in a lawful and environmentally responsible manner. Each Collaborator is responsible for all required environmental, safety, and health compliance, notice, and monitoring related to its facility in accordance with U.S. Federal, State, and local law and regulations. Collaborators shall abide by the environmental, safety, and health directives of the host facility in which the Cooperative Work is being performed, and any U.S. Federal, State, or local laws and regulations pertaining to environment, safety, and health that are applicable to the host facility.

10.4 U.S. Competitiveness

All Non-Navy Collaborators agree that any product, process, or service using Intellectual Property arising from the performance of this Agreement shall be manufactured substantially in the United States.

10.5 Public Release of This Agreement

This Agreement, without funding information (Article 5) and Appendices, may be released to the public.

Article 11. MODIFICATIONS AND NOTICES

11.1 Amendments

If a Collaborator wishes to modify this Agreement, the Collaborators shall confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by all executing officials of the Collaborators of this Agreement or their successors.

11.2 Termination

11.2.1 Termination by Mutual Consent

The Collaborators may elect to terminate this Agreement at any time by mutual consent of all Collaborators. Such termination shall not be effective until a written termination agreement is signed by the executing officials of all Collaborators of this Agreement or their successors.

11.2.2 Unilateral Termination

[Navy Collaborator] may unilaterally terminate this entire Agreement at any time by giving the other Collaborators written notice signed by its executing official of this Agreement or **[his/her]** successor, not less than thirty (30) days prior to the desired termination date. A Non-Navy Collaborator may unilaterally terminate its involvement in this Agreement at any time by giving the other Collaborators written notice signed by its executing official of this Agreement or **[his/her]** successor, not less than thirty (30) days prior to the desired termination date. If any Non-Navy Collaborator unilaterally terminates its involvement in this Agreement, any option for an Exclusive License to a Subject Invention and any Exclusive License to a Subject Invention granted by or pursuant to this Agreement shall simultaneously be terminated.

If the remaining Non-Navy Collaborators and **[Navy Collaborator]** also wish to terminate this Agreement, they may do so in accordance with Article 11.2.1. If the remaining Non-Navy Collaborators and **[Navy Collaborator]** wish to continue this Agreement, an amendment in accordance with Article 11.1 will be written to modify the Agreement to accommodate this change and the withdrawal of the exiting Non-Navy Collaborator(s). This amendment will be signed after the termination date of the unilaterally terminating Collaborator(s).

11.3 Notices

All notices pertaining to or required by Articles of this Agreement, except those pertaining solely to the prosecution of any patent, trademark, or service mark, shall be in writing and shall be signed by an authorized representative of the Technology Transfer Office for **[Navy Collaborator]** or the preferred contact for each of the Non-Navy Collaborators, and all such notices shall be delivered by hand, sent by courier with proper registration, or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

If to **[Navy Collaborator]**:

[Use the official Navy Collaborator mailing address for the Technology Transfer Office.]

If to **[Non-Navy Collaborator]**:

[Specify the mailing address for the preferred contact for each Non-Navy Collaborator.]

A Collaborator shall notify the other Collaborators of a change of address in the manner set forth above.

Notices pertaining solely to the prosecution of any patent, trademark, or service mark related to this Agreement shall be in writing and shall be signed by and sent to the Collaborator's legal counsel for Intellectual Property. Legal counsel for Intellectual Property for each Collaborator

shall send a copy of any such notice to the Technology Transfer Office for **[Navy Collaborator]**. If **any** Collaborator fails to identify such counsel upon request, then such notices shall be sent to the points of contact specified above.

Article 12. SURVIVING PROVISIONS

The Articles covering Definitions, Representations and Warranties, Funding, Reports and Publications, Intellectual Property, Tangible Property, Liability, General Provisions, Modifications and Notices, and Surviving Provisions shall survive the completion, termination, or expiration of this Agreement.

Article 13. DURATION

This Agreement expires **[specify a time no greater than three (3) years]** after its Effective Date, unless otherwise extended in writing according to the provisions of Article 11.

Article 14. SIGNATURES

[ORTA: Repeat signature block for each Non-Navy Collaborator.]

For **[Non-Navy Collaborator]**:

I, the undersigned, am duly authorized to bind **[Non-Navy Collaborator]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200 ,

By:

Title:

For the Department of the Navy:

I, the undersigned, by 15 U.S. Code 3710a and Navy regulations, am duly authorized to bind the U.S. Navy to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200 ,

By:

Title:

Navy Organization:

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APPENDIX A
STATEMENT OF WORK

Between

[Navy Collaborator]

And

[Non-Navy Collaborator]

And

[Non-Navy Collaborator]

The Collaborators agree to perform the following tasks:

[Navy Collaborator] will be responsible for the following tasks (list as applicable):

- 1.
- 2.
- 3.

[ORTA: List tasks for each Non-Navy Collaborator.]

[Non-Navy Collaborator] will be responsible for the following tasks (list as applicable):

- 1.
- 2.
- 3.

[Navy Collaborator] and **[Non-Navy Collaborator(s)]** will be responsible for the following joint tasks (if applicable):

- 1.
- 2.
- 3.

APPENDIX B

<p style="text-align: center;">CONFIRMATORY LICENSE AGREEMENT</p>	<p>1. APPLICATION FOR (Title of Invention)</p>
<p>2. INVENTOR(S) AND AFFILIATION</p>	
<p>3. PATENT APPLICATION SERIAL NO.</p>	<p>4. PATENT APPLICATION FILING DATE</p>
<p>5. NAVY ACTIVITY (Name, address, point of contact)</p>	<p>6. NON-NAVY ACTIVITY (Name, address, point of contact)</p>
<p>7. CRADA AGREEMENT NO.</p>	<p>8. DATE OF THIS AGREEMENT</p>
<p>9. The Invention identified above is a "Subject Invention" under Article 7 Intellectual Property included with the CRADA identified in Box 7 between the Department of the Navy and Non-Navy Activity identified in Box 6.</p> <p><i>This document is confirmatory of the nonexclusive, irrevocable, paid-up license to practice the identified Subject Invention or have that Subject Invention practiced throughout the world by or on behalf of the receiving party, and of all other rights acquired by the receiving party by the referenced clause.</i></p> <p><i>This license is granted to: (Select one)</i></p> <p>_____ the Government</p> <p>_____ Non-Navy Activity identified in Box 6</p> <p><i>Under this CRADA in the identified Invention, Patent Application and any resulting patent.</i></p> <p><i>The licensee is hereby granted an irrevocable power to inspect and make copies of the above-identified Patent Application.</i></p> <p>_____ ACTIVITY NAME OF LICENSOR</p> <p>_____ SIGNATURE</p> <p>_____ NAME (Typed or Printed)</p> <p>_____ TITLE</p> <p>_____ BUSINESS TELEPHONE</p>	

Section III - 4

Clinical Trials Non-Standard CRADA - Explanation

The Clinical Trials Non-Standard CRADA has considerable additions to the Navy Standard CRADA. In particular there are added definitions to Article 1:

- Adverse Drug Experience
- Clinical Brochure
- Independent Ethics Committee
- Institutional Review Board
- Protected Health Information
- Protocol
- Serious Adverse Drug Experiences
- Source Document
- Study Device
- Study Drug
- Study Patient
- Unanticipated Adverse Drug Effect
- Unexpected Adverse Drug Experiences

Other additional Articles include the following:

- Article 3.1.1 Records
 - 3.1.1.1 Complete and Accurate Records
 - 3.1.1.2 Retention of Records
 - 3.1.1.3 Communication of Study Results to Study Patients
- 3.1.2 Audits
 - 3.1.2.1 **[Non-Navy Collaborator]** Auditing and Source Document Verification
 - 3.1.2.2 Inspections and Audits
- 3.1.3 Protected Health Information

Article 6.5 Adverse Drug Experiences, Annual Reports, Other Investigational New Drug Data

Other additional appendices that may be needed depending on the Agreement:

- Appendix C Non-Navy Collaborator Use of Third Party/Navy Collaborator Use of Third Party
- Appendix D Budget Data
- Appendix E Privacy of Protected Health Information

Other additional language:

See paragraphs 3-5 of the PREAMBLE

NON-STANDARD

NAVY CLINICAL TRIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

BETWEEN

[NAVY COLLABORATOR]

AND

[NON-NAVY COLLABORATOR]

AGREEMENT TITLE:

AGREEMENT NUMBER: NCRADA - [Navy Org] - [last two digits of CY] - [serial number]

AGREEMENT ADMINISTRATORS:

[NAVY COLLABORATOR]

Technology Transfer Office: [insert name, organization code, telephone number, e-mail address]

Legal Counsel [OPTIONAL]: [insert name, organization code, telephone number, e-mail address]

Principal Investigator: [insert name, organization code, telephone number, e-mail address]

[NON-NAVY COLLABORATOR]

Preferred Contact: [insert name, telephone number, e-mail address]

Legal Counsel [OPTIONAL]: [insert name, telephone number, e-mail address]

Principal Investigator: [insert name, telephone number, e-mail address]

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NON-STANDARD

NAVY CLINICAL TRIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

BETWEEN

[NAVY COLLABORATOR]

AND

[NON-NAVY COLLABORATOR]

PREAMBLE

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), the **[NAVY COLLABORATOR]**, located at **[supply appropriate address]**, and **[NON-NAVY COLLABORATOR]**, whose corporate headquarters are located at **[supply appropriate address]** enter into this Cooperative Research and Development Agreement (CRADA), which shall be binding upon the Collaborators and their assignees according to the clauses and conditions hereof and for the term and duration set forth.

The U.S. Federal Technology Transfer Act of 1986, as amended, provides for making the expertise, capabilities, and technologies of U.S. Federal laboratories accessible to other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons in order to improve the economic, environmental, and social well-being of the United States by stimulating utilization of U.S. federally funded technology developments and/or capabilities.

[NON-NAVY COLLABORATOR] conducts business in the research and development, manufacture, and marketing of therapeutic pharmaceutical products and has the interest, resources, capabilities, and technical expertise to transition the results of Naval research and development for public use.

[NAVY COLLABORATOR] has extensive expertise, capabilities, and information in the conduct of clinical research within investigational pharmaceutical products and requirements, processes, and related procedures, and, in accordance with the U.S. Federal Technology Transfer Act, desires to make this expertise and technology available for use in the public and private sectors.

The purpose of this Agreement is to provide for the conduct of certain research in the United States as set forth in **[NON-NAVY COLLABORATOR]**'s Protocol **[cite Protocol number]**, attached hereto as Appendix E, and all future amendments thereto, all of which are incorporated herein by reference and made part of this Agreement, and entitled [*title of clinical Protocol.*"]

[ORTA, the previous two paragraphs should be expanded as appropriate to include specific background information.]

NOW THEREFORE, the Collaborators agree as follows:

[Note: Specialized definitions required for this Agreement may be added alphabetically within the DEFINITIONS. If specialized definitions are added, they must be included in the Table of Contents.]

Article 1. DEFINITIONS

As used in this Agreement, the following terms shall have the meanings defined below, which are equally applicable to both the singular and plural forms of nouns or any tense of verbs.

1.1 “Adverse Drug Experience” means an adverse event as defined under 21 CFR Section 310.305, Records and Reports Concerning Adverse Drug Experience, and other applicable Federal Regulations.

1.2 “Agreement” means this Cooperative Research and Development Agreement (CRADA) with its Appendices, amendments, and exhibits, if any.

1.3 “Classified Information” means all Data classified in accordance with the national security laws of the United States.

1.4 “Clinical Brochure” means a document containing all the relevant information about a drug, including animal screening, preclinical toxicology, and detailed pharmaceutical data. Also included, if available, is a summary of current knowledge about pharmacology, mechanism of action, and a full description of the clinical toxicities.

1.5 “Collaborator” means the Navy participant or the Non-Navy participant represented and bound by the signatories of this Agreement.

1.6 “Controlled Unclassified Information (CUI)” means Government Data, Information, or materials provided to or resulting from this Agreement that may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation.

1.7 “Cooperative Work” means research, development, engineering, or other tasks performed under this Agreement by **[NAVY COLLABORATOR]** or **[NON-NAVY COLLABORATOR]** working individually or together, pursuant to the Objectives (Article 2), the Statement of Work (Appendix A) and the Protocol (Appendix E).

1.8 “Data” means recorded information of any kind regardless of the form or method of the recording, including computer software.

1.9 “Effective Date” means the date of the last signature of the Collaborators executing this Agreement.

1.10 “Exclusive License” means the grant by the owner of Intellectual Property of the exclusive right to make, use, or sell a patented invention.

1.11 “FDA” means the Food and Drug Administration, U.S. Department of Health and Human Services.

1.12 “Government” means the Government of the United States of America.

1.13 “Government Purpose Rights” means the right of the Government 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. Government Purpose Rights includes competitive procurement, but does not include the right to have or permit others to use Data for commercial purposes.

1.14 “Independent Ethics Committee (IEC)” means an independent body (a review board or a committee, institutional, regional, national or supranational), consisting of medical/scientific professionals and non-medical/non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the Protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting the informed consent of Study Patients.

1.15 “Information” means all data, trade secrets, and commercial and financial information. (Chapter 5 Subsection II of Title 5 USC).

1.16 “Institutional Review Board (IRB)” means an independent body consisting of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a clinical trial, by, among other things, reviewing, approving, and providing continuous review of Protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the Study Patients.

1.17 “Intellectual Property” means the property of ideas, examples of which include, but are not limited to, patents, trademarks, copyrights, and trade secrets.

1.18 “Invention” means any invention or discovery that is or may be patentable or otherwise protected under Title 35, United States Code, or any novel variety of plant that is or may be patentable under the Plant Variety Protection Act. (15 USC 3703(9))

1.19 “Invention Disclosure” means the document identifying and describing to organizational management the Making of an Invention.

1.20 “Made” when used in conjunction with any Invention means the conception or first actual reduction to practice of such Invention. (15 USC 3703(10))

1.21 “Militarily Critical Technologies (MCT)” means those technologies identified in the Militarily Critical Technologies List and under the Export Administration Act of 1979, as amended.

1.22 “Non-Subject Data” means any Data that are not Subject Data.

1.23 “Non-Subject Invention” means any Invention that is not a Subject Invention.

1.24 “Patent Application” means an application for patent protection for an Invention with any domestic or foreign patent-issuing authority.

1.25 “Principal Investigator (PI)” means that person having the responsibility for the performance of the Cooperative Work on behalf of a Collaborator, pursuant to 21 CFR Section 312.

1.26 “Proprietary Information” means information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information:

is not known or available from other sources without obligations concerning its confidentiality;

has not been made available by the owners to others without obligation concerning its confidentiality;

is not already available to the Government without obligation concerning its confidentiality; and

has not been developed independently by persons who have had no access to the information. (FAR/DFARS Definition)

1.27 “Protected Health Information” means information regarding diagnosis, history or treatment that allows unique identification of an individual (“Protected Health Information”), as that term is defined by 45 CFR Section 164.501.

1.28 “Protocol” means **[NON-NAVY COLLABORATOR]**’s Protocol **[cite Protocol number and give title of the Protocol]** incorporated into this Agreement by reference and attached in Appendix E.

1.29 “Restricted Access Information” means Subject Data generated by **[NAVY COLLABORATOR]** that would be Proprietary Information if the Information had been obtained from a Non-Federal Collaborator participating in a CRADA (15 USC 3710a). Under 15 USC 3710a(c)(7)(B), the Collaborators mutually may agree to provide appropriate protection to Subject Data generated by **[NAVY COLLABORATOR]** (Restricted Access Information) against public dissemination or release under the Freedom of Information Act (FOIA) for a period of up to five (5) years after development of the Information.

1.30 “Serious Adverse Drug Experiences”, is defined by 21 CFR 312.32(a) as any Adverse Drug Experience occurring at any dose that results in any of the following outcomes: death, life-threatening Adverse Drug Experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

1.31 “Source Document” means original documents, data and records as defined in the Guideline for Good Clinical Practice, Section 1.52, published in the Federal Register, May 9, 1997 (62 FR 25692).

1.32 “Study Device” means any physical item contrived for a specific purpose used in medical treatment that is designed, made, and/or adapted to assist a person to perform a particular task.

1.33 “Study Drug” means clinical doses of **[insert name of drug]** or any of the other pharmaceutical compounds used in the performance of the Cooperative Work.

1.34 “Study Patient” means an individual who participates in the Cooperative Work, either as a recipient of the Study Drug(s) or as a control.

1.35 “Subject Data” means that Data first recorded in the performance of the Cooperative Work.

1.36 “Subject Invention” means any Invention Made in the performance of the Cooperative Work.

1.37 “Tangible Property” means personal or real property that can be physically touched or held.

1.38 “Third Party” means a Non-Navy participant who is not a Collaborator but who works on behalf of a Collaborator and is bound to this Agreement as provided in Appendix C.

1.39 “Unanticipated Adverse Device Effect”, is defined by 21 CFR 812.3(s) as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

1.40 “Unexpected Adverse Drug Experiences”, is defined by 21 CFR 312.32(a) as any Adverse Drug Experience, the specificity or severity of which is not consistent with the current investigator brochure or product labeling, as available.

1.41 “Unlimited Rights” means the right to use, modify, reproduce, release, disclose, perform, or display Data or Computer Programs in whole or in part, in any manner and for any purpose whatsoever, and to have or permit others to do so.

Article 2. OBJECTIVES

[Describe the specific, realizable results or benefits to be gained by each Collaborator at the conclusion of this Agreement. State the desired outcome by each Collaborator, including any intentions for commercialization, if appropriate. This Article, the Statement of Work and Appendix E, are the defining articles for the Cooperative Work to be done by the Collaborators.]

Article 3. RESPONSIBILITIES

The Collaborators shall provide personnel, facilities, and equipment necessary for, and shall perform, the Cooperative Work.

3.1 **[NAVY COLLABORATOR]** Personnel and Facilities

The Cooperative Work done by **[NAVY COLLABORATOR]** will be performed under the program guidance of **[name]**, PI, **[NAVY COLLABORATOR]** Code **[supply organizational code identification]**, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within the facilities of **[NAVY COLLABORATOR]** or done on behalf of **[NAVY COLLABORATOR]** by Third Parties in support of this Agreement. **[NAVY COLLABORATOR]** PI shall supervise and direct any and all other **[NAVY COLLABORATOR]** or Third Party personnel assigned to the Cooperative Work.

[Note to ORTA: If service or support contractor personnel are being used by Navy Collaborator, refer to the Navy CRADA Handbook (Handbook).]

3.1.1 Records

3.1.1.1 Complete and Accurate Records

[NAVY COLLABORATOR] PI shall maintain complete and accurate records of the status and progress of the Cooperative Work and shall provide such information to **[NON-NAVY COLLABORATOR]** upon request. **[NAVY COLLABORATOR]** PI shall promptly complete, and allow **[NON-NAVY COLLABORATOR]** access to, **[NON-NAVY COLLABORATOR]**-supplied case report forms for all Study Patients. Upon **[NON-NAVY COLLABORATOR]**'s request, **[NAVY COLLABORATOR]** PI shall correct any case report form errors and/or omissions by promptly submitting **[NON-NAVY COLLABORATOR]**-supplied forms for resolving document discrepancies. At all times **[NON-NAVY COLLABORATOR]** shall remain the sole owner of the case report forms and document discrepancy resolution forms.

3.1.1.2 Retention of Records

[NAVY COLLABORATOR] shall retain and preserve one (1) copy only of all Subject Data for the longer of: (i) two (2) years after the last marketing authorization for the Study Drug has been approved or **[NON-NAVY COLLABORATOR]** has discontinued its research with respect to such drug; or (ii) such longer period as required by applicable global regulatory requirements. At the end of such period, **[NAVY COLLABORATOR]** PI shall notify **[NON-NAVY COLLABORATOR]** of their intent to destroy all such material. **[NON-NAVY COLLABORATOR]** shall have thirty (30) days to respond to **[NAVY COLLABORATOR]**'s notice, and **[NON-NAVY COLLABORATOR]** shall have a further opportunity to retain such materials at **[NON-NAVY COLLABORATOR]**'s expense.

3.1.1.3 Communication of Study Results to Study Patients

[NAVY COLLABORATOR]'s PI is encouraged to disclose a summary of the results of the Cooperative Work to Study Patients in accordance with the publications provisions of this Agreement.

3.1.2 Audits

3.1.2.1 **[NON-NAVY COLLABORATOR]** Auditing and Source Document Verification

[NAVY COLLABORATOR] PI shall cooperate fully and make all necessary documents (including but not limited to Subject Data/Source Documents) and personnel available to **[NON-NAVY COLLABORATOR]** to permit **[NON-NAVY COLLABORATOR]** to examine, analyze, verify, monitor and audit the Cooperative Work as necessary. **[NAVY COLLABORATOR]**'s PI has been informed of the purpose of Source Document verification and fully understands this will be part of the **[NON-NAVY COLLABORATOR]**'s monitoring process. **[NAVY COLLABORATOR]**'s PI understands which Subject Data and items must be included in the Source Document and for which Subject Data and/or items the case report form will stand as the Source Document. **[NON-NAVY COLLABORATOR]** shall have the right to monitor and audit the trial, including access to records and personnel involved in the conduct of the Cooperative Work.

[NAVY COLLABORATOR]'s PI and the personnel assisting the **[NAVY COLLABORATOR]**'s PI shall also participate as necessary in follow-up monitoring visits and audits to ensure compliance with all applicable laws and regulations.

3.1.2.2 Inspections and Audits

[NAVY COLLABORATOR] and/or its PI shall make all necessary Subject Data and Source Documents available to a regulatory authority or other governmental authorities, or the IRB/IEC for inspection or auditing. In the event **[NAVY COLLABORATOR]** and/or its PI receives notice that it or the IRB/IEC shall be the subject of an inspection, investigation or audit by a regulatory authority, or other governmental authorities, **[NAVY COLLABORATOR]** and/or its PI receiving such notice shall immediately notify **[NON-NAVY COLLABORATOR]**. In the event neither **[NAVY COLLABORATOR]** nor its PI does not receive prior notice of said inspection, investigation or audit, **[NAVY COLLABORATOR]** or its PI shall notify **[NON-NAVY COLLABORATOR]** as soon as possible after receiving notice of said inspection, investigation or audit. **[NAVY COLLABORATOR]** and/or its PI shall provide **[NON-NAVY COLLABORATOR]** with copies of any documents received from or provided to a regulatory authority or other governmental authorities.

3.1.3 Protected Health Information

[NAVY COLLABORATOR] shall comply with all laws and regulations, including without limitation the regulations of the Health Insurance Portability and Accountability Act (HIPAA), governing the privacy and security of health information. To the extent required by applicable law, **[NAVY COLLABORATOR]** will also require its PI to comply with applicable law.

[NAVY COLLABORATOR] shall treat all Protected Health Information as protected from disclosure to the extent required by applicable law. **[NAVY COLLABORATOR]** and **[NON-NAVY COLLABORATOR]** will implement and maintain such privacy and security safeguards as are necessary to ensure that Protected Health Information is adequately protected from unauthorized access.

[NAVY COLLABORATOR]'s PI shall ensure that all consents and authorizations required by applicable law are obtained from Study Patient, such that **[NON-NAVY COLLABORATOR]** and each of **[NON-NAVY COLLABORATOR]**'s contractors are permitted to access the Protected Health Information of any Study Patient for the purpose of fulfilling any obligation under this Agreement or for the purpose of complying with any requirement under applicable law or any other legal or regulatory requirement to which **[NON-NAVY COLLABORATOR]** is subject.

In the event that this Agreement or any practices which could be or are employed in exercising rights under the Agreement are inconsistent with or do not satisfy the requirements of applicable law relating to the privacy of Protected Health Information, the Collaborators shall take any action necessary to bring performance under this Agreement into compliance with such applicable law, including amending or modifying this Agreement.

3.1.4 **[NON-NAVY COLLABORATOR]**'s personnel who perform Cooperative Work at **[NAVY COLLABORATOR]** facilities will be supervised by the **[NON-NAVY COLLABORATOR]** PI.

3.2 **[NON-NAVY COLLABORATOR]** Personnel and Facilities

The Cooperative Work done by **[NON-NAVY COLLABORATOR]** will be performed under the program guidance of **[name]**, **[NON-NAVY COLLABORATOR]** PI, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within the facilities of **[NON-NAVY COLLABORATOR]** or done on behalf of **[NON-NAVY COLLABORATOR]** by Third Parties in support of this Agreement.

[NAVY COLLABORATOR] personnel who perform Cooperative Work at **[NON-NAVY COLLABORATOR]** facilities will be supervised by the **[NAVY COLLABORATOR]** PI.

3.3 Security Regulations and Directives

Each Collaborator will abide by the safety and security regulations and directives of the host facility in which the Cooperative Work is being performed.

[This is the place to add any special security requirements for personnel doing Cooperative Work at the Collaborators' facilities. If the Cooperative Work covers unclassified Military Critical Technology (MCT), the Non-Government Collaborator must be certified to handle MCT data. MCT data must be controlled in accordance with the International Trade in Arms Regulations (ITAR). MCT certification is established using DD Form 2345, called an "Export-Controlled DoD Technical Data Agreement". If the Cooperative Work covers classified topics, a security clearance must be put in place for the Non-Navy Collaborator's facilities and personnel using a DoD Contract Security Classification Specification, DD Form 254, completed through [Navy Collaborator]'s Security Office. Refer to the CRADA Handbook.]

Article 4. REPRESENTATIONS AND WARRANTIES

4.1 **[NAVY COLLABORATOR]**'s Representations and Warranties

[NAVY COLLABORATOR] hereby warrants and represents to **[NON-NAVY COLLABORATOR]** as follows:

4.1.1 **[NAVY COLLABORATOR]** is a Federal laboratory of the U.S. Department of the Navy (Navy) as defined by 15 USC 3710a (d)(2)(A) and Department of Defense Instruction 5535.8, dated May 14, 1999.

4.1.2 The performance of the activities specified by this Agreement is consistent with the **[specify the appropriate mission area]** and technology transfer missions of **[NAVY COLLABORATOR]** (15 USC 3710a).

4.1.3 The Department of the Navy official executing this Agreement for **[NAVY COLLABORATOR]** has the requisite power and authority to enter into this Agreement and to bind **[NAVY COLLABORATOR]** to perform according to the terms of this Agreement.

4.1.4 **[NAVY COLLABORATOR]** and any employees, agents or contractors assigned to this Cooperative Work, including its PI, are not presently subject to debarment or suspension by any agency of the Government. Should **[NAVY COLLABORATOR]** or any employees, agents, or contractors assigned to this Cooperative Work be debarred or suspended during the term of this Agreement or thereafter, **[NAVY COLLABORATOR]** will notify **[NON-NAVY COLLABORATOR]** within thirty (30) days of receipt of a final notice. **[NON-NAVY COLLABORATOR]** may then elect to terminate this Agreement.

4.2 **[NON-NAVY COLLABORATOR]**'s Representations and Warranties

[NON-NAVY COLLABORATOR] hereby warrants and represents to **[NAVY COLLABORATOR]** as follows:

[The following Article 4.2.1 is for a single commercial entity. Choose the appropriate alternatives to Article 4.2.1 from those listed in the Handbook according to the nature of the Non-Navy Collaborator: a university, nonprofit entity, State or local government, directly or indirectly foreign owned, controlled, or influenced (FOCI) entity, multiple Collaborators, and their respective means of organization and/or State laws.]

4.2.1 **[NON-NAVY COLLABORATOR]** is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)). **[NON-NAVY COLLABORATOR]**, as of the Effective Date of this Agreement, is a corporation duly organized, validly existing, and in good standing under the laws of **[indicate State or Commonwealth]**.

4.2.2 The official executing this Agreement for **[NON-NAVY COLLABORATOR]** has the requisite power and authority to enter into this Agreement and to bind **[NON-NAVY COLLABORATOR]** to perform according to the terms of this Agreement.

[The following Article 4.2.3 is for a single commercial entity. Choose the appropriate alternatives to Article 4.2.3 from those listed in the Handbook according to the nature of the organization as private industry, university, or nonprofit entity, State or local government, or FOCI and their respective means of organization and/or State laws.]

4.2.3 The Board of Directors and stockholders of **[NON-NAVY COLLABORATOR]** have taken all actions required by law, its Certificate or Articles of Incorporation, its bylaws or otherwise, to authorize the execution and delivery of agreements, such as this Agreement.

4.2.4 The execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any agreement binding on **[NON-NAVY COLLABORATOR]**. Furthermore, the execution and delivery of this Agreement does not contravene any material provision of, or constitute a material default under, any valid order of any court, or any regulatory agency or other body having authority to which **[NON-NAVY COLLABORATOR]** is subject.

4.2.5 **[NON-NAVY COLLABORATOR]** is not presently subject to debarment or suspension by any agency of the Government. Should **[NON-NAVY COLLABORATOR]** be debarred or suspended during the term of this Agreement or thereafter, **[NON-NAVY COLLABORATOR]** will notify **[NAVY COLLABORATOR]** within thirty (30) days of receipt of a final notice. **[NAVY COLLABORATOR]** may then elect to terminate this Agreement and any licenses and options granted under this Agreement.

4.2.6 **[NON-NAVY COLLABORATOR]** **[is/is not]** a small business as defined in 15 USC 632 and implementing regulations (13 CFR 121.101 et seq.) of the Administrator of the Small Business Administration.

4.3 Joint Representations

The Collaborators make the following representations.

4.3.1 Except as expressly provided herein, there is no express or implied warranty as to any research, Invention, or product, whether tangible or intangible. In particular, except as expressly provided herein, the Collaborators make no express or implied warranty as to the merchantability or fitness for a particular purpose of any research, Invention, or product, whether tangible or intangible. **[NAVY COLLABORATOR]** acknowledges that the Subject Data is intended to be submitted to the FDA by **[NON-NAVY COLLABORATOR]**; **[NAVY COLLABORATOR]** shall provide Subject Data to **[NON-NAVY COLLABORATOR]** in a manner adequate to fulfill this particular purpose. Likewise, the Collaborators make no express or implied warranty as to any Cooperative Work, Subject Invention, Subject Data, or other product resulting from the Cooperative Work.

4.3.2 The use and dissemination of Information and materials exchanged under this Agreement will be in accordance with all U.S. laws and regulations, including those pertaining to national security and export control. Nothing in this Agreement shall be construed as a license to export Information or to permit any disclosure in violation of law, regulation, or Department of Defense policy. The exporting Collaborator is responsible for obtaining any export licenses that may be required by U.S. Federal law.

Article 5. FUNDING

[IF PAYMENTS ARE TO BE MADE directly from Non-Navy Collaborator to Navy Collaborator, use the following Articles.]

5.1 Payment Schedule

[NON-NAVY COLLABORATOR] agrees to pay **[NAVY COLLABORATOR]** the following fees/costs in accordance with the payment schedule provided in the budget document attached as Appendix D and incorporated herein by reference.

[Insert amount to be paid, identify the task for which payment is made, the schedule of the tasks, and date of payment or, if preferred, the date and amount of each scheduled payment.]

Checks will be payable to:

[Specify endorsement. Do not specify an individual by name but rather an organization (or job title or function) that has the requisite authority to receive funds for the Navy.]

Each check and its cover correspondence shall refer to Navy CRADA number "NCRADA-**[NAVY COLLABORATOR]**-**[last two digits of CY]**-**[lab CRADA sequence number]**."

Checks will be mailed to:

[Specify address, including the name of the authorized recipient, title, and appropriate organizational code.]

5.2 Insufficient and Excess Funds

[NAVY COLLABORATOR] may discontinue performance under this Agreement if the funds provided by **[NON-NAVY COLLABORATOR]** for performance by **[NAVY COLLABORATOR]** are insufficient or are not provided as specified in Article 5.1. In the event **[NON-NAVY COLLABORATOR]** fails to tender the Government the required payment within fifteen (15) days after its respective due date, **[NON-NAVY COLLABORATOR]** shall be in default under this Agreement for failure to make payments. If **[NON-NAVY COLLABORATOR]** is in default for this reason, **[NAVY COLLABORATOR]** shall notify **[NON-NAVY COLLABORATOR]**. If **[NON-NAVY COLLABORATOR]** does not cure the default within fifteen (15) days of receipt of notice, **[NAVY COLLABORATOR]** may proceed to terminate the Agreement in accordance with Article 11.2.2, may cancel any option for an Exclusive License to a Subject Invention, and may terminate any Exclusive License granted pursuant to this Agreement.

Funds that **[NON-NAVY COLLABORATOR]** paid under Article 5.1 and that **[NAVY COLLABORATOR]** has not obligated or expended at the time of completion, expiration, or termination of this Agreement shall be returned to **[NON-NAVY COLLABORATOR]** after **[NAVY COLLABORATOR]**'s submission of a final fiscal report to **[NON-NAVY COLLABORATOR]**.

5.3 No New Commitments

[NAVY COLLABORATOR] shall make no new commitments concerning this Agreement after receipt of a written termination notice from **[NON-NAVY COLLABORATOR]** in accordance with Article 11.2 and shall, to the extent practicable, cancel all outstanding commitments by the termination date. Should such cancellation result in any costs incurred by **[NAVY COLLABORATOR]**, **[NON-NAVY COLLABORATOR]** agrees that such costs shall be chargeable against any funding that it provided to **[NAVY COLLABORATOR]**.

5.4 Accounting Records

[NAVY COLLABORATOR] shall maintain current accounts, records, and other evidence supporting all its expenditures against funding provided by **[NON-NAVY COLLABORATOR]** under this Agreement and shall retain such records for at least twelve (12) months after the completion, expiration, or termination of this Agreement. **[NAVY COLLABORATOR]** shall provide **[NON-NAVY COLLABORATOR]** a financial report within four (4) months after completion, expiration, or termination of this Agreement.

[IF NO PAYMENTS ARE TO BE MADE by Non-Navy Collaborator to Navy Collaborator, or Navy Collaborator is using in-house funding or Government funds already received, use ONLY the following phrase and remove Article Titles 5.1 through 5.4 from the Table of Contents]

Each Collaborator will fund its own efforts.

[Consult the Handbook for the situations in which payments are made only after the completion of a critical milestone in the Cooperative Work or in the case where Navy Collaborator's participation is contingent upon receipt of funds from another Government Organization.]

Article 6. REPORTS AND PUBLICATIONS

6.1 Interim Reports

The Collaborators shall submit **[optional: insert number or frequency for each interim written report]** interim written reports to each other on the progress of the Cooperative Work as mutually agreed.

6.2 Final Reports

The Collaborators shall submit to each other a final report within four (4) months of the completion, termination, or expiration of this Agreement that includes the results obtained and a list of all Subject Inventions Made.

6.3 Agreement to Confer Prior to Publication or Public Disclosure

The Collaborators agree to confer and consult prior to any publication or public disclosure of Subject Data to ensure that no Proprietary Information, Restricted Access Information, Government Classified Information, CUI, or MCT Information is released and that patent rights are not compromised. Prior to any such publication or public disclosure of Subject Data, each Collaborator shall be offered a period not less than fifteen (15) days and not to exceed thirty (30) days, unless otherwise mutually agreed in writing by the Collaborators, to review any proposed abstract, publication, presentation, or other document for public disclosure that contains Subject Data. For the purposes of this Article, the term "disclosure" shall include, but not be limited to, submission of any manuscript for peer review prior to publication. It is the responsibility of the Collaborator intending to make public disclosure of Subject Data to notify the other Collaborator of such intent.

If a Collaborator objects to a proposed public disclosure, that Collaborator must so notify the other Collaborator within thirty (30) days of the date of notice of intent to disclose publicly.

If no objection is received by the Collaborator intending to make public disclosure, concurrence is assumed. If a Collaborator objects on the grounds that patent rights may be compromised, a Patent Application must be filed by the responsible Collaborator within ninety (90) days of the date of notification of intent to make public disclosure, or by another date mutually agreed to by the Collaborators. If a Collaborator objects to the release of Information on the grounds that the Information is Proprietary Information, Restricted Access Information, or Information whose dissemination is restricted by U.S. security laws or regulations, the disclosure shall be postponed until: (a) the Information no longer meets the definitions of Proprietary Information, Restricted Access Information, or is no longer covered by U.S. security laws or regulations; or (b) the Proprietary Information, Restricted Access Information, or Information whose dissemination is restricted by U.S. security laws or regulations is removed from the disclosure.

6.4 Classified Information

Any presentation that includes Subject Data that are Classified Information or otherwise restricted Data must have prior review and approval by **[NAVY COLLABORATOR]** pursuant to the pertinent security laws, regulations, and directives.

6.5 Adverse Drug Experiences

All Adverse Drug Experiences that are either Serious or Unexpected shall be reported to the **[NON-NAVY COLLABORATOR]** within twenty four (24) hours of the occurrence. Details about all such Adverse Drug Experiences shall be communicated to the **[NON-NAVY COLLABORATOR]** in writing via Form 7443. A sample **[NON-NAVY COLLABORATOR]** Form 7443 is attached to this Agreement as Appendix F. This form is to be faxed to the **[NON-NAVY COLLABORATOR]** at **[telephone number]**. For **[NON-NAVY COLLABORATOR]** reporting purposes, **[NON-NAVY COLLABORATOR]** considers any report of pregnancy, cancer or overdose as Serious and shall be notified of the event on Form 7443 by fax at the number listed above. Any report of a death or life-threatening event shall be communicated to the **[NON-NAVY COLLABORATOR]** by telephone even before a Form 7443 is prepared. **[NON-NAVY COLLABORATOR]**'s **[name of preferred contact]** is the primary contact for Serious Adverse Drug Experiences discussions.

Article 7. INTELLECTUAL PROPERTY

7.1 Data

7.1.1 General Provisions Applying to All Data

7.1.1.1 Ownership

Each Collaborator shall have title to all Data generated by that Collaborator. Notwithstanding the foregoing, for all purposes, **[NAVY COLLABORATOR]** shall treat Subject Data it generates as Restricted Access Information.

7.1.1.2 No Implied License

Unless otherwise specifically provided, the Collaborators agree that the exchange of Data of any kind does not confer a license to any Invention claimed in any patent or Patent Application or to the subject matter of any copyright, trademark/service mark, or other form of Intellectual Property protection.

7.1.1.3 Marking of Data

7.1.1.3.1 Data Provided With Less Than Unlimited Rights

Each Collaborator shall mark all Data that it provides with less than Unlimited Rights with a marking that clearly identifies the limited rights.

7.1.1.3.2 Data that are Proprietary Information or Restricted Access Information

[NON-NAVY COLLABORATOR] shall place a proper proprietary marking on each medium used for recording Data that **[NON-NAVY COLLABORATOR]** delivers to **[NAVY COLLABORATOR]** under this Agreement that **[NON-NAVY COLLABORATOR]** asserts is Proprietary Information. **[NON-NAVY COLLABORATOR]** hereby requests that it wishes Subject Data generated by **[NAVY COLLABORATOR]** to be marked as Restricted Access Information, with the duration of the protection thus conferred to be five (5) years from its creation. The Collaborators together shall confer to determine if such marking is appropriate, with reference to the Definitions of Article 1. If the Collaborators mutually agree to the marking then:

(a) For Non-Subject Data that are Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[NON-NAVY COLLABORATOR]** - **[NAVY COLLABORATOR]** MAY USE ONLY FOR PURPOSE OF CRADA NUMBER “NCRADA-**[NAVY COLLABORATOR]** - [last two digits of CY]-[lab CRADA sequence number]”;

(b) For Subject Data that are Proprietary Information, the marking shall read:

“PROPRIETARY INFORMATION OF **[NON-NAVY COLLABORATOR]** - GOVERNMENT HAS GOVERNMENT PURPOSE RIGHTS UNDER CRADA NUMBER “NCRADA-**[NAVY COLLABORATOR]** - [last two digits of CY]-[lab CRADA sequence number]”;

(c) For Data that are Restricted Access Information, the marking shall read:

“RESTRICTED ACCESS INFORMATION - PROTECT IN ACCORDANCE WITH CRADA NUMBER “NCRADA-**[NAVY COLLABORATOR]** - [last two digits of CY]-[lab CRADA sequence number]” UNTIL [Insert Date: Insert negotiated date not to exceed five (5) years from the generation of a Restricted Access Information document]”.

[ORTA, insert full name of Non-Navy Collaborator in the statements above and see Handbook regarding date for Restricted Access Information.]

7.1.1.3.3 Data That are Subject to 35 USC 205

[NAVY COLLABORATOR] shall mark Data it provides under this Agreement that disclose one or more Inventions in which the Government owns or may own a right, title or interest, and that are subject to confidentiality under 35 USC 205. Such Data shall be marked:

“**[NAVY COLLABORATOR]** DATA PROTECTED FROM RELEASE OR DISCLOSURE UNDER 35 USC 205.”

[Note to ORTA: Insert full name of Navy Collaborator in the above marking.]

7.1.1.3.4 Data That are Classified Information, CUI, MCT, or Otherwise Restricted

Each Collaborator shall mark all Data that are Classified Information, CUI, MCT, or otherwise restricted by U.S. security or export control laws or regulations that it provides under this Agreement.

[Note to ORTA: No standard marking is provided. Marking will vary according to the type of Data provided and should be consistent with Navy Collaborator's marking regulations and policies.]

7.1.1.4 Protection of Data

Except for the rights granted in Article 7.1.2.2, Data shall be protected in accordance with the proper markings of its owner and as provided by, at a minimum, the requirements of 15 USC 3710a. Proprietary Information will be protected only if it is properly marked as such. Information provided in intangible form that is Proprietary Information must be designated Proprietary Information at the time it is delivered, followed within fifteen (15) days by a writing summarizing the exact Information to be protected. The Collaborator receiving Information in an intangible form that is designated as Proprietary Information shall be responsible for protecting the Information as Proprietary Information during the fifteen (15) day notification period. After the fifteen (15) day period, if no written summary has been received, the receiving Collaborator need not continue to protect the Information received in intangible form.

Restricted Access Information shall be protected from public dissemination for five (5) years.

Classified Information, CUI, MCT, or otherwise restricted Information shall be protected in accordance with the security laws of the United States.

7.1.1.5 Release of Data Under the Freedom of Information Act

Data in the possession of **[NAVY COLLABORATOR]** that are not marked CUI, Proprietary Information of **[NON-NAVY COLLABORATOR]** or Restricted Access Information must be released by **[NAVY COLLABORATOR]** where such release is required pursuant to a request under the Freedom of Information Act (FOIA) (5 USC 552). **[NAVY COLLABORATOR]** shall protect Data that are properly marked CUI, Proprietary Information of **[NON-NAVY COLLABORATOR]** or Restricted Access Information from release under the FOIA for as long as the marked Data meet the definition of CUI, Proprietary Information or Restricted Access Information. Prior to release of any such Data, **[NAVY COLLABORATOR]** shall promptly notify **[NON-NAVY COLLABORATOR]** of any request for Data of **[NON-NAVY COLLABORATOR]** regardless of whether the requested Data are marked Proprietary Information.

7.1.1.6 FDA Documents

If this Agreement involves a product regulated by the FDA, then **[NON-NAVY COLLABORATOR]** or **[NAVY COLLABORATOR]**, as appropriate, may file any required documentation with the FDA. In addition, the Collaborators authorize and consent to allow each other or its contractor or agent access to, or to cross-reference, any documents filed with the FDA related to the product.

7.1.2 Subject Data

7.1.2.1 Delivery of Requested Subject Data

Each Collaborator shall have the right to review and receive delivery of all Subject Data generated by the other Collaborator. Requested Subject Data shall be delivered to the requesting Collaborator within fifteen (15) days of the request.

7.1.2.2 Rights in Subject Data

Except as represented in Article 4.3.2, the Collaborators shall have Unlimited Rights in all Subject Data that are not Proprietary Information or Restricted Access Information. Notwithstanding 15 USC 3710a, **[NON-NAVY COLLABORATOR]** grants Government Purpose Rights in any Subject Data furnished by **[NON-NAVY COLLABORATOR]** to **[NAVY COLLABORATOR]** under this Agreement that are properly marked as Proprietary Information. The Government has Government Purpose Rights in Subject Data that are Restricted Access Information.

7.1.3 Rights in Non-Subject Data

The Collaborators shall have Unlimited Rights in any Non-Subject Data delivered under this Agreement that are not Proprietary Information.

[NAVY COLLABORATOR] has a limited right to use, reproduce, and disclose only to Government employees for use in support of the Cooperative Work any Non-Subject Data that are properly marked as Proprietary Information and are provided by **[NON-NAVY COLLABORATOR]** under this Agreement. Such Proprietary Information can be used only for the purpose of performing the Cooperative Work unless consent to other use or disclosure is obtained from **[NON-NAVY COLLABORATOR]** in writing.

[NON-NAVY COLLABORATOR] shall have a limited right to use, reproduce, or disclose Non-Subject Data that may describe one or more Inventions in which the Government owns or may own a right, title or interest, if such Non-Subject Data are provided by **[NAVY COLLABORATOR]** under this Agreement. In accordance with 35 USC 205, such Non-Subject Data are to be held in confidence. Such Non-Subject Data shall be properly marked by **[NAVY COLLABORATOR]** and the limited rights of **[NON-NAVY COLLABORATOR]** shall be defined by a separate non-disclosure agreement.

7.2 Copyrights

7.2.1 Copyright by **[NON-NAVY COLLABORATOR]**

[NON-NAVY COLLABORATOR] may copyright works of authorship prepared pursuant to this Agreement if eligible for copyright protection under Title 17 USC.

7.2.2 Copyright License to the Government

[NON-NAVY COLLABORATOR] grants to the Government a nonexclusive, irrevocable, paid-up license in copyrighted works of authorship, including software (17 USC 106) prepared pursuant to this Agreement for any purpose, consistent with the rights in Data described in Article 7.1.

7.2.3 Copyright Statement

[NON-NAVY COLLABORATOR] shall include the following statement on any text, drawing, mask work or other work of authorship, that may be copyrighted under 17 USC, that is created in the performance of this Agreement:

“The U.S. Government has a copyright license in this work pursuant to a Cooperative Research and Development Agreement with **[NAVY COLLABORATOR]**.”

[ORTA: Insert the full name of Navy Collaborator in the statement above.]

7.3 Trademarks and Service Marks

7.3.1 Ownership of Trademarks and Service Marks

The Collaborator first establishing a trademark or service mark for goods or services with which the mark is used shall be considered the owner of the mark.

7.3.2 Obligation of Employees to Report Trademarks and Service Marks

Employees of both Collaborators shall report the adoption of a trademark or service mark associated with the Cooperative Work to their employer within thirty (30) days of the first use of the mark. Use includes internal use of any product or service of the Cooperative Work.

7.3.3 Obligation of Collaborators to Notify Each Other

Each Collaborator shall notify the other Collaborator within thirty (30) days of their employee's report of the first use of a trademark or service mark.

7.3.4 Responsibility for Filing an Application for Trademark or Service Mark

The Collaborator owning a trademark or service mark shall establish the use of the mark in intra- and interstate commerce and shall be responsible for filing all applications for trademark or service mark registration as appropriate.

7.3.5 License to Use Trademark or Service Mark

The Collaborator owning the trademark or service mark as defined in Article 7.3.1, shall grant a paid-up, irrevocable, nonexclusive license to the other Collaborator for use of the trademark or service mark on the goods or services for which the mark is intended to be used.

7.4 Subject Inventions

7.4.1 Obligation to Report Subject Inventions

7.4.1.1 Collaborators' Instructions to Employees

Each Collaborator shall instruct its employees to submit an Invention Disclosure to that Collaborator for all innovations, solutions to technical problems, or unique increases to the general body of knowledge resulting from the Cooperative Work. For the purposes of this Article, these innovations, solutions, and increases to knowledge shall be deemed Inventions.

7.4.1.2 Timely Invention Disclosure by Inventors

Within ninety (90) days of Making an Invention resulting from the Cooperative Work, unless a shorter time period is required by circumstances, the inventor(s) shall submit an Invention Disclosure to their employer.

In the case of an Invention Made jointly by inventors from both Collaborators, the inventors shall submit an Invention Disclosure with their respective employer.

7.4.1.3 Obligation to Provide Invention Disclosures to the Other Collaborator

Each Collaborator shall provide the other Collaborator with a copy of each Invention Disclosure reporting a Subject Invention within sixty (60) days of receiving the Invention Disclosure from its inventor(s).

7.4.2 Determination of Subject Inventions

The Collaborators shall review each Invention Disclosure resulting from the Cooperative Work and shall confer and consult to determine whether an Invention Disclosure represents a Subject Invention.

7.4.3 Title to and Ownership of Subject Inventions

Each Collaborator shall be entitled to own the Subject Inventions of its employees. Each Collaborator shall cooperate with the other Collaborator to obtain inventor signatures on Patent Applications, assignments or other documents required to secure Intellectual Property protection. For any Invention Made jointly by employees of the Collaborators, each Collaborator shall have ownership of the Subject Invention in the form of an undivided interest.

7.4.4 Filing of Patent Applications

7.4.4.1 Filing of Patent Applications on Solely Made Inventions

Each Collaborator has primary responsibility for filing Patent Applications on the Subject Inventions of its employee(s).

Notwithstanding such primary responsibility, by mutual agreement, the Collaborators may identify which Collaborator shall file a Patent Application on any Subject Invention.

7.4.4.2 Filing of Patent Applications on Jointly Made Inventions

In the case of an Invention jointly Made by employees of both Collaborators, the Collaborators shall confer and agree as to which Collaborator will file any Patent Application. Officers of the non-filing Collaborator shall cooperate with the filing Collaborator to obtain signatures on documents that are needed to file a Patent Application.

7.4.4.3 Preserving Intellectual Property Rights

The Collaborator responsible for filing of a Patent Application on any Subject Invention shall file such Patent Application at least sixty (60) days prior to any bar date or one year from the date the Invention Disclosure was received, whichever comes first. If no Patent Application is filed within the specified time period, the other Collaborator may assume control of filing the Patent Application and take title to the Subject Invention on ten (10) days written notification. The Collaborator that relinquished the responsibility to file shall retain a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Subject Invention practiced throughout the world by or on its behalf.

7.4.4.4 Filing Deadlines

The Collaborator responsible for filing any Patent Application for a Subject Invention shall notify the other Collaborator of all filing deadlines for prosecution of any Patent Application and maintenance of any patents on the Subject Invention. Notwithstanding the primary responsibility defined in Article 7.4.4.1, sixty (60) days prior to any filing deadline, the Collaborators shall confer to determine if the filing Collaborator intends to respond to the filing deadline. The non-filing Collaborator will be permitted to take action if the filing Collaborator declines.

7.4.4.5 Copies and Inspection

7.4.4.5.1 Copies of Prosecution Papers

Each Collaborator filing a Patent Application on a Subject Invention shall provide the other Collaborator with a copy of any communication relating to prosecution of said Patent Application within thirty (30) days of receipt of such communication.

7.4.4.5.2 Access to Patent Application File and Right to Make Copies

Upon written request, the filing Collaborator shall give the other Collaborator a Power of Attorney or an Authorization to Act in a Representative Capacity with respect to any Subject Invention(s). In the event the filing Collaborator fails or declines to take action, the other Collaborator shall be empowered to do all that is necessary to secure Intellectual Property protection for the Subject Invention.

7.4.4.6 Rights of Inventors if the Collaborators Decline to File a Patent Application

In the event both Collaborators decline to file a Patent Application on a Subject Invention, the Government will renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

In the event both Collaborators decline to file a Patent Application on a Subject Invention, **[NON-NAVY COLLABORATOR]** may, at its sole discretion, renounce its entitlement and leave its rights to the inventor(s) who may retain ownership of the Invention, subject to the retention by each Collaborator of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have the Invention practiced throughout the world by or on its behalf.

7.4.5 Nonexclusive License to Subject Inventions

7.4.5.1 Nonexclusive License Grant

Each Collaborator grants to the other Collaborator a nonexclusive, irrevocable, paid-up license to practice a Subject Invention Made by employees of the granting Collaborator or have the Subject Invention practiced throughout the world by or on behalf of the other Collaborator. No nonexclusive license granted under this Agreement shall permit licensee to grant sublicenses.

7.4.5.2 Confirmatory Nonexclusive License Agreement

Each Collaborator has the obligation to provide a Confirmatory License Agreement (Appendix B) to the other Collaborator for each nonexclusive license within ninety (90) days of the date of filing.

7.4.6 Option for Exclusive License to Subject Inventions

[NAVY COLLABORATOR] gives **[NON-NAVY COLLABORATOR]** the option of acquiring an Exclusive License in a future defined field(s) of use in the Government's rights in any Subject Invention Made in whole or in part by a **[NAVY COLLABORATOR]** employee. For the duration of any such option, **[NAVY COLLABORATOR]** shall neither disclose the Subject Invention to any Third Party nor enter into any negotiations for the use of such Subject Invention by a Third Party. The license shall be for reasonable consideration. In order to exercise this option, **[NON-NAVY COLLABORATOR]** must notify **[NAVY COLLABORATOR]** in writing within one hundred and eighty (180) days of the filing of a Patent Application. Unless another time period is mutually agreed upon between the Collaborators, **[NON-NAVY COLLABORATOR]** must execute an Exclusive License to the Subject Invention within one hundred and eighty (180) days of election to exercise the option, or the Invention shall be made available for licensing by the public in accordance with 37 CFR Part 404.

Any Exclusive License granted by the Government in a Subject Invention is subject to the statutorily required reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the Subject Invention or have that Subject Invention practiced throughout the world by or on behalf of the Government (15 USC 3710a).

7.4.7 Limitation on Assignment of Licenses Granted Under This Agreement

No license granted under this Agreement shall be assigned, licensed or otherwise disposed of except to the successor in interest of that part of **[NON-NAVY COLLABORATOR]**'s business to which such license pertains.

[The following Article 7.4.8 is to be used for a Non-Navy Collaborator that is "not" directly or indirectly foreign owned, controlled, or influenced (FOCI). For FOCI organizations identified as such in Article 4.2.1, use the appropriate alternative to Article 7.4.8 listed in the CRADA Handbook under "MODIFICATIONS FOR CRADAs WITH A FOCI ENTITY".]

7.4.8 Termination of License Granted and Cancellation of Exclusive License Option to Subject Inventions

7.4.8.1 Exclusive Licenses and Exclusive License Option

[NAVY COLLABORATOR] may terminate any Exclusive License or cancel any option for an Exclusive License to a Subject Invention granted under this Agreement in the event that:

(a) **[NON-NAVY COLLABORATOR]** is in default for failure to make payment as agreed in Article 5; or

(b) The Agreement is terminated unilaterally by **[NON-NAVY COLLABORATOR]**; or

(c) **[NON-NAVY COLLABORATOR]** fails to perform according to the Statement of Work (Appendix A); or

(d) **[NON-NAVY COLLABORATOR]** becomes a foreign owned, controlled, or influenced (FOCI) organization that does not qualify under the requirements of Executive Order 12591, Section 4(a).

7.4.8.2 Nonexclusive Licenses

[NAVY COLLABORATOR] shall terminate any nonexclusive license to a Subject Invention granted under this Agreement if **[NON-NAVY COLLABORATOR]** becomes a FOCI organization that does not qualify under the requirements of Executive Order 12591, Section 4(a).

7.5 Non-Subject Inventions

7.5.1 Ownership of Non-Subject Inventions

Each Collaborator owns its Non-Subject Inventions.

7.5.2 Rights Under Other Agreements

Nothing in this Agreement is intended to change the rights in Intellectual Property acquired by the Collaborators in any other contract or agreement between the **[NON-NAVY COLLABORATOR]** and the Government.

7.5.3 No License to Non-Subject Inventions

This Agreement does not grant any Collaborator a license, express or implied, to any Non-Subject Invention.

[Each paragraph in the following Article 7.5.4 is optional.]

7.5.4 Preexisting Non-Subject Inventions Pertinent to the Cooperative Work

Non-Subject Inventions Made prior to the Effective Date and pertinent to the Cooperative Work that are specifically identified as property of **[NAVY COLLABORATOR]** include but are not limited to the following:

[List Invention Title, inventor name(s), patent number, or Navy case number if an Invention disclosure, or Patent Application Serial Number, and date of issue (for patents only).]

Non-Subject Inventions Made prior to the Effective Date and pertinent to the Cooperative Work that are specifically identified as property of **[NON-NAVY COLLABORATOR]** include but are not limited to the following:

[List Invention Title, inventor name(s), patent number, or attorney's docket number if an Invention disclosure or Patent Application Serial Number, and date of issue (for patents only).]

7.6 Research License

Each Collaborator shall allow the other Collaborator to practice any of its Non-Subject Inventions for the purpose of performing the Cooperative Work.

No license, express or implied, for commercial application(s) is granted to either Collaborator in Non-Subject Inventions by performing the Cooperative Work.

For commercial application(s) of Non-Subject Inventions, a license must be obtained from the owner.

Article 8. TANGIBLE PROPERTY

8.1 Title to Preexisting Tangible Property

Each Collaborator shall retain title to all Tangible Property to which it had title prior to the Effective Date of this Agreement.

8.2 Tangible Property Purchased by Collaborators to Perform the Cooperative Work

Each Collaborator shall retain title to all Tangible Property that it purchases during the period of this Agreement. **[NON-NAVY COLLABORATOR]** cannot take title to any Government Tangible Property under this Agreement. Collaborator consumables to be used in the Cooperative Work of this Agreement are the property of the purchasing Collaborator until consumed.

8.3 Title to Developed Tangible Property

All Tangible Property developed under this Agreement with all components purchased by one Collaborator shall be the property of that Collaborator. Tangible Property having any component purchased by **[NAVY COLLABORATOR]** shall be the property of the Government, unless such Tangible Property can reasonably be separated without damage to the other individual components. After this Agreement is completed, expired, or terminated, if separation of components can be made without damage, the Collaborators may, by mutual agreement, separate the Tangible Property into its components and the separated components shall remain the property of the Collaborator that purchased them.

8.4 Tangible Property Operational and Disposition Costs

During the period of and upon completion, expiration, or termination of this Agreement, each Collaborator shall be responsible for all costs of maintenance, removal, storage, repair, disposal, and shipping of all Tangible Property to which it has title.

8.5 Disposal of Tangible Property

Disposal of Tangible Property shall be in accordance with applicable U.S. Federal, State, and local property disposal laws, environmental laws, and regulations.

Article 9. LIABILITY

9.1 Extent of Government Liability

The Government shall be solely liable for the negligent or wrongful acts of its officers and employees to the extent provided for in the Federal Tort Claims Act (28 USC 2671 et. seq.) and in other applicable laws and regulations of the United States that specifically waive sovereign immunity. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the United States.

9.2 Extent of **[NON-NAVY COLLABORATOR]** Liability

[NON-NAVY COLLABORATOR] is solely responsible for its actions and the actions of those acting for **[NON-NAVY COLLABORATOR]** in the performance of this Agreement and for any damages that may arise from any suit, action, or claim, and for any costs from or incidental to any suit, action, or claim, including but not limited to settlement and defense costs. Further, **[NON-NAVY COLLABORATOR]** agrees that in any suit, action or claim brought by anyone not a party to this Agreement based on actions of **[NON-NAVY COLLABORATOR]**, **[NON-NAVY COLLABORATOR]** shall not pursue any actions to enter the Government as a party in such suit, action or claim unless the Government has some liability under the Federal Tort Claims Act.

9.3 *Force Majeure*

No Collaborator shall be liable for the consequences of any *force majeure* that (1) is beyond its reasonable control; (2) is not caused by the fault or negligence of such Collaborator; (3) causes such Collaborator to be unable to perform its obligations under this Agreement; and (4) cannot be overcome by the exercise of due diligence. In the event of the occurrence of a *force majeure*, the Collaborator unable to perform shall promptly notify the other Collaborator. The Collaborators shall suspend performance only for such period of time as is necessary to overcome the result(s) of the *force majeure* and shall use their best efforts to resume performance as quickly as possible.

Article 10. GENERAL PROVISIONS

10.1 Characteristics of the Agreement

10.1.1 Entire Agreement

This Agreement constitutes the entire agreement between the Collaborators concerning the Cooperative Work and supersedes any prior understanding or written or oral agreement relative to the Cooperative Work.

10.1.2 Severability

The illegality or invalidity of any Article of this Agreement shall not impair, affect, or invalidate any other Article of this Agreement.

10.1.3 Interpretation of Headings

Headings of the Articles of this Agreement are for convenience of reference only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

10.2 Agreements Between Collaborators

10.2.1 Governing Laws

United States Federal Laws shall govern this Agreement for all purposes.

10.2.2 Independent Parties/Entities

The relationship of the Collaborators to this Agreement is that of independent parties and not as agents of each other, partners, or participants in a joint venture. Each Collaborator shall maintain sole and exclusive control over its personnel and operations.

10.2.3 Assignment/Subcontracting

[Note to ORTAs: Refer to the Handbook for a discussion on issues related to the use of contractors during the execution of a CRADA.]

10.2.3.1 Neither Collaborator may allow Third Parties to perform any part of the Cooperative Work under this Agreement without express written consent of the other Collaborator. If consent is obtained, the Collaborator requesting such consent shall remain fully responsible for the portion of the Cooperative Work to be accomplished under a third-party agreement, and the Third Party is not a Collaborator of this Agreement. Any third-party agreement to perform a portion of the Cooperative Work shall contain terms consistent with this Agreement.

10.2.3.2 This Agreement shall not be assigned or otherwise transferred by either Collaborator without the prior written consent of the other Collaborator, except to the successor of that part of **[NON-NAVY COLLABORATOR]**'s business to which this Agreement pertains.

10.2.3.3 If **[NON-NAVY COLLABORATOR]** or its successor or assignee is a U.S. company, and becomes, during the term of this Agreement or thereafter, directly or indirectly owned, controlled, or influenced by a foreign company or government (FOCI), then **[NON-NAVY COLLABORATOR]** or its successor or assignee shall promptly notify **[NAVY COLLABORATOR]** to that effect.

10.2.4 Disputes

10.2.4.1 Settlement and Resolution

[NAVY COLLABORATOR] and **[NON-NAVY COLLABORATOR]** agree to use reasonable efforts to reach a fair settlement of any dispute. If such efforts are unsuccessful, remaining issues in dispute will be referred to the signatories or their successors for resolution. If a dispute continues, the remaining issues may be submitted to the Chief of Naval Research (CNR), or the CNR designee, for resolution. This Agreement does not prevent any Collaborator from pursuing disputes in a U.S. Federal court of competent jurisdiction. No Collaborator will pursue litigation in a U.S. Federal court until after the CNR, or the CNR designee, decides the dispute, or until sixty (60) days after the dispute was first submitted to the CNR, or the CNR designee, whichever comes first.

10.2.4.2 Continuation of Cooperative Work

If payments or installment payments are to be made as stated under Article 5, **[NON-NAVY COLLABORATOR]** will not start or continue cooperative work until payments or installment payments are received.

10.2.5 Waivers

None of the provisions of this Agreement shall be considered waived by either Collaborator unless such waiver is given in writing to the other Collaborator, signed by the executing official of this Agreement or the official's successor having the authority to bind the Collaborator making the waiver. The failure of either Collaborator to insist upon strict performance of any of the terms and conditions herein, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any right of either Collaborator under this Agreement.

10.2.6 Use of Name or Endorsements

Except as provided for in Article 7.2.3, **[NON-NAVY COLLABORATOR]** shall not use the name of **[NAVY COLLABORATOR]** or any other Government entity on any product or service that is directly or indirectly related to either this Agreement or any patent license or assignment associated with this Agreement without the prior approval of **[NAVY COLLABORATOR]**. By entering into this Agreement, **[NAVY COLLABORATOR]** does not directly or indirectly endorse any product or service provided, or to be provided, by **[NON-NAVY COLLABORATOR]**, its successors, assignees, or licensees. **[NON-NAVY COLLABORATOR]** shall not in any way imply that the Department of the Navy endorses any such product or service.

10.3 Environment, Safety, and Health

Each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste in its custody during the course of this Agreement. At the conclusion of this Agreement, each Collaborator shall be responsible for the handling, control, and disposition of any and all hazardous substances or waste still in its possession. Each Collaborator shall obtain at its own expense all necessary permits and licenses as required by U.S. Federal, State, and local law and shall conduct such handling, control, and disposition in a lawful and environmentally responsible manner. Each Collaborator is responsible for all required environmental, safety, and health compliance, notice, and monitoring related to its facility in accordance with U.S. Federal, State, and local law and regulations. Collaborators shall abide by the environmental, safety, and health directives of the host facility in which the Cooperative Work is being performed, and any U.S. Federal, State, or local laws and regulations pertaining to environment, safety, and health that are applicable to the host facility.

10.4 U.S. Competitiveness

[NON-NAVY COLLABORATOR] agrees that any product, process, or service using Intellectual Property arising from the performance of this Agreement shall be manufactured substantially in the United States.

10.5 Public Release of This Agreement

This Agreement, without funding information (Article 5) and Appendices, may be released to the public.

Article 11. MODIFICATIONS AND NOTICES

11.1 Amendments

If a Collaborator wishes to modify this Agreement, the Collaborators shall confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by both executing officials of this Agreement or their successors.

11.2 Termination

11.2.1 Termination by Mutual Consent

The Collaborators may elect to terminate this Agreement at any time by mutual consent. Such termination shall not be effective until a written termination agreement is signed by both executing officials of this Agreement or their successors.

11.2.2 Unilateral Termination

A Collaborator may unilaterally terminate this entire Agreement at any time by giving the other Collaborator written notice signed by the executing official of this Agreement or **[his/her]** successor, not less than thirty (30) days prior to the desired termination date. If **[NON-NAVY COLLABORATOR]** unilaterally terminates this Agreement, any option for an Exclusive License to a Subject Invention and any Exclusive License to a Subject Invention granted by or pursuant to this Agreement shall simultaneously be terminated.

11.3 Notices

All notices pertaining to or required by Articles of this Agreement, except those pertaining solely to the prosecution of any patent, trademark, or service mark, shall be in writing and shall be signed by an authorized representative of the Technology Transfer Office for **[NAVY COLLABORATOR]** or the preferred contact for **[NON-NAVY COLLABORATOR]**, and all such notices shall be delivered by hand, sent by courier with proper registration, or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

If to **[NAVY COLLABORATOR]**:

[Use the official Navy Collaborator mailing address for the Technology Transfer Office.]

If to **[NON-NAVY COLLABORATOR]**:

[Specify the mailing address for the preferred contact.]

A Collaborator shall notify the other Collaborator of a change of address in the manner set forth above.

Notices pertaining solely to the prosecution of any patent, trademark, or service mark related to this Agreement shall be in writing and shall be signed by and sent to the Collaborator's legal counsel for Intellectual Property. Legal counsel for Intellectual Property for each Collaborator shall send a copy of any such notice to the Technology Transfer Office for **[NAVY COLLABORATOR]**. If either Collaborator fails to identify such counsel upon request, then such notices shall be sent to the points of contact specified above.

Article 12. SURVIVING PROVISIONS

The Articles covering Definitions, Representations and Warranties, Funding, Reports and Publications, Intellectual Property, Tangible Property, Liability, General Provisions, Modifications and Notices, and Surviving Provisions shall survive the completion, termination, or expiration of this Agreement.

Article 13. DURATION

This Agreement expires **[specify a time no greater than three (3) years]** after its Effective Date, unless otherwise extended in writing according to the provisions of Article 11.

Article 14. SIGNATURES

For **[NON-NAVY COLLABORATOR]**:

I, the undersigned, am duly authorized to bind **[NON-NAVY COLLABORATOR]** to this Agreement and do so by affixing my signature hereto.

Entered into this ____ day of _____ 200__.

By: _____

Name:

Title:

For the Department of the Navy:

I, the undersigned, by 15 USC 3710a and Navy regulations, am duly authorized to bind the U.S. Navy to this Agreement and do so by affixing my signature hereto.

Entered into this ____ day of _____ 200__.

By: _____

Name:

Title:

Navy Organization:

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APPENDIX A
STATEMENT OF WORK

The Collaborators agree to perform the following tasks:

[NAVY COLLABORATOR] will be responsible for the following tasks (list as applicable):

1. Obtain all necessary IRB approvals
- 2.
- 3.

[NON-NAVY COLLABORATOR] will be responsible for the following tasks (list as applicable):

- 1.
- 2.
- 3.

[NAVY COLLABORATOR] and **[NON-NAVY COLLABORATOR]** will be responsible for the following joint tasks (if applicable)

- 1.
- 2.
- 3.

[Note: Add the following appendices, each on its own page.]

APPENDIX C

[Non-Navy Collaborator Use of Third Party/Navy Collaborator Use of Third Party]

APPENDIX D

[Budget Data, as required]

APPENDIX E

Clinical Trials Protocol

APPENDIX F

[Form 7443]

APPENDIX G

PRIVACY AND SECURITY OF PROTECTED HEALTH INFORMATION

(a) *Definitions.* As used in this clause:

Individual has the same meaning as the term “individual” in 45 CFR 164.501 and 164.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

Privacy Rule means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

Protected Health Information has the same meaning as the term “protected health information” in 45 CFR 164.501, limited to the information created or received by The Business Associate/Collaborator from or on behalf of the Government.

Required by Law has the same meaning as the term “required by law” in 45 CFR 164.501 and 164.103.

Secretary means the Secretary of the Department of Health and Human Services or his/her designee.

Security Rule means the Health Insurance Reform: Security Standards at 45 CFR part 160, 162 and part 164, subpart C.

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR 160.103, 164.501 and 164.304.

(b) The Business Associate/Collaborator agrees to not use or further disclose Protected Health Information other than as permitted or required by the Agreement or as Required by Law.

(c) The Business Associate/Collaborator agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

(d) The Business Associate/Collaborator agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits in the execution of this Agreement.

(e) The Business Associate/Collaborator agrees to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate/Collaborator of a use or disclosure of Protected Health Information by the Business Associate/Collaborator in violation of the requirements of this Agreement.

(f) The Business Associate/Collaborator agrees to report to the Government any security incident involving protected health information of which it becomes aware.

(g) The Business Associate/Collaborator agrees to report to the Government any use or disclosure of the Protected Health Information not provided for by this Agreement.

(h) The Business Associate/Collaborator agrees to ensure that any agent, to whom it provides Protected Health Information received from, or created or received by the Business Associate/Collaborator on behalf of the Government agrees to the same restrictions and conditions that apply through this agreement to the Business Associate/Collaborator with respect to such information.

(i) The Business Associate/Collaborator agrees to ensure that any agent, to whom it provides electronic Protected Health Information, agrees to implement reasonable and appropriate safeguards to protect it.

(j) The Business Associate/Collaborator agrees to provide access, at the request of the Government, and in the time and manner designated by the Government to Protected Health Information in a Designated Record Set, to the Government or, as directed by the Government, to an Individual in order to meet the requirements under 45 CFR 164.524.

(k) The Business Associate/Collaborator agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Government directs or agrees to pursuant to 45 CFR 164.526 at the request of the Government or an Individual, and in the time and manner designated by the Government.

(l) The Business Associate/Collaborator agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Business Associate/Collaborator on behalf of, the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner designated by the Government or the Secretary, for purposes of the Secretary determining the Government's compliance with the Privacy Rule.

(m) The Business Associate/Collaborator agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(n) The Business Associate/Collaborator agrees to provide to the Government or an Individual, in time and manner designated by the Government, information collected in accordance with this Clause of the Agreement, to permit the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

GENERAL USE AND DISCLOSURE PROVISIONS

Except as otherwise limited in this Agreement, the Business Associate/Collaborator may use or disclose Protected Health Information on behalf of, or to provide services to, the Government if such use or disclosure of Protected Health Information would not violate the Privacy Rule, the Security Rule or the Department of Defense Health Information Privacy Regulation if done by the Government.

SPECIFIC USE AND DISCLOSURE PROVISIONS

(a) Except as otherwise limited in this Agreement, the Business Associate/Collaborator may use Protected Health Information for the proper management and administration of the Business Associate/Collaborator or to carry out the legal responsibilities of the Business Associate/Collaborator.

(b) Except as otherwise limited in this Agreement, the Business Associate/Collaborator may disclose Protected Health Information for the proper management and administration of the Business Associate/Collaborator, provided that disclosures are required by law, or the Business Associate/Collaborator obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate/Collaborator of any instances of which it is aware in which the confidentiality of the information has been breached.

(c) Except as otherwise limited in this Agreement, the Business Associate/Collaborator may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 CFR 164.504(e)(2)(i)(B).

(d) Business Associate/Collaborator may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

OBLIGATIONS OF THE GOVERNMENT

Provisions for the Government to Inform the Business Associate/Collaborator of Privacy Practices and Restrictions

(a) Upon request the Government shall provide the Business Associate/Collaborator with the notice of privacy practices that the Government produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

(b) The Government shall provide the Business Associate/Collaborator with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Business Associate/Collaborator's permitted or required uses and disclosures.

(c) The Government shall notify the Business Associate/Collaborator of any restriction to the use or disclosure of Protected Health Information that the Government has agreed to in accordance with 45 CFR 164.522.

PERMISSIBLE REQUESTS BY THE GOVERNMENT

The Government shall not request the Business Associate/Collaborator to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Business Associate/Collaborator as otherwise permitted by this clause.

TERMINATION

(a) Termination. A breach by the Business Associate/Collaborator of this clause, may subject the Business Associate/Collaborator to termination under any applicable default or termination provision of this Agreement.

(b) Effect of Termination.

(1) If this agreement has records management requirements, the records subject to the Clause should be handled in accordance with the records management requirements. If this agreement does not have records management requirements, the records should be handled in accordance with paragraphs (2) and (3) below.

(2) If this agreement does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this Agreement, for any reason, the Business Associate/Collaborator shall return or destroy all Protected Health Information received from the Government, or created or received by the Business Associate/Collaborator on behalf of the Government. This provision shall apply to Protected Health Information that is in the possession of agents of the Business Associate/Collaborator. The Business Associate/Collaborator shall retain no copies of the Protected Health Information.

(3) If this agreement does not have records management provisions and the Business Associate/Collaborator determines that returning or destroying the Protected Health Information is infeasible, the Business Associate/Collaborator shall provide to the Government notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Government and the Business Associate/Collaborator that return or destruction of Protected Health Information is infeasible, the Business Associate/Collaborator shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Business Associate/Collaborator maintains such Protected Health Information.

MISCELLANEOUS

(a) Regulatory References. A reference in this Clause to a section in the Privacy Rule or Security Rule means the section as in effect or as amended, and for which compliance is required.

(b) Survival. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this Clause shall survive the termination of this Agreement.

(c) Interpretation. Any ambiguity in this Clause shall be resolved in favor of a meaning that permits the Government to comply with the Privacy Rule or Security Rule.

Section III - 5

Limited Purpose CRADAs - Explanation

Guidance for Use/Department of the Navy Limited Purpose Cooperative Research and Development Agreement for Equipment or Material Transfer

Statutory Authority and Purpose

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended) a Department of the Navy Collaborator and a Non-Navy Collaborator may enter into a Cooperative Research and Development Agreement (CRADA). These Limited Purpose CRADAs (LP-CRADA) are restricted to the exchange of existing equipment or material that the Collaborators need for their own research, test, evaluation, development or engineering activities. There is no joint work performed under the LP-CRADAs, but there is a mutual interest in the results. Data and intellectual property of the Collaborators is protected.

These LP-CRADAs are not a substitute for a Work-for-Others Agreement. A Work-for-Others Agreement is used where a Navy laboratory is willing to provide an existing product, material or service without competing with the private sector. The working capital fund laboratory is not interested in the research outcome.

These LP-CRADAs are to be used when a laboratory and Non-Navy Collaborator both have an interest in the research outcome. A report to all collaborators on the results of the research is required. The key is that the Provider has equipment or material that the parties want evaluated or used by the Recipient. Acceptable collaborative purposes include determining suitability of the equipment or material for Recipient's purpose or to determine if there is mutual interest or need for a more formal CRADA, a patent license agreement or procurement.

Please consult with your laboratory's attorney to be sure you are selecting the proper business instrument.

Appropriate Non-Navy Collaborators

The U.S. Federal Technology Transfer Act of 1986, as amended, provides for making the expertise, capabilities, and technologies of U.S. Federal laboratories accessible to other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons; in order to improve the economic, environmental, and social well-being of the United States by stimulating utilization of U.S. Federally funded technology developments and/or capabilities in the U.S.

Navy Model Agreements

The Limited Purpose CRADA is an approved CRADA. Two model agreements are included with this Guidance. One for bringing "things" in and one for sending "things" out. The first model agreement, Model #1, describes the transfer of equipment or material from a Navy Provider out to a Non-Navy Recipient; the second model agreement, Model #2, describes the transfer of equipment or material from a Non-Navy Provider to a Navy Recipient.

If training is needed to operate the equipment or perform a specific test, the Provider must conduct the training, including on-site training, if necessary.

Funding Options

A Department of Navy laboratory as defined by the U.S. Federal Technology Transfer Act of 1986, as amended, may not issue funds to the Non-Navy Collaborator under a LP-CRADA, but the Navy laboratory may receive funds from the Non-Navy Collaborator.

Payment of shipping will depend on each specific circumstance and should be closely coordinated with both the laboratory comptroller and general attorney.

Non-Disclosure Agreement

If a Non-Disclosure Agreement (NDA) is used for the performance of an LP-CRADA, the laboratory's intellectual property or general attorney should be involved in the preparation or review of the NDA. Examples of Non-Disclosure Agreements can be found in Section IV - 1 of this document.

Liability

When the U.S. Government is the Recipient, liability for the loss or destruction of equipment or material that was to be returned to the Provider is still limited by the Federal Tort Claims Act (FTCA). The Government may agree in advance on a maximum settlement value to any liability action allowed under the FTCA. When the Recipient is the Non-Navy Collaborator, the Recipient agrees to assume all risks, direct or consequential, from their use, storage and/or disposal of the equipment or material.

Legal Review

Legal review is obtained at the laboratory to ensure compliance with the laboratory's mission, statutes, regulations, instructions and executive directives. If the model LP-CRADA is changed, the modification is noted and a written explanation of its necessity is to be provided by local legal counsel and is included with the Agreement when it is forwarded to ONR.

Signature Process

As with any Navy CRADA, the signature process is in accordance with SECNAVINST 5700.16A dated 7 March 2000. Specifically, the laboratory commanding officer has the authority to enter into a CRADA and sign such Agreements for the DON provided that the requirements of SECNAVINST 5700.16A are met.

Actions After Signature

An electronic copy of the signed LP-CRADA, along with any other supporting documents, should be forwarded to ONR at the following address:

Office of Naval Research
Technology Transfer Program, Code 03TSB
875 North Randolph Street
Arlington, VA 22203-1995
dorothy.vincent@navy.mil

The Navy Technology Transfer Program Office enters information on the LP-CRADA into the Defense Technology Transfer Information System (DTTIS) database within thirty (30) days after the LP-CRADA has been signed.

The DTTIS database provides ONR with a record of the activities carried out pursuant to each LP-CRADA sufficient to support discussion and evaluation of the LP-CRADAs in terms of their stimulation of productivity, technology and innovation. This information is included in the triennial report by the Secretary of Commerce to Congress.

The ORTA manager is to also include information on LP-CRADAs in the annual technology transfer business plan submitted to ONR as required by the Department of Defense.

ONR Consultation

Please direct inquiries to Ms. Dottie Vincent at 703-696-4792; dorothy.vincent@navy.mil.

A LIMITED PURPOSE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(LP-CRADA)
FOR EQUIPMENT OR MATERIAL TRANSFER
(FROM NAVY PROVIDER TO NON-NAVY RECIPIENT)

FROM

[NAVY PROVIDER]

TO

[NON-NAVY RECIPIENT]

AGREEMENT NUMBER: LP-CRADA-[Navy Org.]-[last two digits of CY]-[serial number]

AGREEMENT ADMINISTRATORS:

[NAVY PROVIDER]

Technology Transfer Office

Point of Contact:

[insert name, organizational code, telephone number, e-mail address]

Legal Counsel:

[insert name, organization code, telephone number, e-mail address]

[NON-NAVY RECIPIENT]

Preferred Contact:

[insert name, telephone number, e-mail address]

Legal Counsel **[Optional]**:

[insert name, telephone number, e-mail address]

A LIMITED PURPOSE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(LP-CRADA)
FOR EQUIPMENT OR MATERIAL TRANSFER
(FROM NAVY PROVIDER TO NON-NAVY RECIPIENT)

PREAMBLE

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), the Department of Navy Collaborator (PROVIDER) and Non-Navy Collaborator (RECIPIENT) described below agree and enter into this Limited Purpose Cooperative Research and Development Agreement (LP-CRADA) to transfer **[choose one: EQUIPMENT or MATERIAL]** according to the clauses and conditions and for the term and duration set in this Agreement.

The PROVIDER is **[state full name and address of Navy Collaborator]**, a Federal laboratory of the United States Department of Navy wholly owned by the U.S. Government whose substantial purpose is the performance of research, development or engineering.

The RECIPIENT is **[name and address of Non-Navy Collaborator]**, a corporation **[substitute appropriate alternate language for a different entity, e.g., a University]** duly organized, validly existing and in good standing under the laws of the **[State or Commonwealth]** of **[indicate name]**. The RECIPIENT **[is/is not]** a small business as defined in 15 USC 632 and implementing regulations (13 CFR 121.101 et seq.) of the Administrator of the Small Business Administration. Further, the RECIPIENT **[is/is not]** directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)) as of the effective date of this Agreement.

Article 1. **[EQUIPMENT/MATERIAL] TO BE TRANSFERRED:**

PROVIDER owns, controls, or otherwise has all rights in **[describe the EQUIPMENT/MATERIAL being transferred]**, hereafter **[EQUIPMENT/MATERIAL]**. PROVIDER has the right to and will transfer **[insert quantity]** of **[EQUIPMENT/MATERIAL]** within **[insert time frame]** to RECIPIENT for the conduct of the research, tests, evaluation, development or engineering efforts and purposes stated below.

Article 2. **PURPOSE FOR TRANSFER (PURPOSE):**

(a) RECIPIENT agrees that it will use the **[EQUIPMENT/MATERIAL]** solely for **[describe project and state intended use]** (PURPOSE) under the direction and control of RECIPIENT's Principal Investigator (PI), **[insert name]**, and will follow the United States Federal statutes, rules and regulations controlling the handling and use of research equipment and/or materials of the type described as the **[EQUIPMENT/MATERIAL]**, as applicable. RECIPIENT agrees that it will not use the **[EQUIPMENT/MATERIAL]** for any commercial or production purposes. This Agreement does not constitute or create a joint venture, partnership or formal business entity of any kind.

(b) This Agreement is not a license in Government Intellectual Property including patents or patent applications except for the limited PURPOSE stated. This Agreement shall not be interpreted to alter any pre-existing rights to the **[EQUIPMENT/MATERIAL]**. PROVIDER reserves the right to provide the **[EQUIPMENT/MATERIAL]** to others. RECIPIENT agrees not to produce, modify or duplicate the **[EQUIPMENT/MATERIAL]** for any purpose unless that intention is stated as part of the research PURPOSE, subparagraph 2(a) supra.

(c) If RECIPIENT desires to use the **[EQUIPMENT/MATERIAL]** for purposes other than the PURPOSE, RECIPIENT agrees, before beginning any such use, to negotiate a full CRADA and/or a license for any patent or other intellectual property, specific for that use, in good faith with PROVIDER as provided by Federal law. It is understood by RECIPIENT that PROVIDER shall have no obligation to grant such a license or enter into a CRADA with RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others as provided by law.

Article 3. **PROPRIETARY INFORMATION:**

RECIPIENT agrees to protect PROVIDER's information protected by 35 USC 205 in the same manner in which it protects its own PROPRIETARY INFORMATION. The Parties shall confer and agree what information created by the Navy PROVIDER shall be designated RESTRICTED ACCESS INFORMATION. RECIPIENT will treat RESTRICTED ACCESS INFORMATION in a manner equivalent to the manner the Government treats PROPRIETARY INFORMATION. It is RECIPIENT's responsibility to properly identify all PROPRIETARY INFORMATION.

"PROPRIETARY INFORMATION" means information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information: (a) is not known or available from other sources without obligations concerning its confidentiality; (b) has not been made available by the owners to others without obligation concerning its confidentiality; (c) is not already available to the Government without obligation concerning its confidentiality; and (d) has not been developed independently by persons who have had no access to the information.

"RESTRICTED ACCESS INFORMATION" means Subject Data generated by Navy Collaborator that would be Proprietary Information if the information had been obtained from a Non-Federal Collaborator participating in a CRADA (15 USC 3710a). Under 15 USC, Section 3710a(c)(7)(B) the Collaborators mutually may agree to provide appropriate protection to Subject Data generated by the Navy Collaborator (Restricted Access Information) against public dissemination or release under the Freedom of Information Act (FOIA) for a period of up to five (5) years after development of the Information. PROVIDER and RECIPIENT will designate all RESTRICTED ACCESS INFORMATION.

"Subject Data" means that Data first recorded in the performance of the Cooperative Work.

"DATA" means all recorded information of any kind regardless of the form or method of the recording, including computer software.

"Government" means the Government of the United States of America.

[Insert the following language if a Nondisclosure Agreement is used: The attached Nondisclosure Agreement (Appendix A) is incorporated as part of this Agreement. If there is a conflict between the terms and conditions of Appendix A and this Agreement, this Agreement shall control except for time periods].

Article 4. **PUBLICATIONS:**

RECIPIENT agrees to provide appropriate acknowledgement of the source of the **[EQUIPMENT/MATERIAL]** in all publications. PROVIDER and RECIPIENT agree to confer and consult to provide a reasonable review period **[optional: insert time limit]** prior to the publication or presentation of DATA regarding the **[EQUIPMENT/MATERIAL]** to assure that no Proprietary or otherwise protected information is released and that patent rights are protected. Publication and/or presentation will be delayed for a reasonable time to afford needed protection. The RECIPIENT shall provide a report of the research results to the PROVIDER within **[insert number of days]** days from the testing of the **[EQUIPMENT/MATERIAL]**.

Article 5. **WARRANTY:**

RECIPIENT agrees that PROVIDER makes no representations and extends no warranty of any kind, either expressed or implied regarding the **[EQUIPMENT/MATERIAL]**. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of **[EQUIPMENT/MATERIAL]** will not infringe any patent, copyright, trademark, or other rights.

Article 6. **LIABILITY:**

RECIPIENT agrees to assume all risks, direct or consequential, from their use, storage and/or disposal of the **[EQUIPMENT/MATERIAL]**. RECIPIENT agrees to defend, indemnify, and hold harmless PROVIDER from any loss, claim, damage, or liability, of any kind, which may arise from their use, storage or disposal of the **[EQUIPMENT/MATERIAL]**. PROVIDER's entire liability is as stated in the Federal Tort Claims Act, Section 2671 *et seq.*

Article 7. **RETURN OF [EQUIPMENT/MATERIAL]:**

RECIPIENT agrees that any and all **[EQUIPMENT/MATERIAL]** and information regarding this **[EQUIPMENT/MATERIAL]** received from PROVIDER, including copies of information, shall remain the property of PROVIDER. These items will be promptly returned or destroyed at the termination of this Agreement in accordance with the directions of the PROVIDER. All requests and responses must be in writing. The **[EQUIPMENT/MATERIAL]** and information will be returned at no expense to the PROVIDER.

Article 8. **PRE-EXISTING INTELLECTUAL PROPERTY RIGHTS:**

Except as expressly provided in this Agreement, no rights are provided to RECIPIENT under any pre-existing patents, patent applications, protected information or other intellectual property of PROVIDER.

Article 9. **INVENTION LICENSE:**

The RECIPIENT shall retain title to any Invention of its employees made in the performance of the PURPOSE. RECIPIENT shall notify PROVIDER of the receipt of any Invention disclosure regarding use or modification of the **[EQUIPMENT/MATERIAL]**. RECIPIENT grants the Government a nonexclusive, irrevocable, paid-up license to practice the Invention, or have the Invention practiced throughout the world by or on behalf of the Government. Upon request, RECIPIENT shall give the Government a written instrument, prepared in a form satisfactory to the Government confirming such rights as appropriate. "Invention" means any invention or discovery which is or may be patentable under Title 35 of the United States Code.

“Patent Application” means U.S. or foreign patent application, continuation, continuation-in-part, divisional, reissue and/or reexamination on any Invention.

Article 10. **DELIVERY:**

It is agreed that the PROVIDER will deliver the **[EQUIPMENT/MATERIAL]** upon execution of this Agreement to the RECIPIENT within **[insert number]** days from the effective date of this Agreement.

Article 11. **DURATION:**

This Agreement will terminate on the earliest of the following dates:

- (1) upon completion of RECIPIENT's proposed research studies with the **[EQUIPMENT/MATERIAL]**, or
- (2) upon thirty (30) days written notice by either Collaborator to the other, or
- (3) **[insert time, not to exceed three (3) years]** from the effective date of this Agreement.

Article 12. **AMENDMENT:**

This Agreement can be amended only by a written amendment mutually agreed to and signed by the Agreement signatories or their successors.

Article 13. **ENTIRE AGREEMENT:**

This Agreement is the entire Agreement between the Collaborators concerning the PURPOSE and supersedes any prior understanding or written or oral agreement relative to the PURPOSE.

Article 14. **GOVERNING LAW:**

United States Federal Law shall govern this Agreement for all purposes.

Article 15. **FUNDS:**

It is agreed and understood that the **[EQUIPMENT/MATERIAL]** is furnished and the Agreement is entered into at no cost to the PROVIDER.

No funds are transferred under this Agreement from the Navy PROVIDER to the Non-Navy RECIPIENT.

[If funds are transferred from Non-Navy Recipient to Navy Provider, specify amount and instructions for delivery of funds].

Checks will be payable to:

[Do not specify an individual by name but rather an organization that has the requisite authority to receive funds for the Navy].

Checks will be mailed to:

[Specify address, including the name of the authorized recipient, title, and appropriate organizational code].

Article 16. **TITLE:**

Each Collaborator shall retain title to all tangible property to which it had title prior to the effective date of this Agreement.

Article 17. **USE OF NAME OR ENDORSEMENTS:**

RECIPIENT shall not use the name of the PROVIDER or any other Government entity on any product or service that is directly or indirectly related to this Agreement without the prior approval of PROVIDER.

Article 18. **PUBLIC RELEASE OF THIS AGREEMENT:**

This Agreement document is releasable to the public.

Article 19. **EFFECTIVE DATE:**

The effective date of this Agreement is the date of execution by the last to sign for the DURATION set in Article 11.

Article 20. **NOTICES:**

All notices will be sent to the Agreement administrators or their successors at the addresses shown in the PREAMBLE.

Article 21. **SURVIVING PROVISIONS:**

All the Articles of this Agreement shall survive its termination.

Article 22. **SIGNATURES:**

Accepted for RECIPIENT:

I, the undersigned, am duly authorized to bind **[NON-NAVY RECIPIENT]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200__.
(month)

By: _____
Name:

Title:

Accepted for PROVIDER:, the undersigned, am duly authorized to bind **[NAVY PROVIDER]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200___.
(month)

By: _____

Name:

Title:

Naval Organization:

A LIMITED PURPOSE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(LP-CRADA)
FOR EQUIPMENT OR MATERIAL TRANSFER
(FROM NON-NAVY PROVIDER TO NAVY RECIPIENT)

FROM

[NON-NAVY PROVIDER]

TO

[NAVY RECIPIENT]

AGREEMENT NUMBER: LP-CRADA-[Navy Org.]-[last two digits of CY]-[serial number]

AGREEMENT ADMINISTRATORS:

[NON-NAVY PROVIDER]

Preferred Contact: **[insert name, telephone number, e-mail address]**

Legal Counsel **[Optional]**: **[insert name, telephone number, e-mail address]**

[NAVY RECIPIENT]

Technology Transfer Office
Point of Contact: **[insert name, organizational code, telephone number, e-mail address]**

Legal Counsel: **[insert name, organization code, telephone number, e-mail address]**

A LIMITED PURPOSE
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(LP-CRADA)
FOR EQUIPMENT OR MATERIAL TRANSFER
(FROM NON-NAVY PROVIDER TO NAVY RECIPIENT)

PREAMBLE

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), the Non-Navy Collaborator (PROVIDER) and Department of Navy Collaborator (RECIPIENT) described below agree and enter into this Limited Purpose Cooperative Research and Development Agreement (LP-CRADA) to transfer **[choose one: EQUIPMENT or MATERIAL]** according to the clauses and conditions and for the term and duration set in this Agreement.

The PROVIDER is **[name and address of Non-Navy Collaborator]**, a corporation **[substitute appropriate alternate language for a different entity, e.g., a University]** duly organized, validly existing and in good standing under the laws of the **[State or Commonwealth]** of **[indicate name]**. The PROVIDER **[is/is not]** a small business as defined in 15 USC 632 and implementing regulations (13 CFR 121.101 et seq.) of the Administrator of the Small Business Administration. Further, the PROVIDER **[is/is not]** directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)) as of the effective date of this Agreement.

The RECIPIENT is the **[state full name and address of Navy Collaborator]**, a Federal laboratory of the United States Department of Navy wholly owned by the U.S. Government whose substantial purpose is the performance of research, development or engineering.

Article 1. **[EQUIPMENT/MATERIAL] TO BE TRANSFERRED:**

PROVIDER owns, controls, or otherwise has all rights in **[describe the EQUIPMENT/MATERIAL being transferred]** hereafter **[EQUIPMENT/MATERIAL]**. PROVIDER has the right to and will transfer **[insert quantity]** of **[EQUIPMENT/MATERIAL]** within **[insert time frame]** to RECIPIENT for the conduct of the research, tests, evaluation, development or engineering efforts and purposes stated below.

Article 2. **PURPOSE FOR TRANSFER (PURPOSE):**

RECIPIENT agrees that it will use the **[EQUIPMENT/MATERIAL]** solely for **[describe project and state intended use]** (PURPOSE) under the direction and control of RECIPIENT's Principal Investigator (PI), **[insert name]**, and will follow the United States Federal statutes, rules and regulations controlling the handling and use of research equipment and/or materials of the type described as the **[EQUIPMENT/MATERIAL]**, as applicable. The PURPOSE is consistent with the mission of the RECIPIENT. In addition, RECIPIENT agrees that it will not use the **[EQUIPMENT/MATERIAL]** for any production purposes. This Agreement does not constitute or create a joint venture, partnership or formal business entity of any kind.

Article 3. **PROPRIETARY INFORMATION:**

RECIPIENT agrees that it will not use PROVIDER's properly marked PROPRIETARY INFORMATION without prior written consent except for the PURPOSE. The Parties shall confer and agree what information created by the Navy RECIPIENT shall be designated RESTRICTED ACCESS INFORMATION. PROVIDER will treat RESTRICTED ACCESS INFORMATION in a manner equivalent to the manner the Government treats PROPRIETARY INFORMATION. It is PROVIDER's responsibility to properly identify all PROPRIETARY INFORMATION.

"PROPRIETARY INFORMATION" means information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information: (a) is not known or available from other sources without obligations concerning its confidentiality; (b) has not been made available by the owners to others without obligation concerning its confidentiality; (c) is not already available to the Government without obligation concerning its confidentiality; and (d) has not been developed independently by persons who have had no access to the information.

"RESTRICTED ACCESS INFORMATION" means Subject Data generated by Navy Collaborator that would be Proprietary Information if the information had been obtained from a Non-Federal Collaborator participating in a CRADA (15 USC 3710a). Under 15 USC, Section 3710a(c)(7)(B) the Collaborators mutually may agree to provide appropriate protection to Subject Data generated by the Navy Collaborator (Restricted Access Information) against public dissemination or release under the Freedom of Information Act (FOIA) for a period of up to five (5) years after development of the Information. PROVIDER and RECIPIENT will designate all RESTRICTED ACCESS INFORMATION.

"Subject Data" means that Data first recorded in the performance of the Cooperative Work.

"DATA" means all recorded information of any kind regardless of the form or method of the recording, including computer software.

"Government" means the Government of the United States of America.

[Insert the following language if a Nondisclosure Agreement is used: The attached Nondisclosure Agreement (Appendix A) is incorporated as part of this Agreement. If there is a conflict between the terms and conditions of Appendix A and this Agreement, this Agreement shall control except for time periods].

Article 4. **PUBLICATIONS:**

Publication of DATA is of prime interest to the RECIPIENT and this Agreement shall not be interpreted to prevent or unreasonably delay publication of research resulting from the use of the **[EQUIPMENT/MATERIAL]** or modifications of the **[EQUIPMENT/MATERIAL]**. RECIPIENT agrees to provide appropriate acknowledgement of the source of the **[EQUIPMENT/MATERIAL]** in all publications. PROVIDER and RECIPIENT agree to confer and consult to provide a reasonable review period **[optional: insert time limit]** prior to the publication or presentation of DATA regarding the **[EQUIPMENT/MATERIAL]** to assure that no PROPRIETARY INFORMATION or RESTRICTED ACCESS INFORMATION is released and that patent rights are protected. Publication and/or presentation will be delayed for a reasonable time to afford needed protection. If the research is not published, the RECIPIENT shall provide a report of the research results to the PROVIDER.

Article 5. **WARRANTY:**

RECIPIENT agrees that PROVIDER makes no representations and extends no warranty of any kind, either expressed or implied regarding the **[EQUIPMENT/MATERIAL]**. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the **[EQUIPMENT/MATERIAL]** will not infringe any patent, copyright, trademark, or other rights.

Article 6. **LIABILITY:**

RECIPIENT shall be liable for damage to the **[EQUIPMENT/MATERIAL]** resulting from RECIPIENT's fault or negligence in accordance with Federal Law, excepting ordinary wear and tear occasioned by normal and ordinary usage. In no event shall RECIPIENT be liable for such wear and tear associated with the usage of the **[EQUIPMENT/MATERIAL]** or for loss, damage, or destruction prior to delivery of the **[EQUIPMENT/MATERIAL]** to the RECIPIENT. **[Optional: In the event of loss or irreparable damage to the [EQUIPMENT/MATERIAL], RECIPIENT'S maximum liability shall not exceed [insert dollar amount]].** PROVIDER agrees to defend, indemnify, and hold harmless RECIPIENT from any loss, claim, damage, or liability, of any kind, which may arise from PROVIDER's use, storage or disposal of the **[EQUIPMENT/MATERIAL]**. RECIPIENT's entire liability is as stated in the Federal Tort Claims Act, Section 2671 *et seq.*

Article 7. **RETURN OF [EQUIPMENT/MATERIAL]:**

RECIPIENT agrees that any and all **[EQUIPMENT/MATERIAL]** and PROPRIETARY INFORMATION regarding this **[EQUIPMENT/MATERIAL]** received from PROVIDER, and any copies of information, including PROPRIETARY INFORMATION, shall remain the property of PROVIDER. These items will be promptly returned or destroyed at the termination of this Agreement in accordance with the directions of the PROVIDER. All requests and responses must be in writing. The **[EQUIPMENT/MATERIAL]** and information will be returned at no expense to the PROVIDER.

Article 8. **PRE-EXISTING INTELLECTUAL PROPERTY RIGHTS:**

Except as expressly provided in this Agreement, no rights are provided to RECIPIENT under any pre-existing patents, patent applications, trade secrets or other intellectual property of PROVIDER.

Article 9. **INVENTION LICENSE OPTION:**

RECIPIENT shall retain title to any Invention of its employees made in the performance of the PURPOSE. RECIPIENT shall notify PROVIDER of the receipt of any Invention disclosure regarding use or modification of the **[EQUIPMENT/MATERIAL]**. PROVIDER has a non-exclusive license to use any improvement made by Navy RECIPIENT. RECIPIENT gives PROVIDER the option, to be exercised within one hundred eighty (180) days after the filing of a Patent Application regarding the Invention, of acquiring an exclusive license in the Government's rights in any Invention. The exclusive license will be subject to a reasonable royalty. Any exclusive license granted by the Government in an invention is subject to the statutorily required reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have that invention practiced throughout the world by or on behalf of the Government.

"Invention" means any invention or discovery which is or may be patentable under Title 35 of the United States Code.

“Patent Application” means U.S. or foreign patent application, continuation, continuation-in-part, divisional, reissue and/or reexamination on any Invention.

Article 10. **DELIVERY:**

It is agreed that the PROVIDER will deliver the **[EQUIPMENT/MATERIAL]** upon execution of this Agreement to the RECIPIENT within **[insert number]** days from the effective date of this Agreement.

Article 11. **DURATION:**

This Agreement will terminate on the earliest of the following dates:

- (1) upon completion of RECIPIENT's proposed research studies with the **[EQUIPMENT/MATERIAL]**, or
- (2) upon thirty (30) days written notice by either Collaborator to the other, or
- (3) **[insert time, not to exceed three (3) years]** from the effective date of this Agreement.

Article 12. **AMENDMENT:**

This Agreement can be amended only by a written amendment mutually agreed to and signed by the Agreement signatories or their successors.

Article 13. **ENTIRE AGREEMENT:**

This Agreement is the entire Agreement between the Collaborators concerning the PURPOSE and supersedes any prior understanding or written or oral agreement relative to the PURPOSE.

Article 14. **GOVERNING LAW:**

United States Federal Law shall govern this Agreement for all purposes.

Article 15. **FUNDS:**

It is agreed and understood that the **[EQUIPMENT/MATERIAL]** is furnished and the Agreement is entered into at no cost to the RECIPIENT.

No funds are transferred under this Agreement from the Navy RECIPIENT to the Non-Navy PROVIDER.

[If funds are transferred from Non-Navy Provider to Navy Recipient, specify amount and instructions for delivery of funds].

Checks will be payable to:

[Do not specify an individual by name but rather an organization that has the requisite authority to receive funds for the Navy].

Checks will be mailed to:

[Specify address, including the name of the authorized recipient, title, and appropriate organizational code].

Article 16. **TITLE:**

Each Collaborator shall retain title to all tangible property to which it had title prior to the effective date of this Agreement.

Article 17. **USE OF NAME OR ENDORSEMENTS:**

PROVIDER shall not use the name of the RECIPIENT or any other Government entity on any product or service that is directly or indirectly related to this Agreement without the prior approval of RECIPIENT.

Article 18. **PUBLIC RELEASE OF THIS AGREEMENT:**

This Agreement document is releasable to the public.

Article 19. **EFFECTIVE DATE:**

The effective date of this Agreement is the date of execution by the last to sign for the DURATION set in Article 11.

Article 20. **NOTICES:**

All notices will be sent to the Agreement administrators or their successors at the addresses shown in the PREAMBLE.

Article 21. **SURVIVING PROVISIONS:**

All the Articles of this Agreement shall survive its termination.

Article 22. **SIGNATURES:**

Accepted for PROVIDER:

I, the undersigned, am duly authorized to bind the **[NON-NAVY PROVIDER]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200__.
(month)

By: _____

Name:

Title:

Accepted for RECIPIENT:

I, the undersigned, am duly authorized to bind the **[NAVY RECIPIENT]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200__.
(month)

By: _____
Name:

Title:

Naval Organization:

Section III - 6

Dealing with Partnership Intermediaries

The Technology Transfer Commercialization Act of 2000 (P.L. 106-404) authorized federal laboratories to enter into contracts with partnership intermediaries to perform services that increase the likelihood of successes in the conduct of cooperative or joint activities with institutions of higher education. The Office of Naval Research Technology Transfer Office has established a process for individual Navy laboratories to enter into partnerships with such organizations.

There are three parts to this Section:

Section III - 6a Partnership Intermediary Agreement - Guidance

Section III - 6b Partnership Intermediary Agreement - Template

Section III - 6c Partnership Intermediary Agreement - Sample Memo

Section III - 6a

Partnership Intermediary Agreement - Guidance

Statutory Authority and Purpose:

The statutory authority for use of partnership intermediaries is Title 15 U.S.C., Section 3715. The Department of Navy (DoN) defines a Partnership Intermediary Agreement (PIA) as a *contract or memorandum of understanding* between a Federal laboratory and an entity known as a partnership intermediary. The PIA provides for the partnership intermediary to perform services for the Federal laboratory that increase the likelihood of success in the conduct of cooperative or joint activities with small business firms, institutions of higher education, or educational institutions.

Appropriate Partnership Intermediary Organizations:

Title 15 U.S.C., Section 3715 (c) defines a “partnership intermediary” in terms of the *organization’s structure and function*.

The *organization’s structure* must be:

- an agency of a State or local government, or
- a nonprofit entity owned in whole or in part by, chartered by, funded in whole or in part by, or operated in whole or in part by or on behalf of a State or local government.

The *organization’s function* must be to assist, counsel, advise, evaluate, or otherwise cooperate with small business firms, institutions of higher education as defined in Section 201(a) of the Higher Education Act of 1965 (Title 20 U.S.C., Section 1141(a)), or educational institutions within the meaning of Section 2194 of Title 10, United States Code.

Policy and Delegation:

Title 15 U.S.C., Section 3715 provides that the Director of a Federal laboratory, or in the case of a federally funded research and development center that is not a laboratory (as defined in Section 3710), a Federal employee who is the contract officer, may enter into a PIA, subject to the approval of the Secretary of the agency.

DoD Instruction 5535.8, DoD Technology Transfer (T2) Program of 14 May 1999, encourages use of partnership intermediaries and delegation of authority for their use.

The Secretary of the Navy, by Reference (b), delegated authority to enter into PIAs to the Chief of Naval Research (CNR). Reference (b) permits the CNR to transfer this authority to the heads of the DON laboratories. This transfer is anticipated to occur once the DON has developed sufficient expertise in the use of PIAs. Requests to sign individual PIAs must be forwarded to ONR in accordance with the procedures provided in Enclosure (1).

Navy Model Agreement:

The DON provides a model PIA (Enclosure (2)). This model Agreement has been developed specifically to conform to legislative and policy regulations and serves as the memorandum of understanding referenced in Title 15 U.S.C., Section 3715. It is not a procurement contract for services.

Funding Options:

Under a PIA, the DON laboratory and/or technical activity may, but is not required to, pay the Federal costs of the PIA out of funds available for the support of its technology transfer function. An appropriate, separate instrument for funding will have to be executed if money is being transferred.

The DON may not receive funds under a PIA.

Legal Review:

Legal review is obtained at the laboratory to ensure compliance with the laboratory mission, statutes, regulations, instructions and executive directives. If the model PIA is changed, the modification is noted and a written explanation of its necessity is reviewed by local legal counsel and is included with the Agreement when it is forwarded to ONR.

Signature Process:

Prior to signature of a PIA, the laboratory commanding officer submits a written memorandum to ONR requesting signature authority. The memorandum includes the following attachments:

- a copy of the PIA;
- a copy of the laboratory legal review including justification of any modifications to the model PIA.

The memorandum and attachments should be mailed to:

Office of Naval Research
Technology Transfer Program, Code 03TSB
875 North Randolph Street
Arlington, VA 22203-1995

An e-mail response from ONR will be sent to the laboratory point of contact acknowledging receipt of the request. Signature authority should be granted within thirty (30) days following the ONR acknowledgement.

The PIA signature authority is granted to the laboratory commanding officer on receipt of an approval memorandum from the CNR.

After approval from CNR, the PIA must be signed by the partnership intermediary and the commanding officer of the laboratory. If the activity is a federally funded research and development center, the Federal employee who is the contract officer must sign the PIA.

Navy laboratory technology transfer personnel may solicit advice and consultation on any PIA issues, at any time. Please direct inquiries to Ms. Dottie Vincent at 703-696-4792 or e-mail at dorothy.vincent@navy.mil.

Actions after Signature:

A hardcopy and an electronic copy of the signed PIA, along with any other supporting documents, should be forwarded to ONR at the address cited above.

The manager of the Office of Research and Technology Applications (ORTA) at each laboratory is to enter information on the PIA into the DTTIS database. The ORTA manager is also to include information on PIAs in the annual technology transfer business plan submitted to ONR and Department of Defense.

Through use of the DTTIS database, ONR will maintain a record of the activities carried out pursuant to each PIA sufficient to support discussion and evaluation of the PIA in terms of their stimulation of productivity, technology and innovation. The information will be included in the triennial report by the Secretary of Commerce to Congress.

PARTNERSHIP INTERMEDIARY AGREEMENT (PIA)

BETWEEN

[NAVY ACTIVITY]

AND

[PARTNERSHIP INTERMEDIARY]

AGREEMENT NUMBER: PIA-**[Navy Org.]**-**[last two digits of CY]**-**[serial number]**

AGREEMENT ADMINISTRATORS:

[NAVY ACTIVITY]

Technology Transfer Office

Point of Contact:

[insert name, organizational code, telephone number, e-mail address]

Legal Counsel:

[insert name, organization code, telephone number, e-mail address]

[PARTNERSHIP INTERMEDIARY]

Preferred Contact:

[insert name, telephone number, e-mail address]

Legal Counsel:

[insert name, telephone number, e-mail address]

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PARTNERSHIP INTERMEDIARY AGREEMENT (PIA)

BETWEEN

[NAVY ACTIVITY]

AND

[PARTNERSHIP INTERMEDIARY]

PREAMBLE

Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), (hereinafter referred to Title 15 United States Code, (U.S.C.), Section 3715) **[NAVY ACTIVITY]**, located at **[supply appropriate address]**, and **[Partnership Intermediary]**, whose headquarters are located at **[supply appropriate address]**, (hereinafter referred to individually as a "Party" or collectively as the "Parties") enter into this Partnership Intermediary Agreement (PIA), which shall be binding upon the Parties according to the clauses and conditions hereof and for the term and duration set forth.

The Parties agree as follows:

Article 1. DEFINITIONS

1.1. The term "Agreement" as used herein shall mean a PIA as authorized by Title 15 U.S.C., Section 3715 for performance of partnership intermediary services. This Agreement is neither a procurement contract subject to the Federal Acquisition Regulation, nor a support agreement subject to the DoD Grant and Agreement Regulations.

1.2. The term "Data" means recorded information of any kind regardless of the form or method of recording.

1.3. The term "Federal Laboratory" means any organization defined in Title 15 U.S.C., Section 3703(6), as amended.

1.4. The term "Government" refers to the United States Government.

1.5. The term "Invention" means any discovery or invention that is or may be patentable or otherwise protected under Title 35, U.S.C., or any novel variety of plant that is or may be patentable under the Plant Variety Act (Title 15 U.S.C., 3703(9)).

1.6. The term "License Agreement" shall mean an agreement to license a Federally-owned invention under Title 35 U.S.C., Section 207-11 and 37 C.F.R. Part 404.

1.7. The term "Proprietary Information" shall mean information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged and confidential provided that such information: is not known or available from other sources without obligations concerning its confidentiality; has not been made available by the owners to others without obligation concerning its confidentiality; is not already available to the Government without obligation concerning its confidentiality; or has not been developed independently by persons who have had no access to the information.

Article 2. PARTIES

2.1. The **[Navy Activity]** **[provide description]**.

2.2. The **[Partnership Intermediary]** **[provide a description that includes a citation to the legal authority establishing the Partnership Intermediary and its mission statement]**.

Article 3. BACKGROUND AND PURPOSE

3.1. Title 15 U.S.C., Section 3715 (Use of Partnership Intermediaries) specifically authorizes the Director of a Federal Laboratory to enter into memoranda of understanding and contracts with State and local governmental agencies and nonprofit entities owned, chartered, funded, or operated by or on behalf of a State or local government to perform partnership intermediary services that increase the likelihood of success in the conduct of cooperative or joint activities with small business firms and educational institutions that need or can make demonstrably productive use of technology-related assistance from a Federal Laboratory. These services include the promotion of cooperative or joint activities with small business firms and educational institutions that need or can make demonstrably productive use of technology-related assistance from Federal Laboratories.

3.2. The purpose of this Agreement is to promote cooperative activities between **[Navy Activity]** and small business firms and educational institutions served by **[Partnership Intermediary]**. The services to be provided by **[Partnership Intermediary]** as hereinafter described are intended to **[insert purpose as authorized under the Statute]**.

Article 4. DESIGNATED REPRESENTATIVES

4.1. The **[Navy Activity]** designated representative responsible for coordination of activities under this Agreement is **[insert name and position of representative]**. The **[Navy Activity]**'s representative will coordinate directly with the designated **[Partnership Intermediary]** representative.

4.2. The **[Partnership Intermediary]**'s designated representative responsible for coordination of activities under this Agreement is **[name and position of the representative]**. The **[Partnership Intermediary]** representative will coordinate directly with the designated **[Navy Activity]** representative.

Article 5. AGREEMENT ACTIVITIES

5.1. To accomplish the purposes of this Agreement, the Parties' representatives will engage in discussions and use their best efforts to identify activities under which small business firms and educational institutions can make demonstrably productive use of technology-related assistance from **[Navy Activity]**. The Parties will use their best efforts to accomplish the purpose of this Agreement.

5.2. [Optional] Licensing **[Navy Activity]** Inventions. **[Navy Activity]** will identify to **[Partnership Intermediary]** such of its Inventions that are available for licensing. **[Partnership Intermediary]** will attempt to locate and identify to **[Navy Activity]** small businesses and educational institutions within its area of responsibility that have an interest in licensing **[Navy Activity]** Inventions. **[Navy Activity]** will engage in discussions with such interested businesses and educational institutions as are identified to it with a view toward reaching a patent license agreement. Such discussions and

any resulting license agreement will be accomplished in full accordance with all applicable Federal laws and regulations. **[Partnership Intermediary]** may choose to participate in the license discussions and provide such other assistance to interested small businesses or educational institutions as is consistent with its corporate charter.

5.3. [Optional] Submission of Research Proposals to **[Navy Activity]**. **[Navy Activity]** will identify to **[Partnership Intermediary]** areas of **[Navy Activity]** research and development activities where the submission of proposals are desired under the **[Navy Activity]** Broad Agency Announcement (BAA). The **[Navy Activity]** BAA is issued under the provisions of paragraphs 35.016 and 6.102(d)(2) of the Federal Acquisition Regulation (FAR). These provisions provide for the use of BAA's by agencies to fulfill requirements for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. **[Partnership Intermediary]** will attempt to locate small businesses and educational institutions interested in submitting proposals, advise those interested in proposal requirements, and provide such other assistance as is within its charter to perform. All proposals received will be considered by **[Navy Activity]** in accordance with applicable Federal laws and regulations.

5.4. [Optional] **[Navy Activity]** Support For Outside Activities. **[Navy Activity]** will identify to **[Partnership Intermediary]** research and development capabilities of **[Navy Activity]** that may be made available to small businesses and educational institutions that need or can make use of technology-related assistance from **[Navy Activity]**. **[Partnership Intermediary]** will attempt to locate and advise such small businesses and interested educational institutions of the availability of such capabilities and the related procedures and conditions. In the preparation and submission of proposals, **[Partnership Intermediary]** may choose to participate and provide such other assistance to interested small businesses or educational institutions as is consistent with its corporate charter. **[Navy Activity]** will fully consider all requests submitted for such support. All support will be provided as appropriate in accordance with applicable Federal laws and regulations.

5.5. [Optional] Technology Marketing Programs and Showcases. **[Navy Activity]** and **[Partnership Intermediary]** will cooperate in planning and presenting various programs that showcase **[Navy Activity]** technology and research and development areas of interest.

5.6. [Optional] Small Business and Educational Institution Technology and Capabilities. **[Partnership Intermediary]** will sponsor activities and programs that showcase the technology and capabilities of small businesses and educational institutions within its area of responsibility that may be of interest to **[Navy Activity]** in connection with its research and development mission.

5.7. [Optional] **[Navy Activity]** **[may describe other activities that are authorized within the scope of Title 15 U.S.C., Section 3715]**.

Article 6. FUNDING

6.1. Other than as expressly provided herein, no funds of either Party are in any way committed or obligated for any purpose whatsoever by virtue of entering into this Agreement. This Agreement does not identify or require the transfer of funds between the Parties. This Agreement shall not be construed to authorize or guarantee funding for any proposals submitted in response to any solicitation, nor shall it be construed as a guarantee of future funding. Nor shall this Agreement be construed as an endorsement of any proposal submitted by any Party or non-Party.

6.2. Each Party shall be responsible for funding its own activities under this Agreement, except as expressly provided herein. Each Party is individually responsible for assuring that its funding commitments are fully in accordance with all fiscal requirements and restrictions applicable to it by law and regulation.

Article 7. INTELLECTUAL PROPERTY

7.1. In the event that employees of the Parties make an Invention or produces technical Data while performing the Agreement activities, each Party shall have title to the Data or Invention made or produced by its employees. Inventions made and Data produced jointly by those employees, shall be jointly owned by the Parties in the form of an equal and undivided interest in the title.

7.2. Rights in intellectual property created under a separate agreement resulting from this Agreement shall be determined in accordance with the terms of the separate agreement.

7.3. No rights in any intellectual property are conveyed or granted by or under this Agreement.

Article 8. PROPRIETARY OR PROTECTED INFORMATION

8.1. During performance of activities under this Agreement, the Parties may require access to Proprietary Information of each other and non-Party small businesses and educational institutions identified by **[Partnership Intermediary]**. Likewise, such non-Party small businesses and educational institutions may require access to information about patentable **[Navy Activity]** Inventions that are exempted from disclosure under Title 35 U.S.C., Section 205 (Confidentiality). The Parties agree to use their best efforts to enter into agreements with each other and any non-Party entities as may be necessary to protect such information from unauthorized use or disclosure and to refrain from using such information for any purpose other than that for which it was furnished.

8.2. No exchange of information under this Agreement is intended to convey to the receiving Party any license or other rights in such information unless otherwise expressly provided in writing by the disclosing Party.

Article 9. GENERAL PROVISIONS

9.1. Relationship of the Parties. The relationship of the Parties is that of independent parties and not as agents of each other, partners, or participants in a joint venture.

9.2. Security. Performance of work under agreements with small businesses and educational institutions established as the result of this Agreement may require access to classified information and secure facilities. Performers of such work may be required to qualify in accordance with applicable security regulations.

9.3. Export Control. Work on certain **[Navy Activity]** research projects may involve militarily critical technology or information the export of which is restricted by statute, executive order, or regulation (including, but not limited to, the Arms Export Control Act, the International Traffic in Arms Regulation, the Export Administration Act). The Party desiring to export shall ensure full compliance with all applicable requirements and restrictions before it makes any disclosure that may be deemed an export of such information. Nothing in this article is intended to waive any requirements imposed by any other U.S. Government agency with respect to disclosure of export controlled information or militarily critical technology to foreign nationals.

9.4. Liability.

9.4.1. Government Liability. **[Navy Activity]** is an activity of the U.S. Government. As such, the sovereign immunity of the United States applies to the activities of **[Navy Activity]**. The Government shall be liable for the negligent or wrongful acts of its officers and employees to the extent provided for in the Federal Tort Claims Act (Title 28 U.S.C., Section 2671 *et seq.*) and other applicable laws and regulations of the United States that specifically waive sovereign immunity. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the United States.

9.4.2. **[Partnership Intermediary]** Liability. **[Partnership Intermediary]** is a state chartered corporation and public instrumentality of the **[indicate State or Commonwealth]**. **[Partnership Intermediary]** and the **[indicate State or Commonwealth]** shall be solely responsible for the actions of **[Partnership Intermediary]** employees and the actions of those acting for it in the performance of this Agreement to the extent provided for under the applicable provisions of the State law. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the **[indicate State or Commonwealth]** in accordance with **[provide citation]**.

9.4.3. *Force Majeure*. Neither Party shall be liable for the consequences of a *force majeure* that (1) is beyond its reasonable control; (2) is not caused by the fault or negligence of such Party; (3) causes such Party to be unable to perform its obligations under this Agreement; and, (4) cannot be overcome by the exercise of due diligence. In the event of the occurrence of a *force majeure*, the Party unable to perform shall notify the other Party. The Parties shall suspend performance only for such period of time as is necessary to overcome the result(s) of the *force majeure* and shall use their best efforts to resume performance as quickly as possible.

9.5. Savings Provision. The illegality or invalidity of any provisions of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.

9.6. Applicable Law. The Parties agree that the laws of the United States of America shall govern this Agreement for all purposes. In the absence of governing Federal law, the laws of the **[identify State or Commonwealth]** shall apply.

9.7. Termination of the Agreement.

9.7.1. Termination by Mutual Consent. The Parties jointly may elect to terminate this Agreement at any time by mutual consent.

9.7.2. Unilateral Termination. Either Party may elect to terminate this Agreement at any time by giving to the other Party not less than thirty (30) days advance written notice of the intent to terminate and the effective date of termination.

9.7.3. Survivability. Article I. DEFINITION, Article VI. FUNDING, Article VII. INTELLECTUAL PROPERTY, Article VIII. PROPRIETARY OR PROTECTED INFORMATION, Article IX. GENERAL PROVISIONS, Article X. PUBLICATIONS, shall survive the completion, termination or expiration of this Agreement. **[Other articles may be added to this list if deemed desirable]**.

9.8. Duration of the Agreement. This Agreement shall remain in effect for **[insert number]** months from its effective date unless previously terminated or extended as provided by this Agreement. The Parties may by mutual written agreement extend the term of the Agreement.

9.9. Property. Each Party shall retain title to all tangible property that it has acquired by purchase or gift and used in performance of tasks under this Agreement.

9.10. Titles and Headings. Titles and headings of the sections and subsections of this Agreement are for convenience of reference only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

9.11. Agreement Not An Exclusive Agreement. The rights granted by **[Navy Activity]** to **[Partnership Intermediary]** under this Agreement to perform the services of this Agreement are not exclusive. The Government may grant permission to other entities to perform the same or similar services at any time.

9.12. Entire Agreement. This Agreement constitutes the entire Agreement between the Parties concerning the subject matter hereof and supersedes any prior understanding or written or oral agreement relative to said matter.

9.13. Reports.

9.13.1. Annual Report. **[Partnership Intermediary]** shall submit to **[Navy Activity]** an annual report summarizing its efforts in furtherance of this Agreement. The report should provide a concise and factual discussion of the results of its efforts to include: a listing of small businesses and educational institution contacts; agreements entered by **[Navy Activity]** with small businesses and academic institutions that it identified; significant accomplishments resulting from those agreements (publications, technological developments, inventions, patents, product development and sales, etc.); any measurable effect upon community business and employment; lessons learned and recommendations for improvement; and such other information deemed pertinent by **[Partnership Intermediary]**.

9.13.2. Final Report. **[Partnership Intermediary]** shall submit a final report summarizing the entire effort during the term of the Agreement in the same topic areas required for the annual report.

9.14. Disputes. The Parties agree to use reasonable efforts to reach a fair settlement of any dispute. If such efforts are unsuccessful, remaining issues in dispute will be referred to the signatories or their successors for resolution.

9.15. Waivers. No provision of this Agreement shall be considered waived by any Party hereto unless such waiver is given in writing to the other Party. The failure of any Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any right provided herein or by law, shall not be deemed a waiver of any right of any Party hereto.

9.16. Amendments. The Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. Such modification shall be effective upon the date of the last signature of the authorized representatives of each of the Parties.

9.17 Use of Name or Endorsements. Neither Party shall use the name of the other Party on any product or service which is directly or indirectly related to this Agreement without the prior approval of the other Party. By entering into this Agreement, neither Party directly or indirectly endorses any product or service provided, or to be provided, by the other Party, its successors, assignees, or licensees. Neither Party shall imply in any way that this Agreement is an endorsement by the other Party of any product or service.

9.18 Notices. All notices are to be sent to the PIA administrators.

Article 10. PUBLICATIONS

10.1. Publication of Results. **[Partnership Intermediary]** is encouraged to publish results of the Agreement. Each article planned for publication shall be submitted to the **[Navy Activity]** designated representative for review and approval prior to submission for publication.

10.2. Governmental Use. Any publication based on or developed under this Agreement will reflect that the U.S. Government is licensed to reproduce and distribute the article for Governmental purposes notwithstanding any copyright or other restrictive legends.

10.3. Disclaimer. Published articles shall contain the statement that "the views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the Department of the Navy or the U.S. Government."

Article 11. EFFECTIVE DATE

11.1 This Agreement shall become effective upon the date of the last signature of the authorized representatives of each of the Parties.

Article 12. SIGNATURES

For **[Partnership Intermediary]**:

I, the undersigned, am duly authorized to bind **[Partnership Intermediary]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200____.
(month)

By: _____

Name:

Title:

Address:

For **[Navy Activity]**:

I, the undersigned, am duly authorized to bind **[Navy Activity]** to this Agreement and do so by affixing my signature hereto.

Entered into this _____ day of _____ 200____.
(month)

By: _____

Name:

Title:

Address:

Section III - 6c

Partnership Intermediary Agreement - Sample Memo

From: **[Navy Activity]**

To: Chief of Naval Research

Subj: PROPOSED NAVY PARTNERSHIP INTERMEDIARY AGREEMENT BETWEEN **[NAVY ACTIVITY]** AND **[PARTNERSHIP INTERMEDIARY]**

Ref: (a) SECNAVINST 5700.16A, "Domestic Technology Transfer (T2)," of 7 March 2000

(b) SECNAV Memorandum "Delegation of Authority to Approve Partnership Intermediary Agreements Under 15 U.S.C., Section 3715 of 25 July 2002

Encl: (1) Partnership Intermediary Agreement (PIA) between **[Navy Activity]** and **[Partnership Intermediary]**

(2) **[Navy Activity]** Written Legal Review of PIA

1. Pursuant to references (a) and (b), a Partnership Intermediary Agreement (PIA) Enclosure (1), between **[Navy Activity]** and **[Partnership Intermediary]** is forwarded for your review and comment. The **[Navy Activity]**'s designated representative responsible for coordination of the activities under this Agreement is **[supply name and organizational code]**, who is the Office of Research and Technology Applications representative and head of the **[Navy Activity]** Technology Transfer Office.
2. All key legal and technical personnel involved at **[Navy Activity]** and **[Partnership Intermediary]** have reviewed the proposed PIA (Enclosure 2), and found it acceptable.
3. I request authority to sign this PIA.

Signature Block

Section III - 7

If the Navy is using a Third Party Contractor and a Subject Invention is Made as a result of the work under a CRADA, the Bayh-Dole rights may be waived by the Contractor with a License Grantback Agreement.

License Grantback Agreement

Patent Application Title: **[Insert Title as on Patent Application]**
Contractor Inventor(s): **[Insert Name(s) as in Patent Application]**
Government Inventor(s): **[Insert Name(s) as in Patent Application]**
Contractor: **[Insert Full Name and Acronym if Any]**
Contract No.: **[Insert Full Navy Contract Number]**
Government Entity: **[Insert Full Name and Acronym, of Government Agency, Department, or Laboratory]**
Agency Docket Nos.: **[Insert Appropriate Assigned Number]**
Inventions: Patent Application No. **[Insert Number]**

License Grant: The Contractor has retained nonexclusive royalty-free license throughout the world in each subject invention in the inventions under FAR 52.227-11. The Contractor hereby relinquishes its nonexclusive royalty-free license throughout the world in each subject invention and grants back to the Government all right, title and interest in and to each subject invention.

Duration: This License shall be in effect until the expiration of the above-referenced U.S. patent applications, including any substitution, division, continuation-in-part, continuation, foreign counterpart and/or reissue and any US or foreign patents that issue therefrom, or until all exclusive or partially exclusive licenses executed by NRL in accordance with applicable provisions at 37 CFR part 404 are terminated, whichever is earlier.

Governing Law: This License shall be governed by and construed in accordance with applicable United States Federal Law, Regulations, Directives, and Instructions.

Signed this _____ Day of _____, 20xx.

I, the undersigned, verify that I am empowered to bind the company and that the company agrees to be bound to this License Grantback Agreement and do so by affixing my signature hereto.

By:

Name and title

[Insert Full Contractor Name]

SECTION IV

EXAMPLES

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Section IV - 1

Non-Disclosure Agreements - Explanation

Non-disclosure agreements are used by industry to protect their proprietary data. The Government protects data by having Non-Federal Collaborators sign non-disclosure agreements. Federal employees are forbidden by statute from disclosing proprietary information received from a contractor. Federal employees are discouraged from signing non-federal non-disclosure agreements because signing such an agreement puts only the signatory at risk, not the local laboratory or the Department of the Navy. The following examples are for a non-disclosure agreement signed by industry when receiving Government information or data and two examples are presented for non-disclosure agreements which can be given by a Federal employee to a non-federal party citing the statutes that the Government employee must honor.

Important references dealing with government disclosure include the following:

- i) 5 U.S.C. § 552(b)(4) (Freedom of Information Act), *available at* <http://www4.law.cornell.edu/uscode/5/552.html>;
- ii) Executive Order 12600 (Predisclosure Notification Procedures for Confidential Commercial Information), *available at* http://www.cftc.gov/foi/foiareference/foia_execorder12600.html;
- iii) 18 U.S.C. § 1905 (Trade Secrets Act), *available at* <http://www4.law.cornell.edu/uscode/18/1905.html>;
- iv) 18 U.S.C. § 1831 *et seq.* (Economic Espionage Act), *available at* <http://www4.law.cornell.edu/uscode/18/plch90.html>; and

Section IV - 1a

Non-Disclosure Agreement for Industry - Example 1

Naval Surface Warfare Center, Panama City Division Non-Disclosure Agreement

01 - ND - NSWC PCD - XXX

This Agreement is entered into by **[insert name, organization, and address]**, (hereafter the Recipient) for the benefit of the Government of the United States of America (hereafter the Government) in consideration of disclosure by the Government, as represented by the Naval Surface Warfare Center, Panama City Division (NSWC PCD), Department of the Navy, of data collected by the United States Government.

NSWC PCD is the holder of **[specify what type of information is being offered by the Government, i.e., sonar data, CAD/CAC algorithms, XYZ sensor etc.]** in which the Government owns or may own a right or interest.

Recipient is desirous of obtaining advance information concerning **[specify precise exchange item]** for the purpose of evaluation. Recipient hereby agrees, in consideration of disclosure to recipient of such information by NSWC PCD, to protect such information in accordance with the terms and conditions of this Agreement.

Recipient agrees that it will use the information for purposes of evaluation only, and that it will disclose the information only to the Recipient's employees and associates who have a need to know the information for such purposes and who are under an obligation to the Recipient not to further disclose to any other person and use it for any other purpose.

All information that is subject to this Agreement shall be in writing and marked with the following legend:

Restricted Information

This information has been made available in confidence for purpose of evaluation only, and may not be further disclosed, or used for any other purpose, without written authorization from Counsel, Naval Surface Warfare Center, Panama City Division, 110 Vernon Avenue, Panama City, Florida 32407.

In the event that Recipient receives an oral disclosure of information that is protectable under this Agreement but has not previously been received in written form, Recipient is under no obligation to hold such orally disclosed information in confidence unless reduced to a writing received by Recipient within one month from the date of oral disclosure and marked with the above identified legend. Recipient agrees to hold such oral disclosures in confidence under the terms of this Agreement until expiration of the one-month period.

Recipients obligation under this agreement shall remain in effect for a period of five (5) years after the date of execution by recipient, or until release of Recipient from any or all obligations under this Agreement is obtained in writing from Counsel, NSWC PCD.

Recipients obligation under this Agreement shall not extend to: (1) Information that is already in the possession of the Recipient; (2) Information that is available to the public; (3) Information that subsequently becomes available to the public; (4) Information that is subsequently developed within the Recipients organization independently, without knowledge of information subject to this Agreement; and (5) Information that is obtained by Recipient from some another source without restriction.

Recipient agrees that neither the Government nor any person acting on its behalf will be responsible for any injury, damage, or loss of any kind whatsoever fro use of the information provided under this Agreement.

IN WITNESS WHEREOF, Recipient, by its authorized representative, has executed the Agreement.

Recipient

By: _____

Name: _____

Title: _____

Date: _____

This attachment to the Non-Disclosure Agreement may be useful if your laboratory requires data on each person having access to the material/information described in the Non-Disclosure Agreement.

Personnel Information

Name _____

Organization _____

Mailing Address _____

City _____ State _____

Country _____ Postal Code (Zip) _____

Email Address _____

Office Phone _____ FAX _____

Social Security Number * _____

Date of Birth _____ Place of Birth _____

US Citizen Yes No (circle the correct response)

INS Number if Naturalized _____

Highest Level Security Clearance Held _____

* Used only if security clearance is needed.

Note: When the recipient/signatory of this Agreement is another Government Agency, its purpose is to give notice and to give record of the date of transfer. The notice is to handle the information as Government proprietary pending patent filings and any commercial actions being undertaken.

Section IV - 1b

Bilateral Non-Disclosure Agreement - Example 2

This Agreement is made by and between **[Navy Collaborator]**, a United States Federal Government Laboratory of the Department of the Navy, located at **[Navy Collaborator address]** and **[Non-Navy Collaborator]**, whose principal address is located at **[Non-Navy Collaborator address]**, **[hereinafter referred to individually as a Party or collectively as the Parties]** to facilitate the following described "Stated Purpose" by protecting non-public and proprietary information from misuse and unauthorized disclosure. This Agreement shall become effective upon the date of last signature by the authorized representatives of each of the Parties.

Subject Matter and Stated Purpose:

- a. The general subject of information to be exchanged is **[Insert Subject]** including technology relating to **[Navy Collaborator]** inventions claimed the following:

[List any Navy cases, patent applications or patents that are related to the subject. Note: Everything in this sentence following the work "including" can be omitted if there are no Navy Collaborator-owned inventions.]

- b. The Stated Purpose of this Agreement is **[insert purpose for exchanging information, e.g. evaluation of Navy-Collaborator technology, possible licensing of Navy-Collaborator technology, etc.]**

The Parties Agree as Follows:

1. Definitions and Specific Requirements. As used in this Agreement, the following terms shall have the meanings as defined.
 - 1.1. Information. As used in this Agreement, the term "Information" includes, but is not limited to, knowledge relating to research, inventions, trade secrets, technology (including designs and specifications of components and systems, the composition of matter, methods and processes, machines and articles of manufacture, applications, and performance data), and business and financial records.
 - 1.2. Disclosure of Information. As used in this Agreement, "Disclosure of Information" shall mean the exchange of Information orally, visually, or on any human or machine readable medium including, but not limited to, oral and visual expressions, demonstrations, audio tapes, video tapes, drawings, computer memory devices, models, prototypes and samples.
 - 1.3. Disclosing Party. As used in this Agreement, "Disclosing Party" shall mean the Party making a Disclosure of Information to the other. Under this Agreement, either or both Parties may be a Disclosing Party.
 - 1.4. Receiving Party. As used in this Agreement, "Receiving Party" shall mean the Party receiving a "Disclosure of Information" from the other. Under this Agreement, either or both Parties may be a Receiving Party.

- 1.5. Protected Information. As used in this Agreement, "Protected Information" shall mean Information provided by a Disclosing Party to a Receiving Party under this Agreement that has been clearly identified through the use of an appropriate marking that puts the Receiving Party on notice that the Disclosing Party considers the Information to be Protected Information under the terms of this Agreement. Protected Information shall not include, and the identification of Information as Protected Information shall not affect the rights of the Parties to use or disclose, Information that:
 - 1.5.1. Was available in the public domain at the time of disclosure and receipt, or subsequently becomes available in the public domain from a source other than the Receiving Party, or
 - 1.5.2. Was in the possession of or known by the Receiving Party prior to the time of the receipt from the Disclosing Party, or
 - 1.5.3. Becomes available to the Receiving Party without restriction as to its disclosure or use from a third party under circumstances permitting its disclosure by the Receiving Party, or
 - 1.5.4. Is developed at any time by or for the Receiving Party independently of the Protected Information.

- 1.6. Appropriate Markings. As used in this Agreement, "Appropriate Markings" shall mean any reasonable method by which a Disclosing Party clearly identifies to a Receiving Party that Information is being disclosed under this Agreement, and is considered by the Disclosing Party to be Protected Information. Protected Information that is disclosed in tangible form shall be clearly marked with a human readable legend, stamp or other written identification prominently affixed or attached to the medium in which the Information is conveyed. This human readable legend, stamp, or other written identification shall reference this Agreement, or shall identify the date that the Receiving Party's obligations with respect to the Protected Information will expire. Use of the marking "Protected Information" is preferred, but the Parties will also recognize other appropriate markings such as "Sensitive Information," "Proprietary Information," "Non-Disclosure Information," and "Business Sensitive Information". The terms Confidential, Secret and Top Secret are established security classifications within the U.S. Government and shall not be used to mark or identify Information as Protected Information.
 - 1.6.1. If Protected Information is disclosed orally or visually in an intangible form, the Disclosing Party shall, prior to disclosure, provide oral or written notice to the Receiving Party that it considers the Information to be Protected Information, and the Receiving Party shall treat such intangible Information as Protected Information. Within thirty (30) calendar days after notice and disclosure, the Disclosing Party shall provide an appropriately marked written summary of the intangible Information to the Receiving Party. If a properly marked written summary is not provided by the Disclosing Party within thirty (30) calendar days, the Information previously conveyed in intangible form will not be Protected Information under this Agreement.

1.6.2. If a Receiving Party has any objection to a marking placed on Information or to any summary of intangible Information transferred to it by the Disclosing Party as Protected Information, the Receiving Party shall, within ten (10) working days of receipt of such Information or summary of intangible Information, bring such objection to the attention of the Disclosing Party. If the Parties are unable to mutually resolve the objection, the Receiving Party shall immediately return the challenged Information or summary to the Disclosing Party.

2. Authorized Access and Disclosure.

- 2.1. A Receiving Party shall not use or disclose Protected Information other than in accordance with the terms and conditions of this Agreement.
- 2.2. A Receiving Party shall take reasonable and appropriate measures to safeguard Protected Information from misuse, theft, loss, destruction, and unauthorized disclosure. Such measures shall be no less than that degree of care the Receiving Party normally takes to preserve and safeguard its own proprietary Information. The Parties shall not be liable for the use or disclosure of Protected Information used or disclosed despite the exercise of reasonable care provided that, upon discovery of any unauthorized use or disclosure, it promptly notifies the Disclosing Party in writing and takes action to prevent further disclosure and to recover any Protected Information already disclosed.
- 2.3. If Protected Information is included in any analyses, reports, or other documents or physical embodiments prepared by the Receiving Party, all such documents and embodiments shall be appropriately protected by the Receiving Party in the same manner as the Receiving Party protects the source Protected Information.
- 2.4. A Receiving Party may provide access to Protected Information to its own employees who reasonably require such access in order to accomplish the Stated Purpose of this Agreement. Prior to being granted access to Protected Information, employees of a Receiving Party shall be advised concerning the requirements and restrictions of this Agreement, directed to use and protect the Protected Information properly, and not to disclose Protected Information without proper authorization. The Receiving Party will document which of its employees have been granted access to Protected Information and so advise the Disclosing Party upon request.
- 2.5. A Receiving Party may provide access to Protected Information to its agents, service contractor employees, collaborators and other non-Parties to this Agreement who reasonably require such access in order to accomplish the Stated Purpose of this Agreement. Before any such non-Party organizations or individuals are granted access to Protected Information, the Receiving Party shall notify and obtain the concurrence of the Disclosing Party. The Receiving Party shall also require non-Party organizations and individuals (other than U.S. Government officers and employees who are prohibited by the Trade Secrets Act, 18 U.S.C. 1905, from making unauthorized use or disclosure of Protected Information) to execute the Supplemental Agreement at Appendix I prior to disclosing any Protected Information.

- 2.6. A Receiving Party shall not disclose Protected Information to any person (including its own employees), nor shall a Receiving Party export any Protected Information from the United States, if such disclosure or export would violate the Arms Export Control Act, the International Traffic in Arms Regulation (22 C.F.R. Part 121 et seq.), the Export Administration Act, the Department of Commerce Export Regulation (15 C.F.R. Part 770 et seq.), the DoD Industrial Security Regulation (DoD 5220.22-R), or any other law or regulation of the United States. A Receiving Party shall first obtain the written consent of the Disclosing Party before requesting authority to export Protected Information from the United States.
- 2.7. The following individuals are designated as the principal points of contact for the transmittal and receipt of Protected Information under this Agreement.

For **[Navy Collaborator]:**

[Name]

[Phone (optional, but recommended)]

[E-Mail (optional, but recommended)]

For **[Non-Navy Collaborator]:**

[Name (optional, but recommended)]

[Phone (optional, but recommended)]

[E-Mail]

3. General Provisions.

- 3.1. All Protected Information owned by a Disclosing Party shall remain the property of the Disclosing Party. Protected Information in tangible form may be retained in the possession of the Receiving Party after termination or expiration of this Agreement only to the extent expressly authorized by the Disclosing Party. Within thirty (30) days after termination or expiration of this Agreement, or upon receipt of a written demand from the Disclosing Party for the return of Protected Information, the Receiving Party shall promptly return (or destroy, if so requested) all tangible forms of Protected Information received from the Disclosing Party. If destruction is requested, the Receiving Party will provide written notification to the Disclosing Party certifying that the destruction has been accomplished.
- 3.2. If samples, models, prototypes, computer programs, or other such embodiments are disclosed as Protected Information, the Receiving Party will not attempt to reverse engineer or otherwise analyze such items unless the written approval of the Disclosing Party is obtained prior to engaging in reverse engineering or analysis.
- 3.3. Each Party shall bear its own costs and expenses incurred under or in connection with this Agreement. Nothing in this Agreement shall be construed as an obligation by either Party to enter into a contract, subcontract, or other business relationship with the other Party.
- 3.4. This Agreement shall not be construed as a Teaming Agreement, Joint Venture, or any other such agreement nor shall it be construed as a commitment to procure or provide any specific products or services. Nothing contained herein shall be construed to grant or confer any rights other than to use the Protected Information for the Stated Purpose under the terms of this Agreement, nor shall anything herein be construed to grant license or other rights to any patents, trademarks, copyrights or other intellectual property whatsoever. The Parties expressly agree that this is an Agreement for protecting Information only.

- 3.5. A RECEIVING PARTY SHALL ACCEPT ALL PROTECTED INFORMATION AND EMBODIMENTS THEREOF ON AN "AS IS" BASIS. THE DISCLOSING PARTY MAKES NO WARRANTY OR REPRESENTATION OF MERCHANTABILITY OR FITNESS FOR ANY PURPOSE.
- 3.6. Either Party, upon thirty (30) days written notice to the other Party, may terminate this Agreement.
 - a. Duration. Unless sooner terminated, this Agreement shall expire **five (5) years** from its effective date.
 - b. Effective Period. Notwithstanding the termination or expiration of this Agreement, all obligations incurred by a Receiving Party with respect to protection, use, disclosure and return or destruction of Protected Information shall survive and remain in effect for **five (5) years** from the date the Protected Information was received.
- 3.7. This Agreement may not be assigned by either Party without the prior express written authorization of the other Party. All obligations incurred by a Receiving Party under this Agreement with respect to Protected Information shall be binding on its authorized successors and assigns.
- 3.8. This Agreement shall be governed by the Federal laws of the United States.
- 3.9. In the event a Receiving Party is subjected to any legal process that seeks to require it to produce Protected Information for inspection or review in a judicial or administrative proceeding, the Receiving Party shall promptly provide notice and a copy of the legal process to the Disclosing Party in order that the Disclosing Party may have an opportunity to challenge the legal process or seek a protective order. If, in the absence of a protective order, a Receiving Party is compelled to produce Protected Information to a tribunal or be found liable in contempt and subjected to a penalty, the Receiving Party may disclose such Protected Information to the tribunal provided the Protected Information so disclosed is clearly marked as Protected Information.
4. This Agreement constitutes the entire agreement between the Parties, and supersedes any prior or contemporaneous agreements, representations and understandings of the Parties with respect to the disclosure of Information covered by this Agreement. It shall not be suspended, modified, or amended except by written agreement of the Parties. The provisions of this Agreement are independent of and separable from each other, and no provision shall be affected or rendered invalid or unenforceable by virtue of the fact that any other provision may be found invalid or unenforceable.

IN WITNESS WHEREOF, the Parties hereto have caused this instrument to be executed by their duly authorized representatives who also warrant their authority to enter into the Agreement on behalf of their respective Parties:

For: **[Navy Collaborator]**

Date: _____

For: **[Non-Navy Collaborator]**

Title:

Date: _____

APPENDIX I

Bilateral Non-Disclosure Agreement

In consideration of being allowed access to Protected Information under the above basic Non-Disclosure Agreement between the **[Navy Collaborator]** and **[Non-Navy Collaborator]**, the Undersigned agrees that:

The basic Non-Disclosure Agreement has been read and the requirements and restrictions with respect to the use, protection, disclosure, and return or destruction of Protected Information are understood. The terms of the Agreement with respect to the use, protection, disclosure, and return or destruction of Protected Information will be complied with by the Undersigned to the same extent as if the Undersigned were an original Party and signatory to the basic Non-Disclosure Agreement. When the Undersigned signs this Agreement as the representative of an Organization, the Undersigned will ensure that all individuals who are authorized access to Protected Information through the Organization will sign and enter into this Supplemental Non-Disclosure Agreement before being granted access to Protected Information.

IN WITNESS WHEREOF, the Undersigned has hereto subscribed individually and/or as representatives of the named Organization.

Signature

Name (Print or Type)

Date

Name and Address of Organization

Section IV - 1c

Non-Disclosure Agreement for Federal Employees - Example 3

Acknowledgement of Responsibility Regarding Privately Owned Proprietary Information

The undersigned Federal Employee acknowledges his/her responsibilities under Title 18, Section 1905 of the United States Code (reproduced below) with regard to the control and protection of privately owned proprietary information. The undersigned Federal Employee acknowledges that, if convicted of a violation of this statute, he/she may be fined or imprisoned, and removed from office or employment.

Employee Signature

Print Employee Name

Date

18 U.S.Code 1905. Disclosure of Confidential Information Generally

Whoever, being an officer or employee of the United States or of any department or agency thereof, any person acting on behalf of the Office of Federal Housing Enterprise Oversight, or agent of the Department of Justice as defined in the Antitrust Civil Process Act (15 U.S.C. 1311-1314), or being an employee of a private sector organization who is or was assigned to an agency under chapter 37 of title 5, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.

Section IV - 1d

Non-Disclosure Agreement for Federal Employees - Example 4

Acknowledgement of Duty of Non-Disclosure
To Protect <enter company's name>'s Confidential Information

- A. Parties. This Acknowledgement is executed by govt employee name ("_____"), a full-time civilian employee of the United States Navy's Naval Surface Warfare Center Panama City Division, Code ____, Panama City, FL.
- B. Purpose. The purpose of this Acknowledgement is to confirm govt employee name's duties to protect Confidential Information received from company for the sole purpose of: describe purpose for which information will be used. The Confidential Information disclosed to govt employee by company will consist of describe information.
- C. Acknowledgement. govt employee acknowledges, by signing below, that the Confidential Information provided by company contains information that is presented in confidence and may contain company's trade secret or commercial or financial information, and further acknowledges the obligation to protect such information from disclosure to the extent authorized or required by:
 - i) 5 U.S.C. § 552(b)(4) (Freedom of Information Act), available at <http://www4.law.cornell.edu/uscode/5/552.html>;
 - ii) Executive Order 12600 (Predisclosure Notification Procedures for Confidential Commercial Information), available at http://www.cftc.gov/foi/foiareference/foia_execorder12600.html;
 - iii) 18 U.S.C. § 1905 (Trade Secrets Act), available at <http://www4.law.cornell.edu/uscode/18/1905.html>;
 - iv) 18 U.S.C. § 1831 *et seq.* (Economic Espionage Act), available at <http://www4.law.cornell.edu/uscode/18/plch90.html>; and
 - v) any other similar statute, order or regulation applicable to United States Government employees.

The foregoing authorities represent govt employee's entire obligation to protect the Confidential Information received under this Agreement. Nothing herein shall be interpreted as giving rise to a private cause of action against govt employee or any other employee of the United States Government.

Accepted:

By _____

Name:

Title _____

Date _____

Section IV - 2

NSCRADA - Article 2. Objectives (2 Examples)

In this section, Article 2 of the Navy Standard CRADA, Collaborators are to describe the specific, realizable results or benefits to be gained by each Collaborator at the conclusion of this Agreement. State the desired outcome by each Collaborator, including any intentions for commercialization, if appropriate. This Article and the Statement of Work, Appendix A, are the defining articles for the Cooperative Work to be done by the Collaborators.

Example 1 - Article 2. Objectives

The objective of this CRADA is to produce a low cost, portable, battery-operated, GPS, station-keeping buoy prototype. The buoy will be capable of carrying an array of sensors including but not limited to a broad-band hydrophone. The buoy will receive position updates using a GPS receiver. The buoy will station-keep as programmed. The sensor data and the current buoy position will be telemetered to a remote receiver.

The buoy must be capable of deployment from a ship-of-opportunity without the use of a crane. The buoy must operate off batteries for a minimum of eight hours from the time of deployment in up to sea-state 3. The buoy must maintain position within a 50 meter diameter watch-circle. Position updates from the buoy must be received at a minimum rate of 1 per 10 seconds.

At the end of this agreement, both [Navy Collaborator] and [Non-Navy Collaborator] will have a prototype design for a station-keeping, GPS buoy. [Navy Collaborator] will use a field of such buoys to establish a portable tracking range for broad use including ballistic impact signature detection and tracking. The buoys will also have commercial uses in oceanographic studies, and in the oil industry.

Example 2 - Article 2. Objectives

Due to public health concerns, large diesel engines, including diesel engines used for Navy applications such as powering tugboats and generating auxiliary power, commercial transportation applications, and stationary diesel engines used for generating electric power, have recently become the subject of increasingly stringent Environmental Protection Agency (EPA) regulations. For example, there may be a relationship between diesel emissions and asthma. These strict new regulations will apply to Navy tugboats and commercial transportation vehicles including railroad locomotives. Regulations include limitations on the emission of oxides of nitrogen and particulates.

In addition to the increased regulation of diesel emissions, volatility in the price of diesel fuel has increased the price of diesel fuel for Navy applications.

The purpose of this CRADA is to perform the initial experiments that will ultimately lead to the development of a control system for large diesel engines, ensuring compliance with EPA, Knox emission standards while optimizing diesel fuel economy. Work will begin with the evaluation of an experimental NO sensor that will form the heart of a diesel engine control system. The [Navy Collaborator] Diesel Engine Test Facility (DEFT) will be used to determine if Ion Mobility Spectrometry (IMPS) with an appropriate NO converter will function adequately as a control system sensor. The U.S. Navy must reduce emissions output from internal combustion engines on the next generation of ships. Therefore, new, affordable, and reliable emission technology will be developed to monitor and eventually control engine performance.

Evaluating this sensor system will leverage ongoing diesel engine emissions research work now underway at [Navy Collaborator] and [Non-Navy Collaborator]. Hopefully, this sensor will respond to Nox emissions over a wide range Nox concentrations and its performance will not be significantly degraded by co-existing gases in diesel exhaust. The IMS system will be compared with a conventional Nox measurement technique in order to evaluate its performance. [Navy Collaborator] will have a chance to assess the sensor for Navy applications during these tests. [Non-Navy Collaborator] will attempt to secure patents on details of the system such as Nox No2 conversion device. [Non-Navy Collaborator] intends to make the device available commercially.

Section IV - 3

NSCRADA - Article 5. Funding (2 Examples)

This section provides two examples of payment schedules when the Non-Navy Collaborator will pay the Navy Collaborator in incremental amounts. When the incremental amounts are received using the payment schedule in the signed CRADA, it is not necessary to amend the CRADA unless there is a change in the Statement of Work.

Example 1:

5.1 Payment Schedule

[Non-Navy Collaborator] agrees to pay **[Navy Collaborator]** the following fees/costs in accordance with the payment schedule below:

- (1) \$X,000 within thirty (30) days of the execution of this Agreement.
- (2) An additional increment of \$X,000 no later than four (4) months from the date of execution of this Agreement.
- (3) An additional increment of \$X,000 no later than seven (7) months from the date of execution of this Agreement.
- (4) An additional increment of \$X,000 no later than nine (9) months from the date of execution of this Agreement.
- (5) An additional increment of \$X,000 no later than twelve (12) months from the date of execution of this Agreement.

Checks will be payable to:

[Specify endorsement. Do not specify an individual by name but rather an organization (or job title or function) that has the requisite authority to receive funds for the Navy.]

Each check and its cover correspondence shall refer to Navy CRADA number "NCRADA-**[Navy Collaborator]**-**[last two digits of CY]**-**[lab CRADA sequence number]**."

Checks will be mailed to:

[Specify address, including the name of the authorized recipient, title, and appropriate organizational code.]

Example 2:

5.1 Payment Schedule

[Non-Navy Collaborator] agrees to pay **[Navy Collaborator]** the following fees/costs in accordance with the payment schedule below:

(a) **[Non-Navy Collaborator]** shall provide one (1) payment of \$X,000 dollars to **[Navy Collaborator]** within fifteen (15) days after the CRADA has been signed by both parties.

(b) **[Non-Navy Collaborator]** shall provide one (1) payment of \$X,000 dollars to **[Navy Collaborator]** after **[Navy Collaborator]** has completed its task 1A, but no more than four (4) months after the CRADA has been signed by both parties.

(c) **[Non-Navy Collaborator]** shall provide one (1) payment of \$X,000 dollars to **[Navy Collaborator]** after **[Navy Collaborator]** has completed its task 1B, but no more than eight (8) months after the CRADA has been signed by both parties.

(d) **[Non-Navy Collaborator]** shall provide one (1) payment of \$X,000 dollars to **[Navy Collaborator]** after **[Navy Collaborator]** has completed its task 1C, but no more than thirteen (13) months after the CRADA has been signed by both parties.

The total amount that **[Non-Navy Collaborator]** pays to **[Navy Collaborator]** shall be \$X,000 dollars.

The funded amount will be used to support **[Navy Collaborator]**'s research as described in the Statement of Work.

Checks will be payable to:

[Specify endorsement. Do not specify an individual by name but rather an organization (or job title or function) that has the requisite authority to receive funds for the Navy.]

Each check and its cover correspondence shall refer to Navy CRADA number "NCRADA-**[Navy Collaborator]**-**[last two digits of CY]**-**[lab CRADA sequence number]**."

Checks will be mailed to:

[Specify address, including the name of the authorized recipient, title, and appropriate organizational code.]

Section IV - 4

NSCRADA - Appendix A - Statement of Work - Explanation

The Statement of Work is one of the most important parts of your CRADA. It should represent a clear description of the work to be performed by each Collaborator separately and work to be performed jointly by the Collaborators. Because of the nature of research and development activities, this Statement of Work may be at a high level; however, it should be detailed enough for each Collaborator to understand his role and responsibilities. Three examples of Statements of Work are provided.

Section IV - 4a

Appendix A - Statement of Work - Example 1

STATEMENT OF WORK
BETWEEN
[NAVY COLLABORATOR]
AND
[NON-NAVY COLLABORATOR]

[Navy Collaborator] will be responsible for the following tasks:

1. **[Navy Collaborator]** will provide the test plan, operational risk management plan, instrumentation plan.
2. **[Navy Collaborator]** will provide **[Non-Navy Collaborator]** a shop area to install the CD-NTP system.
3. **[Navy Collaborator]** will conduct VOC Remediation/Elimination Program at **[Navy Collaborator]** facilities. Analysis will include, but not be limited to, evaluation of the developmental remediation system to remove and eliminate VOCs extracted from ground-water clean-up processes. This developmental system will be analyzed and verified during conduct of the VOC Remediation and Elimination Program Demonstration. The analysis will improve the Government's environmental site compliance and will provide technical data to both the Government and Industry for application to other sites.
4. **[Navy Collaborator]** will provide still photos and personnel to operate the site.
Schedule:
 1. Draft Project Plan no later than 30 days after effective date of CRADA.
 2. Final Project Plan no later than 30 days after Draft Project Plan.
 3. Draft Operational Risk Management Plan not later than 30 days after the effective date of CRADA.
 4. Final Operational Risk Management Plan not later than 30 days after the Draft Operational Risk Management Plan.
 5. Draft Installation Plan no later than 30 days after effective date of CRADA.
 6. Final Installation Plan no later than 30 days after Draft Installation Plan.
 7. Conduct Test Program (TBD).
 8. **[Navy Collaborator]** will provide 7 days notice to **[Non-Navy Collaborator]** prior to project meetings, schedule (TBD).

[Non-Navy Collaborator] will be responsible for the following tasks:

1. **[Non-Navy Collaborator]** will review the drafts of the Project Plan, Operational Risk Management Plan, & Installation Plan and provide comments on those drafts to the **[Navy Collaborator]** after review.
2. **[Non-Navy Collaborator]** will deliver in working order the prototype system of the VOC reactor to **[Navy Collaborator]** identified site.

3. **[Non-Navy Collaborator]** will provide engineering consulting services for the installation and maintenance of the VOC reactor.
4. **[Non-Navy Collaborator]** will be present for the installation of the system as well as perform in field start up and diagnostics of the equipment installed.
5. **[Non-Navy Collaborator]** will provide field verification of the system's operation.
6. **[Non-Navy Collaborator]** will familiarize **[Navy Collaborator]** personnel with system operation and fundamentals.
7. **[Non-Navy Collaborator]** will attend meetings (TBD-Task 1. above) prior to the conduct of VOC reactor demonstration.

[Navy Collaborator] and [Non-Navy Collaborator] will be responsible for the following joint tasks:

1. Both partners will assist in the preparation and installation of equipment.
2. Both partners will collaborate to complete a Final Test Report no later than 120 days after completion of the project.

Section IV - 4b

Appendix A - Statement of Work - Example 2

APPENDIX A

STATEMENT OF WORK BETWEEN **[NAVY COLLABORATOR]** AND **[NON-NAVY COLLABORATOR]**

[Navy Collaborator] will be responsible for the following tasks:

1. Provide personnel, facilities, equipment, and support for promoting transfer of existing and future **[Navy Collaborator]** UUV applicable technology to foster development of improved capabilities in this area.
2. Provide access for **[Non-Navy Collaborator]** to **[Navy Collaborator]**'s UUV technology through data, demonstrations, consultation, and documentation.
3. Provide **[Non-Navy Collaborator]** access during and after oceanographic surveys for video/film documentation of applicable UUV technologies.
4. Review and assist **[Non-Navy Collaborator]** in preparing the Research and Development Plan in support of improving **[Navy Collaborator]**'s existing UUVs.
5. Develop Top Level Requirements (TLR) for an UUV that can adequately perform hydrographic, oceanographic, and /or bathymetric surveys.

[Non-Navy Collaborator] will be responsible for the following tasks:

1. Provide personnel for collecting and documenting (audio and visual) mission survey data of existing and future UUV related technology.
2. Develop Top Level Requirements (TLR) for an UUV that is suitable for commercial use in industries such as: telecommunications, oil & gas, and ship/aircraft wreck surveys, etc.
3. Provide personnel who will conduct training and execute other technical support to **[Navy Collaborator]** for integration of applicable **[Non-Navy Collaborator]** navigation technology (to include software and hardware) in UUVs for military surveys.
4. Provide a Research and Development Plan in support of improving **[Navy Collaborator]** existing UUV operations. This plan will guide efforts within this agreement for specific technology development. This plan will be reviewed, and if necessary revised, annually by both partners for accuracy, pertinence, and reasonable expectation of achieving its objectives. The first year's (Y2001) R&D Plan is Attachment 1 to this Appendix.

5. Request prior approval for all commercial uses of **[Navy Collaborator]** equipment that is in possession of **[Non-Navy Collaborator]**. At a minimum, use must be in support of and consistent with specific tasks delineated in the R&D Plan and in full compliance with any Government regulations and/or restrictions including, but not limited to, foreign national restrictions and MCT list export restrictions that may pertain to the specified equipment.
6. Ensure that any non-signatory party to this agreement that **[Non-Navy Collaborator]** may team with or allow to use **[Navy Collaborator]** equipment is in full compliance of all Government regulations and/or restrictions that may pertain to the specified equipment including, but not limited to, foreign national restrictions and MCT list export restrictions, and shall include adequate insurance and indemnification provisions. Such use shall be in direct support of specific tasks delineated in the R&D Plan.

[Navy Collaborator] and [Non-Navy Collaborator] will be responsible for the following joint tasks:

1. Strive to construct an UUV based on the TLR for military survey.
2. Strive to construct an UUV based on the TLR for commercial ocean search and survey.

Section IV - 4c

Appendix A - Statement of Work - Example 3

APPENDIX A

STATEMENT OF WORK

BETWEEN

[NAVY COLLABORATOR]

And

[NON-NAVY COLLABORATOR]

[Navy Collaborator] will be responsible for the following tasks (list as applicable):

1. This institution acknowledges and accepts responsibilities for protecting the rights and welfare of all human subjects involved in the research which it sponsors or conducts and will follow all pertinent regulations (FDA, OPRR, DoD, and others) when involved in such research. This institution encourages and promotes an institutional atmosphere that safeguards the rights and welfare of human subjects. This institution will conduct annual protocol reviews and submit reports to the oversight committee as required in the pertinent regulations.
2. The investigator will process each protocol through the Institutional Review Board (IRB) at **[Navy Collaborator]**. In addition, comply with local, state, and federal regulations while conducting the research.
3. Review each protocol provided by **[Non-Navy Collaborator]**. The Investigator to let **[Non-Navy Collaborator]** know if **[Navy Collaborator]** will participate in a specific protocol.
4. The Investigator will follow each protocol and amendments as describe. Any variation will be provided to the **[Non-Navy Collaborator]** Protocol Coordinator and **[Navy Collaborator]** IRB.
5. Administrative duties will be performed as required by the protocol; reporting, charting of patient participation, obtaining appropriate consent forms, and other duties as described in the protocol.
6. **[Non-Navy Collaborator]** Protocol Coordinator will have access to patient charts. Documentation will be available during EVMS inspection.

[Non-Navy Collaborator] will be responsible for the following tasks (list as applicable):

1. Supply each complete protocol and/or amendment to the Investigator at **[Navy Collaborator]** for review. Each protocol will format and information will comply with Navy regulations.
2. The Project Administrator is responsible for data management, preparing reports as requested by **[Navy Collaborator]**, documenting adverse reactions in a timely manner.
3. Chart reviews to be completed to verify pertinent pre-entry examinations. Verify dates of therapy, administration of subsequent doses, and ensure appropriate methods were followed.

4. Verify adherence of protocols. If a protocol deviation occurs, ensure accurate documentation of deviation.
5. Ensure adverse drug reactions are appropriately reported.
6. Verify patient disease status and document. Ensure adequacy of follow-up exams.
7. Drug accountability records. The Protocol Coordinator shall ensure accurate drug inventory at all times. In addition, the Protocol Coordinator will supply drugs as listed in each protocol. Ensure accountability and participant records are accurate.

[Navy Collaborator] and [Non-Navy Collaborator] will be responsible for the following joint tasks:

1. Each facility will ensure annual continuing reviews are conducted through each IRB. Informed consent is approved each year.

SECTION V

GUIDELINES AND DISCUSSIONS

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Section V - 1

Definitions

The following include discussions to clarify terms and definitions in the Navy Standard CRADA. Items that are discussed include the following: Conception and Reduction to Practice; Controlled Unclassified Information; Restricted Access Information; and Government Purpose Rights.

Section V - 1a

“Conception” and “Reduction to Practice”

The following information may be particularly useful when considering how the defined term “Made” is defined in a CRADA and how “Made” is used throughout the CRADA. The definition “Made” in the CRADA is as follows: “Made” when used in conjunction with any Invention (15 USC 3703(10)) and where “Invention” in the CRADA is defined as follows. “Invention” means any invention or discovery that is or may be patentable or otherwise protected under Title 35, United States Code, or any novel variety of plant that is or may be patentable under the Plant Variety Protection Act (15 USC 3703(9)).

An important concept in patent law that needs to be understood by both the scientific and engineering communities is: when has “invention” occurred. “Invention” can be comprised of two basic aspects, conception and reduction to practice, but at a minimum comprises conception. Conception is thought of as the mental part of the invention and actual reduction to practice as the physical part of the invention. Currently the United States (US) patent laws are based on a “first to invent” system whereas every other country in the world is based on a “first to file” system. As recently as spring 2007, the United States Patent and Trademark Office (PTO) proposed legislation to Congress to change the US patent laws to a “first to file” system. Even if the laws were to change, corroboration by an independent witness of the invention will always be required in inventorship determinations.

Conception is the “idea” part of invention. Case law has defined it as the formation “in the mind of the inventor of a definite and permanent idea of a complete and operative invention, as it is thereafter to be applied in practice.” See, Hybitech, Inc. v. Monoclonal Antibodies, Inc., 231 USPQ at 87-88 (Fed. Cir. 1986). The idea can be formed by more than one inventor. The “idea” of the invention must be complete and permanent to such a degree that one of ordinary skill in the art could physically complete the invention, i.e., could actually reduce the idea to practice by simply reading the disclosure of the idea. Another way to say this is that one of ordinary skill in the art must be able to determine from the disclosure the means for effectively carrying out the idea. If further undue research or undue experimentation is needed, there is no definite and permanent idea of the complete and operative invention. Thus, if more experimentation or research is needed in order to practice the invention then conception is not enough for invention to have occurred. One’s idea should be adequately described in one’s notebook and corroborated by an independent witness who understands the idea.

Reduction to Practice is defined as either “constructive reduction to practice” or “actual reduction to practice.” Constructive reduction to practice occurs when the patent application is filed with the PTO. On the other hand, actual reduction to practice occurs when there is a physical article, physical syntheses or formation of a compound or composition or the physical practice of a process or method. Corroboration by an independent witness of the actual reduction to practice should be found in one’s notebook.

Corroboration requires that at least one independent witness understands the disclosure as found in the inventor’s notebook and then signs and dates the notebook. It is required that each witness sign and date the notebook at each stage of research, including the conception of the invention, actual reduction to practice, experimental results and if a chemical invention, use.

For more information please contact John Forrest at john.forrest@navy.mil.

Section V - 1b

Controlled Unclassified Information (CUI)

Discussion:

SECNAV M-5510.36 states that an individual's need-to-know applies to classified and controlled unclassified information (CUI). CUI is for official Government use and must not be released to the general public or foreign nationals. Persons disclosing CUI must ensure the individual receiving the information has the appropriate need-to-know.

CUI must be safeguarded. During normal working hours CUI must be kept face down on your desk. After normal working hours CUI should be locked in a desk drawer or in a locked office. CUI should not be transmitted via non-secure means. CUI e-mail must be encrypted.

The definition used in the NSCRADA for Controlled Unclassified Information follows:

- 1.4 "Controlled Unclassified Information (CUI)" means Government Data, Information, or materials provided to or resulting from this Agreement that may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation.

The Secretary of the Navy has provided a more detailed definition as follows:

Controlled Unclassified Information (CUI). CUI is defined and governed by laws, international agreements, Executive Orders, and regulations that address the identification, marking, protection, handling, transmission, transportation, and destruction. Categories of Controlled Unclassified Information include:

- a. For Official Use Only (FOUO) information, as defined under the Freedom of Information Act (FOIA); protective measures; Law Enforcement Sensitive Information (LES);
- b. Department of State (DOS) Sensitive But Unclassified (SBU) (formerly Limited Official Use (LOU)) information;
- c. DoD and DOE Unclassified Nuclear Information (UCNI);
- d. Drug Enforcement Administration (DEA) Sensitive Information;
- e. Unclassified information in technical documents requiring distribution statements; and
- f. National Geospatial Intelligence Agency Limited Distribution Information.

Developing Policy and Implementation

The DoD Deputy Chief Information Officer on 28 December 2007 issued a Memorandum (Transition to New Markings for Controlled Unclassified Information) that describes the implementation plan to develop uniform new markings and directives dealing with CUI, a process to be completed within five years. On May 7, 2008 President Bush formally approved the adoption of "Controlled Unclassified Information" as the single definition to be used throughout the executive branch for all information within the scope of that definition, and established a corresponding new CUI Framework for designating, marking, safeguarding, and disseminating information designated CUI. This Presidential memo is included at the end of this section.

Federal recommendations for safeguarding, dissemination, and authorized markings from the CUI implementation task force include the following reference:

<http://www.whitehouse.gov/nsc/infosharing>

- Two safeguarding levels:
 - Controlled - approximately equivalent to current FOUO requirements, except for electronic transmission
 - Controlled Enhanced
- Two dissemination standards:
 - Standard Dissemination
 - Specified Dissemination - requires additional dissemination guidance be stated
- Three authorized markings:
 - Controlled Standard Dissemination
 - Controlled Specified Dissemination
 - Controlled Enhanced Specified Dissemination

This is a dynamic process, and you are advised to contact your laboratory security office as implementation proceeds. This will impact the way in which information will be transmitted to your CRADA partners in the future.

Memorandum For The Heads Of Executive Departments And Agencies

SUBJECT: Designation and Sharing of Controlled Unclassified Information (CUI)

Purpose

(1) This memorandum (a) adopts, defines, and institutes "Controlled Unclassified Information" (CUI) as the single, categorical designation henceforth throughout the executive branch for all information within the scope of that definition, which includes most information heretofore referred to as "Sensitive But Unclassified" (SBU) in the Information Sharing Environment (ISE), and (b) establishes a corresponding new CUI Framework for designating, marking, safeguarding, and disseminating information designated as CUI. The memorandum's purpose is to standardize practices and thereby improve the sharing of information, not to classify or declassify new or additional information.

Background - The Current SBU Environment

(2) The global nature of the threats facing the United States requires that (a) our Nation's entire network of defenders be able to share information more rapidly so those who must act have the information they need, and (b) the United States Government protect sensitive information, information privacy, and other legal rights of Americans. A uniform and more standardized governmentwide framework for what has previously been known as SBU information is essential for the ISE to succeed. Accordingly, this memorandum establishes a standardized framework designed to facilitate and enhance the sharing of Controlled Unclassified Information.

Definitions

(3) In this memorandum, the following terms have the meaning indicated:

- a. "Controlled Unclassified Information" is a categorical designation that refers to unclassified information that does not meet the standards for National Security Classification under Executive Order 12958, as amended, but is (i) pertinent to the national interests of the United States or to the important interests of entities outside the Federal Government, and (ii) under law or policy requires protection from unauthorized disclosure, special handling safeguards, or prescribed limits on exchange or dissemination. Henceforth, the designation CUI replaces "Sensitive But Unclassified" (SBU).
- b. "CUI Council" is a subcommittee of the Information Sharing Council (ISC), created by the Intelligence Reform and Terrorism Prevention Act of 2004 (Public Law 108-458) (IRTPA).
- c. "CUI Framework" refers to the single set of policies and procedures governing the designation, marking, safeguarding, and dissemination of CUI terrorism-related information that originates in departments and agencies, regardless of the medium used for the display, storage, or transmittal of such information.
- d. "CUI Framework Standards Registry" (the "CUI Registry") refers to the official list of, and recognized standards for, CUI markings including "safeguarding," and "dissemination" maintained by the Executive Agent.
- e. "Departments and Agencies" means executive agencies as defined in section 105 of title 5, United States Code; the United States Postal Service; but not the Government Accountability Office.

f. "Enhanced Safeguarding" is a handling requirement that means the information so designated is subject to measures more stringent than those normally required because inadvertent or unauthorized disclosure would create a risk of substantial harm. This requirement is indicated by the marking "Controlled Enhanced."

g. "Executive Agent" means the National Archives and Records Administration (NARA).

h. "Information" means any communicable knowledge or documentary material, regardless of its physical form or characteristics, that is owned by, is produced by or for, or is under the control of the Federal Government.

i. "Information Sharing Environment" means an approach that facilitates the sharing of "terrorism information," as defined by section 1016 of IRTPA.

j. "Safeguarding" means measures and controls that are prescribed to protect controlled unclassified information.

k. "Sensitive But Unclassified" refers collectively to the various designations used heretofore within the Federal Government for documents and information that are sufficiently sensitive to warrant some level of protection from disclosure but that do not warrant classification.

l. "Specified Dissemination" is a handling instruction that means the information so designated is subject to additional instructions governing the extent to which dissemination is permitted.

m. "Standard Dissemination" is a handling instruction that means dissemination is authorized to the extent it is reasonably believed that dissemination would further the execution of lawful or official mission purpose, provided that individuals disseminating this information do so within the scope of their assigned duties.

n. "Standard Safeguarding" is a handling requirement that means the information so designated is subject to baseline safeguarding measures that reduce the risks of unauthorized or inadvertent disclosure. This requirement shall be indicated through the use of the marking "Controlled."

o. "Terrorism-Related Information" means (i) information, as defined by Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110-53, section 504; (ii) homeland security information, as defined by 6 U.S.C. 482(f); and (iii) law enforcement information relating to terrorism.

Policy - The CUI Framework

(4) The uniform use of CUI is essential to fostering an effective ISE. All departments and agencies shall apply the CUI Framework, which consists of the following policies and standards, as outlined in paragraphs 5-19 for the designation, marking, safeguarding, and dissemination of any CUI terrorism-related information within the ISE that originates in departments and agencies, regardless of the medium used for its display, storage, or transmittal.

(5) All CUI shall merit one of two levels of safeguarding procedures: standard (marked "Controlled") or enhanced (marked "Controlled Enhanced").

(6) All CUI shall merit one of two levels of dissemination controls: "Standard Dissemination" or "Specified Dissemination."

(7) All CUI shall be (a) categorized into one of three combinations of safeguarding procedures and dissemination controls, and (b) so indicated through the use of the following corresponding markings:

(i) "**Controlled with Standard Dissemination**" meaning the information requires standard safeguarding measures that reduce the risks of unauthorized or inadvertent disclosure. Dissemination is permitted to the extent that it is reasonably believed that it would further the execution of a lawful or official purpose.

(ii) "**Controlled with Specified Dissemination**" meaning the information requires safeguarding measures that reduce the risks of unauthorized or inadvertent disclosure. Material contains additional instructions on what dissemination is permitted.

(iii) "**Controlled Enhanced with Specified Dissemination**" meaning the information requires safeguarding measures more stringent than those normally required since the inadvertent or unauthorized disclosure would create risk of substantial harm. Material contains additional instructions on what dissemination is permitted.

(8) Any additional CUI markings may be prescribed only by the Executive Agent. Use of additional CUI markings is prohibited unless the Executive Agent determines that extraordinary circumstances warrant the use of additional markings.

(9) Departments and agencies shall apply the CUI Registry's standards. The originator of CUI may not impose any additional safeguarding or dissemination requirements upon the recipient(s). No department or agency shall create CUI categories or rules outside the CUI Framework.

(10) Recipients of CUI shall report any unauthorized or inadvertent disclosures to the designating agency.

(11) All CUI shall be marked in a clear manner and conform to statutory and regulatory requirements, if any, regarding markings. Recipients of CUI that is not marked shall mark the information appropriately and inform the originator that it has been so marked.

(12) Wherever possible, it is expected that departments and agencies will re-mark archived or legacy material when it is incorporated into the ISE.

(13) CUI markings may inform but do not control the decision of whether to disclose or release the information to the public, such as in response to a request made pursuant to the Freedom of Information Act (FOIA).

(14) Originating departments and agencies shall retain control of decisions regarding whether to disseminate CUI materials beyond their Standard or Specified Dissemination instructions, including any dissemination to the media or general public.

(15) Material that contains both CUI and non-CUI information, or that contains multiple categories of CUI, should be marked accordingly by portions such that those categorical distinctions are apparent.

(16) The CUI markings shall be incorporated into ISE-related information technology (IT) projects under development or developed in the future and shall be reflected in plans for new information technologies.

(17) The CUI markings shall be used regardless of the medium through which the information appears or conveys. Oral communications should be prefaced with a statement describing the controls when necessary to ensure that recipients are aware of the information's status.

(18) Departments or agencies shall not impose safeguarding requirements or dissemination controls on information in the ISE that is neither classified nor CUI.

(19) When a department or agency receives CUI originating from a State, local, tribal, private sector, or foreign partner, any nonfederal legacy markings shall be retained, unless the originator authorizes its removal.

(20) Implementation of the CUI Framework shall commence upon the date of this memorandum and shall be completed within 5 years.

CUI Framework Implementation

(21) The Executive Agent shall be responsible for overseeing and managing implementation of this CUI Framework.

(22) The Executive Agent shall have the following authorities and responsibilities:

a. Develop and issue CUI policy standards and implementation guidance consistent with this memorandum, including appropriate recommendations to State, local, tribal, private sector, and foreign partner entities for implementing the CUI Framework. As appropriate, establish new safeguarding and dissemination controls, and, upon a determination that extraordinary circumstances warrant the use of additional CUI markings, authorize the use of such additional markings;

b. Establish and chair the CUI Council;

c. Establish, approve, and maintain safeguarding standards and dissemination instructions, including "Specified Dissemination" requirements proposed by the heads of departments and agencies;

d. Publish the CUI safeguarding and dissemination standards in the CUI Registry;

e. Monitor department and agency compliance with CUI policy, standards, and markings;

f. Establish baseline training requirements and develop an ISE-wide CUI training program to be implemented by departments and agencies;

g. Provide appropriate information regarding the CUI Framework to the Congress, to State, local, tribal, and private sector entities, and to foreign partners;

h. Advise the heads of departments and agencies on the resolution by the CUI Council of complaints and disputes among such departments and agencies concerning the proper designation or marking of CUI; and

i. Establish, in consultation with affected departments and agencies, a process that addresses enforcement mechanisms and penalties for improper handling of CUI.

(23) A CUI Council is hereby established as a subcommittee of the ISC. Its members shall be drawn from the ISC's membership. The CUI Council shall:

- a. Serve as the primary advisor to the Executive Agent on issues pertaining to the CUI Framework;
- b. Advise the Executive Agent in developing procedures, guidelines, and standards necessary to establish, implement, and maintain the CUI Framework;
- c. Ensure coordination among the departments and agencies participating in the CUI Framework;
- d. Advise the Executive Agent on the resolution of complaints and disputes among departments and agencies about proper designation or marking of CUI; and
- e. As appropriate, consult with the ISC's State, Local, Tribal, and Private Sector Subcommittee.

(24) The head of each department and agency with possession of terrorism-related information shall:

- a. Ensure the implementation of the CUI Framework within such department or agency;
- b. Promulgate guidance for the implementation of the CUI Framework within such department or agency, consistent with ISE-wide CUI policies issued by the CUI Executive Agent, as established in paragraph 21;
- c. Adopt markings listed in the CUI Registry maintained by the Executive Agent as the exclusive CUI markings used by such department or agency, consistent with paragraphs 5-8 of this memorandum;
- d. Propose any necessary "Specified Dissemination" instructions to the Executive Agent for approval and listing in the CUI Registry;
- e. Designate an appropriately qualified senior official from within the department or agency as its representative on the CUI Council;
- f. Implement a CUI training program for their respective department or agency, based on the ISE-wide training program established by the Executive Agent, and ensure all appropriate personnel (i) understand CUI policies and procedures, and (ii) can apply them when creating, disseminating, or safeguarding CUI material;
- g. Establish a process that enables their respective department or agency to address noncompliance with the new CUI Framework within the agency, and ensure management and oversight issues or concerns can be elevated to the appropriate department or agency decision-makers;
- h. Establish a process within their respective department or agency that, where appropriate, promptly raises to the Executive Agent matters of concern regarding the Framework; and
- i. Ensure full implementation of the CUI Framework, consistent with policies, guidance, and standards established by the Executive Agent, within 5 years of the date of this memorandum.

Designating CUI

(25) Information shall be designated as CUI and carry an authorized CUI marking if:

- a. a statute requires or authorizes such a designation; or
- b. the head of the originating department or agency, through regulations, directives, or other specific guidance to the agency, determines that the information is CUI. Such determination should be based on mission requirements, business prudence, legal privilege, the protection of personal or commercial rights, safety, or security. Such department or agency directives, regulations, or guidance shall be provided to the Executive Agent for review.

(26) Notwithstanding the above, information shall not be designated as CUI:

- a. to (i) conceal violations of law, inefficiency, or administrative error; (ii) prevent embarrassment to the Federal Government or any Federal official, any organization, or agency; (iii) improperly or unlawfully interfere with competition in the private sector; or (iv) prevent or delay the release of information that does not require such protection;
- b. if it is required to be made available to the public; or
- c. if it has already been released to the public under proper authority.

Exceptions to CUI

(27) This memorandum requires that all CUI originated by departments and agencies and shared within the ISE shall conform to the policies and standards for the designating, marking, safeguarding, and disseminating established in accordance with this memorandum. However, infrastructure protection agreements not fully accommodated under the CUI Framework (and its associated markings, safeguarding requirements, and dissemination limitations) shall be considered exceptions to this CUI Framework. Infrastructure protection exceptions include and apply to information governed by or subject to the following regulations:

- a. 6 CFR Pt. 29 - PCII (Protected Critical Infrastructure Information);
- b. 49 CFR Pts. 15 (Department of Transportation) & 1520 (Department of Homeland Security/Transportation Security Administration) - SSI (Sensitive Security Information);
- c. 6 CFR Pt. 27 - CVI (Chemical Vulnerability Information); and
- d. 10 CFR Pt. 73 - SGI (Safeguards Information).

(28) The CUI Framework shall be used for such information to the maximum extent possible, but shall not affect or interfere with specific regulatory requirements for marking, safeguarding, and disseminating.

(29) The affected department or agency is authorized to select the most applicable CUI safeguarding marking for the regulation. Any additional requirements for the safeguarding beyond that specified under the CUI Framework shall be appropriately registered in the CUI Registry. Any regulatory marking shall follow the CUI marking, and a specified dissemination instruction shall articulate any additional regulatory requirements.

General Provisions

(30) This memorandum:

- a. shall be implemented in a manner consistent with applicable law, including Federal laws protecting the information privacy rights and other legal rights of Americans, and subject to the availability of appropriations;
- b. shall be implemented in a manner consistent with the statutory authority of the principal officers of departments and agencies as heads of their respective departments or agencies;
- c. shall not be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, and legislative proposals; and
- d. is intended only to improve the internal management of the Federal Government and is not intended to, and does not, create any rights or benefits, substantive or procedural, enforceable at law or in equity by a party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

Section V - 1c

Restricted Access Information

The Navy Standard CRADA contains the following definition for the Restricted Access Information:

“Restricted Access Information” means Subject Data generated by **[Navy Collaborator]** that would be Proprietary Information if the Information had been obtained from a Non-Federal Collaborator participating in a CRADA (15 USC 3710a). Under 15 USC 3710a(c)(7)(B), the Collaborators mutually may agree to provide appropriate protection to Subject Data generated by **[Navy Collaborator]** (Restricted Access Information) against public dissemination or release under the Freedom of Information Act (FOIA) for a period of up to five (5) years after development of the Information.

Upon request by Non-Navy Collaborator, Data that are determined by mutual agreement with the Navy Collaborator to meet the definition of Restricted Access Information must be properly marked. The marking includes the negotiated date of expiration from the date of creation. The negotiated date **may be less than five years**.

If the Non-Navy Collaborator is using Proprietary Information originating from a Small Business Information Research award, please consult “SBIRs and CRADAs” in this section of the Handbook.

Section V - 1d

Government Purpose Rights

Definition from US Navy Standard CRADA:

1.10 “Government Purpose Rights” means the right of the Government 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. Government Purpose Rights includes competitive procurement, but does not include the right to have or permit others to use Data for commercial purposes.

Discussion:

Government Purpose Rights grant to the Government the right to use or permit others to use technical data for purposes of a Government competitive procurement, **but does not include the right to permit others to use the data for commercial purposes.**

“Government Purpose Rights” - means the rights to:

- i) Use, modify, reproduce, release, perform, display, or disclose technical data **within the Government without restriction**; and,
- ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to: use, modify, reproduce, release, perform, display, or disclose that data (to include computer software or computer software documentation) for Government purposes.

Frequently Asked Questions (potential questions from a non-Federal CRADA partner):

1. May the Government use Data generated from our CRADA to make a competitive procurement award to another non-Federal party?

Answer: Yes, if the procurement is for Government purposes only.

2. What is meant by ‘commercial purposes’?

Answer: There is no explicit definition of "commercial purposes." It does not include selling products and services to the Federal Government. It does include selling to non-governmental entities (i.e., consumers, corporations, etc.). The question becomes whether it includes sales to state and local, or even foreign, governments. The general understanding is that it does, and only sales to the U.S. Government fall under the purview of Government Purpose Rights.

Section V - 2

The Use of Contractors - Explanation

In the Navy Standard CRADA, Article 10.2.3.1 Work by Third Parties, states that “Neither Collaborator may allow third parties to perform any part of the Cooperative Work under this Agreement without express written consent of the other Collaborator.” In Section III - 2a of this Handbook, you will find a template for the case in which the Navy states its approval to the Non-Navy Collaborator the use of their Third Party choice in the CRADA. The two sections which follow provide discussion on the use of Third Parties to provide either CRADA administrative support or technical work in the performance of a CRADA.

If the Navy is using a Third Party Contractor and a Subject Invention is Made as a result of the work under a CRADA, the Bayh-Dole rights may be waived by the Contractor with a License Grantback Agreement (see Section III - 7 for a template).

Section V - 2a

The Use of Contractors in Cooperative Research and Development Agreements (CRADAs)

Use of Support Contractors to Accomplish the Technology Transfer Office (TTO) Mission:

1. Special consideration must be given whenever the Government employs the services of a support contractor to accomplish any aspect of the Technology Transfer Office (TTO) mission. This includes: (1) using support contractors within the TTO as administrative/clerical support as well as in direct support of negotiating and managing Patent License Agreements (PLAs) and Cooperative Research and Development Agreements (CRADAs); and, (2) using support contractor services to assist in accomplishing the Government's collaborative research and development (R&D) obligations under CRADAs.
2. When support contractors are used within the TTO, there is a particular need for: (1) ensuring that sufficient non-disclosure provisions are included in the support contract to require support contractor employees to properly safeguard information they receive against unauthorized use and disclosure (see the attached model contract clause); (2) ensuring that TTO non-Government customers (potential collaborators and licensees): (a) are made aware up-front as to the status (contractor or Government employee) of all individuals working in the TTO with whom they come into contact, (b) provide written consent to share their information with non-Government support personnel, and, (c) to request, at their option, a direct nondisclosure agreement with the contractor employing the non-Government support personnel before information is disclosed; and, (3) ensuring that appropriate provisions are included in the support contract to avoid potential organizational conflicts of interest (OCIs) that may occur when a support contractor competes for Government requirements (see the attached model contract clause).
3. In order to address these matters, an appropriate contract provision must be included in all contracts supporting a TTO whenever contractor employees could potentially have access to company proprietary information or controlled Government information. Any non-disclosure agreements filed with a TTO as a result of this policy must be provided to the appropriate Contracting Officer for inclusion in the applicable contract file.
4. Special consideration must also be given whenever the use of support contractors is considered to accomplish any of the Government's R&D tasks under the SOW of a CRADA. In particular, the Contracting Officer and TTO must ensure that appropriate arrangements have been made between support contractors accomplishing the Government's CRADA R&D obligations and the CRADA partner regarding rights in inventions and technical data.
5. The TTO should refer to local counsel for specific guidance pertinent to the TTO's situation in view of the general guidance provided above at 1-4.

References:

18 USC 1905 Trade Secrets Act
FAR Part 9.5 (OCI)
35 USC 202; 15 USC 3701a(b)(1) (Invention Rights)

Model Contract Clause:

USE AND SAFEGUARDING OF PROPRIETARY INFORMATION. The Contractor shall perform tasks in support of the Technology Transfer Program that include, but are not limited to, negotiation of Cooperative Research and Development Agreements (CRADAs) and Patent License Agreements (PLAs).

- A. In the performance of such tasks, the Contractor may be given access to proprietary information submitted to the Government by non-Government businesses and organizations. The Contractor agrees: (1) to ensure that the non-Government party has provided written consent for delivery to and receipt by the Contractor of the non-Government party's proprietary information that may be subject to the Trade Secrets Act (18 U.S.C. 1905), (2) to protect all proprietary information it receives in performance of the Contract from unauthorized use or disclosure for as long as it is considered proprietary by the business or organization that submitted it to the Government; (3) to advise the businesses and organizations whose proprietary information will be received by the Contractor of (a) the Contractor's status and (b) willingness to enter into a nondisclosure agreement with the business or organization; and, (4) to ensure that all Contractor employees who have access to such proprietary information are made aware of and comply with the requirements and restrictions contained herein. The Contractor shall furnish copies of all nondisclosure agreements to the Head of the Technology Transfer Office.

- B. The Contractor's independent and objective judgment must be relied upon by the Government in the negotiation and award of CRADAs and PLAs. To avoid the possibility of even the appearance of a conflict-of-interest, the Contractor agrees that it is precluded for five years from the date of award of a CRADA or PLA from independently pursuing the same or closely related technology or acting as a consultant or subcontractor for any other business or organization that is pursuing the same or closely related technology.

Section V - 2b

The Use of Contractors in Cooperative Research and Development Agreements (CRADAs)

Types of contractors who supply goods and services that involve Intellectual Property (IP) rights:

1. Service Contractors:
People doing a specific task on a relevantly short-term basis under contract to the Government, e.g., manufacturing, testing, repairing equipment, etc.

Typically commercial goods or services, and rarely Research and Development (R&D).
2. Support Contractors:
People working for the Government on a contract basis to perform R&D. Often support contractors will work at Government facilities using Government equipment. Their contract with the Government should have a patent rights clause.
3. Third Party:
Third parties are parties other than the Federal laboratory and the CRADA Collaborator, but have entered into an agreement with either of these entities. Because of this agreement, they may have IP rights in subject matter developed under the CRADA. These IP rights must be addressed.

The CRADA Collaborator may also be working with a third party. The CRADA Collaborator must be able to warrant that no other agreement that they enter into will detract from their ability to fully deliver the IP rights that they are obligated to deliver to the Government under the CRADA. There are certain IP rights that both the Government and the CRADA Collaborator are required to receive under the Technology Transfer Act.

Understanding the Rules:

Service contractors and support contractors are not treated differently under the Federal Acquisition Regulations (FAR). Both of these types of contractors will have the right to elect title to any inventions that they develop. At the same time, CRADA Collaborators have the right to negotiate for an exclusive license to any inventions developed under the CRADA. This potential conflict must be resolved in any CRADA where the Government uses service or support contractors.

Federal Register Notice dated September 11, 2000 (Volume 65, Number 176).

Summary:

This proposed rule would authorize Federal agencies to use an alternate patent rights clause in certain contracts with non-profit organizations and small business firms to provide support services at a Government-owned and-operated laboratory in connection with a CRADA between the laboratory and a collaborating party.

If the third party agreement includes the new proposed FAR clause, the third party may be required to reach an agreement with the CRADA Collaborator to allocate the IP rights in any invention developed, at least in part, by third party personnel in performance of work under the CRADA.

If the third party agreement does not include the new proposed FAR clause, then the third party agreement must be modified to provide for the proper allocation of IP rights in any invention developed, at least in part, by third party personnel in performance of work under the CRADA.

Model for Handbook:

For CRADAs where the Government intends or anticipates the use of support contractors in performance of the CRADA Statement of Work (SOW), and where the support contract includes the new proposed FAR clause, the CRADA should include the following language after Article 10.2.3.1:

“The Government intends to use support contractors for at least part of the tasks assigned to the Government in the SOW. [Non-Navy Collaborator] is advised that these support contractors have certain rights to inventions developed at least in part by their employees in support of work under this CRADA. The support contractor will be required to reach an agreement with [Non-Navy Collaborator] regarding these IP rights.”

For other CRADAs where the Government intends or anticipates the use of third party personnel in performance of the CRADA SOW, the third party contract must be modified to comply with the terms of the CRADA. Suggested language for this modification is as follows:

“The contractor is aware that employee A is being assigned to work on tasks assigned to the Government under CRADA XXX. The contractor has read the terms and conditions of that CRADA and in the event that any Subject Invention is made by employee A while performing tasks under CRADA XXX, the contractor agrees that the CRADA Collaborator will have a nonexclusive license, and the right to negotiate for an Exclusive License in any such Subject Invention, under the terms and conditions set forth in the CRADA.”

The following is language that has been used by NAVAIR. Please contact Paul Fritz, ORTA, Patuxent River, for more information at paul.fritz@navy.mil:

Assignment/Subcontracting - 1st Example:

Neither Collaborator may allow third parties (contractor support personnel) to perform any part of the Cooperative Work under this Agreement without express written consent of the other Collaborator. If consent is obtained, the Collaborator requesting such consent shall remain fully responsible for the portion of the Cooperative Work to be accomplished under a third-party agreement, and the third party is not a Collaborator of this Agreement. Any third-party agreement to perform a portion of the Cooperative Work shall contain terms consistent with this Agreement.

XXXXX intends to use third parties (contractor support personnel) for at least part of the tasks described in the Statement of Work and test plan.

XXXXX third parties (contractor support personnel) agree not to communicate with XXXXX.

XXXXX agrees XXXXX will be using third Parties (contractor support personnel) to install, integrate, calibrate, operate, collect data, and uninstall XXXXX equipment listed in Appendix C of this Agreement.

XXXXX agrees not to communicate with XXXXX third parties (contractor support personnel).

XXXXX agrees to only communicate with XXXXX personnel, XXXXX.

This Agreement shall not be assigned or otherwise transferred by either Collaborator without the prior written consent of the other Collaborator, except to the successor of that part of XXXXX's business to which this Agreement pertains.

If XXXXX or its successor or assignee is a U.S. company, and becomes, during the term of this Agreement or thereafter, directly or indirectly owned, controlled, or influenced by a foreign company or government (FOCI), then XXXXX or its successor or assignee shall promptly notify XXXXX to that effect.

Assignment/Subcontracting - 2nd Example:

The Government intends to use support contractors for at least part of the tasks assigned to the Government in the SOW. XXXXX is advised that these support contractors have certain rights to inventions developed at least in part by their employees in support of work under this CRADA.

This Agreement shall not be assigned or otherwise transferred by either Collaborator without the prior written consent of the other Collaborator, except to the successor of that part of XXXXX's business to which this Agreement pertains.

If XXXXX or its successor or assignee is a U.S. company, and becomes, during the term of this Agreement or thereafter, directly or indirectly owned, controlled, or influenced by a foreign company or government (FOCI), then XXXXX or its successor or assignee shall promptly notify XXXXX to that effect.

Proposed Modification Language for ABC and XYZ Companies:

The contractor is aware that (employee A) is being assigned to work on tasks assigned to the Government under Cooperative Research and Development Agreement (CRADA) number NSCRADA-NAWCADPAX-07-XXX. The contractor has read the terms and conditions of that CRADA and in the event that any Subject Invention is made by (employee A) while performing tasks under NSCRADA-NAWCADPAX-07-XXX, the contractor agrees that the Government will have all right, title, and interest in any such Subject Invention, under the terms and conditions set forth in the CRADA. The contractor further agrees that the contractor shall not have any right, title, or interest in any Subject Data as defined in Paragraph 1.23 of NSCRADA-NAWCADPAX-07-XXX and will assign said rights to the Government upon completion of the CRADA.

Section V - 3

Classified CRADAs

Classified CRADAs - Practical Considerations and Key Elements:

The following discussions are based in part on the NAVAIR experience and therefore, policies may differ to some extent within other Navy commands.

Upon initiation of a new CRADA effort, the ORTA provides a CRADA security questionnaire to the Navy Principal Investigator in order to collect necessary information regarding classified/unclassified, computer usage (information assurance), involvement of foreign nationals, etc. At the appropriate time, the ORTA submits the completed CRADA security questionnaire, a copy of the draft CRADA document, and a draft DD Form 254 (if a classified CRADA) to the Industrial Security Division of the Navy laboratory intending to execute the CRADA. The Industrial Security team then initiates a CRADA contract security review to determine whether the Non-Navy Collaborator is properly credentialed to participate in a classified CRADA. When the CRADA contract security review has been completed and the CRADA approved, a representative of the Industrial Security team will convey this approval to the ORTA. If the CRADA is not approved, the existence of any deficiencies will be brought to the attention of the ORTA who will then take actions to ensure that these deficiencies are addressed either by the Navy Principal Investigator, the Non-Navy Collaborator, or both, as necessary. Among the critical items and specific criteria examined by the Industrial Security team are the following:

Facility Clearance:

In order for a Non-Navy Collaborator to receive or generate classified information, it is necessary that the entity hold a facility clearance for that specific location at which the classified information will be received/generated. The Industrial Security Division of the Navy laboratory intending to execute the CRADA will contact the Defense Security Service (DSS) to ascertain whether a facility clearance exists. *It may not be practical to pursue a classified CRADA with a company that does not have a facility clearance already in place. The approval process for obtaining a facility clearance is lengthy and rigorous.*

CAGE Code:

A Commercial and Government Entity (CAGE) Code or "CAGE Code" is an identifier assigned to vendors as part of the Central Contractor Registration (CCR) process. The Industrial Security Division of the Navy laboratory intending to execute the CRADA will use the CAGE code during its CRADA contract security review. The CAGE code can be obtained directly from the Non-Navy Collaborator, or alternately, from on-line search engines such as BINCS (Business Identification Number Cross-reference System).

https://www.bpn.gov/bincs/begin_search.asp

DD Form 254 "Security Classification Specification":

For all classified CRADAs, the ORTA will prepare and submit a preliminary draft of a DD Form 254 to the Industrial Security Division of the Navy laboratory intending to execute the CRADA. This form will stipulate the level of safeguarding required, as well as specific details regarding use of COMSEC, INTEL, SCI, FOUO, OPSEC Requirements, etc. The DD Form 254 will include the

appropriate distribution statement for all subsequent reports generated as a result of CRADA activities. The draft DD Form 254 will be approved and signed by an authorized representative of the Industrial Security Division of the Navy laboratory intending to execute the CRADA. At the time of CRADA execution, the signed DD Form 254 will be forwarded, by the ORTA, to the Non-Navy Collaborator as a certified acknowledgment of Non-Navy Collaborator's ability to participate in the classified CRADA.

DD 2345 “Militarily Critical Technical Data Agreement”:

As stated in CRADA Article 3.3, if part the work on the Agreement will involve access to and work on Militarily Critical Technology (MCT) that must be controlled in accordance with DoDD 5230.25, the Non-Navy Collaborator must have a current MCT certification and a copy of its Militarily Critical Technical Data Agreement, DD Form 2345, must be submitted to the Navy laboratory intending to execute the CRADA, prior to obtaining access to or working on MCT technology under the Agreement. A copy of the certified DD Form 2345 is then included as Appendix C of the CRADA. If the Non-Navy Collaborator does not have a current, certified DD Form 2345, one must be applied for by completing the necessary application and submitting it, along with supporting documentation to the U.S./Canada Joint Certification Office, Defense Logistics Information Service (DLIS), in Battle Creek, Michigan. The application form can be downloaded from the DLIS website:

<http://www.dlis.dla.mil/JCP/forms/DD2345Form.pdf>

OPSEC Plan:

In the case of classified CRADAs or unclassified CRADAs involving FOUO information, the Non-Navy Collaborator will be required to submit a preliminary draft of an OPSEC Plan that conforms to guidelines presented in DI-MGMT-80934A “OPSEC Plan Guidance.” The OPSEC Plan is typically submitted to the Industrial Security Division of the Navy laboratory intending to execute the CRADA for approval and recommendation.

Guidance Documents to be Provided to the Non-Navy Collaborator:

Signed DD Form 254 Security Classification Specification
DD5400.7-R FOUO Guidance
Information Assurance Manual SecNav M-5239.1
Navy IA Program OPNAVINST 5239.1B
OPSEC Contract Data Requirements List OMB-No. 0704-0188
OPSEC Plan Guidance DI-MGMT-80934A

Security Considerations for FOCI Companies:

Special Security Agreement

American-based corporations that are foreign owned, controlled, or influenced are able to conduct business with DoD by virtue of a Special Security Agreement (SSA) that is predicated on the establishment of a “firewall” between the U.S. subsidiary and its foreign ownership that is intended to ensure that sensitive or classified information is not vulnerable to foreign disclosure. The SSA certifies that the company will abide by regulations and practices outlined in the NISPOM, particularly with regard to access to classified or sensitive information by unauthorized individuals. Either the ORTA or a security specialist can confirm the existence of a SSA by contacting the Defense Security Services (DSS).

In CRADAs involving FOCI companies, it is recommended that the following paragraph, or suitable alternate language, be added to Article 4.2.1:

***[Non-Navy Collaborator]** certifies that it maintains data and information in accordance with the National Industrial Security Program Operating Manual (NISPOM), and in accordance with NISPOM, maintains adequate protective measures preventing unauthorized disclosure of classified information to personnel not otherwise cleared to receive such information. Additionally, **[Non-Navy Collaborator]** certifies that it maintains facility security procedures in accordance with NISPOM and in accordance with its Special Security Agreement (SSA), as may be amended.*

Foreign Disclosure Assessment:

During the CRADA contract security review, an assessment will be made of the potential for foreign disclosure of classified or otherwise sensitive information. In some instances, this will require the submission of a "Foreign Firm Questionnaire" to the parent Navy Command under which the Navy laboratory intending to execute the CRADA is aligned.

Section V - 4

Collaborations and Transactions with Foreign Persons, Entities, and Dealing with Foreign Owned, Controlled or Influenced (FOCI) Entities

Special diligence must be exercised in advance of discussions, exchanges of technical information, collaborations, and negotiation of business transactions (licensing inventions, CRADAs, and sales) with foreign persons, entities, and any entities that are “foreign owned, controlled, or influenced (FOCI).” This Section discusses the issues that most frequently present themselves when dealing with foreign persons, entities, and FOCI, and provides references to relevant authorities for resolving those issues. This Section includes the following:

- V - 4a Foreign Disclosure and Export Control Questions and Answers - Collaborations and Transactions with Foreign Persons and Entities
- V - 4b An Example of One Navy Laboratory’s Due Diligence Program for Dealing with Foreign Persons, Entities and FOCI
- V - 4c Summary of Foreign Disclosure Determination and Export Control Requirements for Licenses and CRADAs
- V - 4d Tool Kit - Links to Foreign Disclosure and Export Control Laws, Regulations, and Other Useful References

Section V - 4a

Foreign Disclosure and Export Control Questions and Answers - Collaborations and Transactions with Foreign Persons and Entities

Due diligence must be exercised in advance of discussions, exchanges of technical information, collaborations, and negotiating agreements with foreign persons and entities (including entities that are foreign owned, controlled, or influenced (FOCI)). The following “questions and answers” cover the issues that are most often present and must be addressed whenever considering dealing with foreign persons, entities, and FOCI.

1. ***Must the Navy International Programs Office (NIPO) be involved (or at least consulted) in all transactions (including disclosures of technical information) involving foreign persons and entities?*** All research proposals/projects that are ***classified*** (or may involve disclosure or development of classified information) or involve ***participation with instrumentalities of a foreign government or an international organization*** must be coordinated with NIPO. NIPO will provide guidance on what type (if any) “international agreement” or other approvals may be necessary for the proposed collaboration or disclosure of technical information. This may be a more or less time consuming process depending upon the technology involved, the identity of the foreign collaborator, and, if an international agreement is required. All disclosures of classified military information (CMI) and controlled unclassified information (CUI) to instrumentalities of a foreign government or international organization require a foreign disclosure determination (FDD) by NIPO or an authority with a delegation of disclosure authority (DDL) from NIPO. The most useful authoritative reference tool for assessing foreign disclosure issues is the Department of the Navy Foreign Disclosure Manual (<http://doni.daps.dla.mil/secnavmanuals.aspx>). It contains an extremely useful list of acronyms, abbreviations, and definitions (many used in this section) relevant to foreign disclosure and export control issues. If a transaction (or disclosure) does not involve classified military information (CMI) and is not with an instrumentality of a foreign government or international organization, then coordination with NIPO is not required (although, consulting with NIPO may result in obtaining useful guidance).
2. ***What is “controlled unclassified information (CUI)”?*** Controlled Unclassified Information (CUI) is unclassified information to which access or distribution limitations have been applied in accordance with national laws, policies, and regulations. CUI is a term used to collectively describe unclassified information that has been determined to be exempt from mandatory disclosure to the public under the Freedom of Information Act (5 U.S.C. 552) *or that is subject to U.S. export controls*. See SECNAVINST 5510.34A for a more complete definition. ***For purposes of this Q&A, CUI is unclassified technical information that is subject to U.S. export control laws.***
3. ***What are the principle U.S. export control systems that apply to “technology transfer” transactions with foreign persons, entities, and FOCI?*** Export controls are established under two systems: one managed by the Department of State (for “military” items); and one managed by the Department of Commerce (for “dual use” items). The Government is covered by and required to comply with both.

- a. The export (and temporary import) of defense articles and services (and related technical information) is controlled in accordance with 22 U.S.C. 2778-2780 (the Arms Export Control Act (AECA)) as implemented in 22 C.F.R. Parts 120-130 (the International Traffic in Arms Regulations (ITAR)). This export control system is managed by the Directorate of Defense Trade Controls (DDTC) within the Department of State. The U.S. Government views the sale, export, and re-transfer of defense articles and defense services as an integral part of safeguarding U.S. national security and furthering U.S. foreign policy objectives. The Directorate of Defense Trade Controls (DDTC) is charged with controlling the export and temporary import of defense articles and defense services covered by the United States Munitions List (USML). The DDTC website provides a wealth of information and useful tools for understanding and complying with the ITAR. The Directorate of Defense Trade Controls (DDTC), Department of State, website is at <http://www.pmdtc.state.gov/>.
 - b. The export of “dual use” items is controlled under the Export Administration Regulation (EAR) by the Bureau of Industry and Security (BIS) in the Department of Commerce. The mission of BIS is to advance U.S. national security, foreign policy, and economic objectives by ensuring an effective export control and treaty compliance system and promoting continued U.S. strategic technology leadership. BIS is charged with controlling the export of dual use items covered by the Commerce Control List (CCL). The Bureau of Industry and Security, Department of Commerce, website is at <http://www.bis.doc.gov/>.
4. **Who are foreign persons and entities (non-U.S. entities)?** The ITAR, EAR, and other authorities have defined what constitutes a foreign person. For purposes of technology transfer, it is most useful to apply the definitions from the ITAR. The following definitions are contained in the ITAR.¹

22 C.F.R. § 120.14 **Person.** *Person* means a natural person as well as a corporation, business association, partnership, society, trust, or any other entity, organization or group, including governmental entities. If a provision in this subchapter does not refer exclusively to a foreign person (§120.16) or U.S. person (§120.15), then it refers to both.

22 C.F.R. § 120.15 **U.S. person.** *U.S. person* means a person (as defined in §120.14 of this part) who is a lawful permanent resident as defined by 8 U.S.C. 1101(a)(20) or who is a protected individual as defined by 8 U.S.C. 1324b(a)(3). It also means any corporation, business association, partnership, society, trust, or any other entity, organization or group that is incorporated to do business in the United States. It also includes any governmental (federal, state or local) entity. It does not include any foreign person as defined in §120.16 of this part.

¹ The Export Administration Regulation (EAR) also provides varied definitions for specific provisions of the EAR at: 15 C.F.R. § 772.1 **Person**; 15 C.F.R. §772.1 **U.S. Person**; 15 C.F.R. § 740.9(a)(2)(i)(C) **U.S. Person**; 15 C.F.R. § 740.14 **U.S. Person**; 15 C.F.R. § 746.2(d) **U.S. Person**; and, 15. C.F.R. § 760.1 **U.S. Person**. Useful definitions and guidance are also contained in the Department of the Navy Foreign Disclosure Manual. <http://doni.daps.dla.mil/secnavmanuals.aspx> See also DFARS 209.104-70 and 252.209-7001.

22 C.F.R. § 120.16 **Foreign person.** *Foreign person* means any natural person who is not a lawful permanent resident as defined by 8 U.S.C. 1101(a)(20) or who is not a protected individual as defined by 8 U.S.C. 1324b(a)(3). It also means any foreign corporation, business association, partnership, trust, society or any other entity or group that is not incorporated or organized to do business in the United States, as well as international organizations, foreign governments and any agency or subdivision of foreign governments (e.g., diplomatic missions).

5. ***When are entities “Foreign Owned, Controlled, or Influenced (FOCI)” and how should/whether we should deal with them?*** When we consider dealing with foreign persons and entities (individuals, corporations, governments, and international organizations), advance consideration must be given to export control and foreign disclosure requirements and restrictions. Extra diligence must also be exercised when we are considering a deal with a U.S. company that is subject to foreign ownership, control, or influence (a “FOCI”). Navy Policy allows collaborative research with entities under FOCI, and requires that steps be taken to ensure that working with the FOCI is in the best interests of the United States. We directly ask potential Non-Federal partners for information to determine whether they are under FOCI in order to ensure foreign interests are not given an opportunity to undermine U.S. security and export controls to gain unauthorized access to critical technology.
- a. U.S. citizenship is a criterion for obtaining a personal security clearance. Thus, while a permanent resident alien is considered to be a U.S. person for purposes of export controls under the ITAR and the EAR, that same individual is not eligible for a personal security clearance. Similarly, although a U.S. corporation is considered to be a U.S. person for export control purposes, that same U.S. corporation may not be eligible to obtain or retain a Facility Clearance (an FCL which is analogous to a personal clearance for a company, university, or other entity). An FCL is a requirement for entities to be awarded classified Government Funding Agreements (contracts, cooperative agreements, and grants) in accordance with the DD 254 (“Department of Defense Contract Security Classification Specification”) applicable to the funding agreement.
 - b. Granting and administering FCLs is a function of the Defense Security Service (DSS): <https://www.dss.mil/GW/ShowBinary/DSS/index.html>.

The DSS administers and implements the Defense portion of the National Industrial Security Program (NISP) pursuant to Executive Order 12829. DSS, through its Personnel Security Clearance Office (PSC), also adjudicates personal security clearances for contractors on behalf of the Department of Defense. The FOCI provisions in the NISPOM, (<http://nsi.org/Library/Govt/Nispom.html#link2>) should be consulted when there are specific questions about the eligibility of an entity under FOCI for a Facility Clearance. Chapter 15 of the Navy Foreign Disclosure Manual also addresses the considerations that need to be made when dealing with FOCI.

The following link is to the DSS FOCI Fact Sheet:

https://www.dss.mil/GW/ShowBinary/DSS/about_dss/fact_sheets/foci_fagsheet.html.

- c. To have access to U.S. classified information and participate in the NISP, a facility - a designated operating entity in private industry or at a college/university - must have a bona fide procurement requirement. Once this requirement has been established, a facility can be processed for an FCL. An FCL is an administrative determination that a facility is eligible to access classified information at the same or lower classification category as the clearance being granted. The FCL may be granted at the Top Secret, Secret or Confidential level. When a determination has been made that a facility meets the eligibility requirements for a FCL, the contractor must execute a Defense Security Agreement which is a legally binding document that sets forth the responsibilities of both parties and obligates the contractor to abide by the security requirements of the National Security Industrial Program Operating Manual (NISPOM):
<http://nsi.org/Library/Govt/Nispom.html>
https://www.dss.mil/GW/ShowBinary/DSS/about_dss/fact_sheets/nisp_faqsheet.html
- d. The National Industrial Security Policy Operating Manual (NISPOM) provides a good discussion of the considerations that should be made in determining whether an entity is under FOCI [See Chapter 2, Section 3 (“Foreign Ownership, Control, or Influence”).² <http://nsi.org/Library/Govt/Nispom.html#link2>“A U.S. company is considered under FOCI whenever a foreign interest has the power, direct or indirect, whether or not exercised, and whether or not exercisable through the ownership of the U.S. company’s securities, by contractual arrangements or other means, to direct or decide matters affecting the management or operations of that company in a manner....” If a U.S. entity is under FOCI, the degree of foreign ownership, control, and influence must be assessed on a case-by-case basis to determine whether a collaborative agreement should be pursued or approved. Of particular importance is the nature of the technology that will be the subject of the agreement (i.e., is it classified, export controlled, or militarily critical technology?).
- e. When a company with an FCL enters into negotiations for the proposed merger, acquisition, or takeover by a foreign interest, it is required to submit notification to DSS of the commencement of such negotiations. The notification shall include the type of transaction under negotiation (stock purchase, asset purchase, etc.), the identity of the potential foreign investor, and a plan to mitigate/negate the FOCI consistent with paragraph 2-303, National Industrial Security Program Operating Manual (NISPOM), in order to retain the FCL. Mitigation plans for FOCI may include many elements including Special Security Agreements and Security Control Agreements. Special Security Agreements (SSAs) and Security Control Agreements (SCAs) are substantially identical arrangements that impose substantial industrial security and export control measures within an institutionalized set of corporate practices and procedures; require active involvement of senior management and certain Board members in security matters (who must be cleared, U.S. citizens); provide for the establishment of a Government Security Committee (GSC) to oversee classified and export control matters; and preserve the foreign person shareholder’s right to be represented on the Board with a direct voice in the business management of the company while denying unauthorized access to classified information.

² <http://nsi.org/Library/Govt/Nispom.html> See also: Chapter 15 of the Department of the Navy Foreign Disclosure Manual (September 2007), <http://doni.daps.dla.mil/secnavmanuals.aspx>; and, SECNAVINST 5510.34A, Paragraph 7q, <http://doni.daps.dla.mil/allinstructions.aspx>.

- f. When considering whether to enter into a CRADA with an entity that is under FOCI, great deference should be accorded to the fact that the entity has been allowed to retain its FCL under an SSA, SCA, or other mitigation plan approved by the DSS (and thereby allowed to continue work on classified Government contracts). Any decision to proceed with a CRADA with an entity that is under FOCI should be coordinated with the servicing security office, laboratory management, any sponsors of the work, NIPO (when required or appropriate). The U.S. Trade Representative must also be consulted. Also, all CRADAs with FOCI are **Non-Standard** and should be designated and processed as such.
6. ***When is coordination with the U.S. Trade Representative required?*** All Navy licenses and CRADAs with "foreign persons or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government)" must be coordinated with the U.S. Trade Representative in accordance with Executive Order 12591.³ The consultation requirement is not equivalent to the assessment of an entity under FOCI as discussed above.
- a. Section 4 of the Executive Order provides (with emphasis added):
- "Sec. 4. *International Science and Technology.*** In order to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad, (a) The head of each Executive department and agency, when negotiating or entering into cooperative research and development agreements and licensing arrangements with foreign persons or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government), shall, ***in consultation with the United States Trade Representative***, give appropriate consideration:
- (1) to whether such foreign companies or governments permit and encourage United States agencies, organizations, or persons to enter into cooperative research and development agreements and licensing arrangements on a comparable basis;
 - (2) to whether those foreign governments have policies to protect the United States intellectual property rights; and
 - (3) where cooperative research will involve data, technologies, or products subject to national security export controls under the laws of the United States, to whether those foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such national security export controls, either through participation in the Coordinating Committee for Multilateral Export Controls (COCOM) or through other international agreements to which the United States and such foreign governments are signatories.

³ <http://www.archives.gov/federal-register/codification/executive-order/12591.html>

- b. The thrust of the Executive Order provision is to ensure U.S. competitiveness. Only **consultation** with (**not concurrence** from) the Trade Representative is required. Note that the considerations that are required under the Executive Order are directed to assessments of “foreign governments.” On that basis, the result of a consultation with the Trade Representative on a CRADA with a company from a specific country should apply equally to other CRADAs with companies in the same country. Coordination with the Trade Representative is accomplished by the Technology Transfer Office (TTO). The current contact information for consultation with the U.S. Trade Representative is:

U.S. Trade Representative
Mr. Christopher Wilson
Deputy Assistant USTR for Intellectual Property
600 17th Street, N.W.
Washington, DC 20508
Telephone: 202-395-9471
Facsimile: 202-395-3891
E-mail: cwilson@ustr.eop.gov

7. **How do we deal with U.S. citizens who represent foreign persons and entities?** For foreign disclosure purposes, a person, regardless of citizenship, who represents a foreign interest in his or her dealings with the U.S. Government, or a person who is officially sponsored by a foreign government or international organization, must be treated as a Foreign National. Thus, a U.S. national will be treated as a foreign person for disclosure purposes when acting as a foreign representative.
8. **Who is primarily responsible for establishing appropriate controls of technical information?** Control of technical information is the responsibility of the principal investigator/project manager. Technical information generated under a project or program should assigned an appropriate “distribution statement.”
 - a. All classified and controlled unclassified technical information must bear one of the distribution statements prescribed by DoD 5230.24. A distribution statement is used to denote the extent of availability of technical information for distribution, release, and disclosure without additional approvals or authorizations. At the time technical information is generated, an appropriate “distribution statement” should be established. Establishing the appropriate “distribution statement” is also the responsibility of the principal investigator/project manager.
 - b. Guidance contained in DoD 5230.25 should be used for making the distribution determination. Distribution Statement A reflects approval for public release and unlimited distribution. Documents that are recommended for Distribution Statement A must reviewed and approved in accordance with the NRL Publications Program (NRLINST 5600.2) to ensure compliance with DoD Directive 5230.9 (“Clearance of DoD Information for Public Release”). The purpose of the review is to ensure full compliance with all applicable foreign disclosure and export control requirements and restrictions.

9. ***What is the first step for ensuring compliance with the export control requirements?***

The first determination that must be made is whether the technology that is proposed for disclosure to a foreign person or entity (anywhere in the world) or may be developed in collaboration with a foreign person or entity is export controlled. This determination requires making an examination of the U.S. Munitions List (USML) and the Commerce Control List (CCL). Both of the lists are accessible on the Internet, and the State Department and Department of Commerce have good websites that explain the requirements and procedures. The USML is at 22 C.F.R. Part 121:

http://www.pmdtcc.state.gov/official_itar_and_amendments.htm.

The CCL is at 15 C.F.R. Part 774 (and explained in Part 738):

http://www.access.gpo.gov/bis/ear/ear_data.html.

- a. Start with the USML. (if a technology is listed on the USML, there is no need to consult the CCL). There are 21 USML Categories listed in Subpart 121.1. Check your technology against the descriptions for each category. Note the results (including negative results) of your search. If there is a match, note the particular provision. If there is no match, proceed to the CCL.
- b. If there is no match on the USML, go to the CCL. Check your technology against the ten categories (Category 0 through Category 9) on the CCL. Note the results (including negative results) of your search.
- c. If the technology to be disclosed is on either list, further analysis will have to be done to determine whether an export license (or, in some cases, a temporary import license) will be required. There are a number of exceptions and exclusions that will have to be considered. The Office of Counsel can assist.

10. ***Who should make the examination of the USML and the CCL?*** There are various ways of dealing with the assessment. At NRL, the “first pass” is conducted by the Principal Investigator (PI) or a Program Participant knowledgeable of the technology. If there is a question about whether a technology belongs on the USML or the CCL, a Commodity Jurisdiction (CJ) Request may be submitted to the Directorate of Defense Trade Controls (DDTC). Requests for a Commodity Jurisdiction determination should be coordinated with the Office of Counsel. http://www.pmdtcc.state.gov/commodity_jurisdiction.htm If the technology is on the CCL and there is a question about the Export Control Classification Number (ECCN) that should be assigned to the technology, a Classification Request may be submitted to the Bureau of Industry and Security (BIS). If the issue cannot be resolved at NRL, the assistance of the Navy International Programs Office (NIPO) may be requested. If the technology is export controlled, that should be reflected on the Distribution Statement for the technical information generated in the collaboration.

11. ***Do the export controls apply to all types of information?*** The export controls generally do not apply to non-technical or administrative information; financial or budget information; human resources information; or, basic marketing information.

12. ***What is a deemed export?*** An export of controlled technical information occurs whenever such information is disclosed to a foreign person anywhere in the world. Such disclosure is considered to be an export to the country of the foreign person to whom the disclosure is made (even if the disclosure is made within the United States, for example, during a visit to a Navy laboratory). If the disclosure of export controlled technical information occurs in the

United States, the disclosure is sometimes referred to as a “**deemed export**.” The BIS website (<http://www.bis.doc.gov/licensing/index.htm>) provides an excellent discussion of deemed exports that should be reviewed in its entirety. The concept of “deemed exports” applies equally to disclosures of technical information listed on the USML as well as the CCL.

13. ***If a technology is listed on the USML or the CCL, does that mean that an export license will be required for the collaboration with a foreign person or entity?*** Not necessarily. There are numerous exemptions from the licensing requirements under the ITAR and EAR. The most important is that for technical information that is “publicly available” or in the “public domain.” For example: if a Navy laboratory licenses a Government invention to a foreign entity, and the patent has been published, the technical information in the published patent is “publicly available” and an export license is not required for disclosure of that technical information to the foreign licensee. There are also special provisions for dealing with Canadian entities (see 22 C.F.R. 126.5 and <http://www.dlis.dla.mil/JCP/>). Coordination with the Office of Counsel should be initiated to establish whether an exemption may apply.
14. ***What if a determination is made that an export license is required?*** If an export license is required (which would be a rare event at most Navy laboratories), the Office of Counsel should be contacted to provide assistance and coordinate with NIPO (as required) the filing of a license application with the State Department under the ITAR or the Commerce Department under the EAR.
15. ***If a technology involved in a disclosure/collaboration with a foreign person or entity is listed on the USML or the CCL, will a foreign disclosure determination (FDD) through organizational security or NIPO also have to be made?*** The requirements and procedures for disclosure of export controlled information (i.e., controlled unclassified information (CUI)) to foreign government entities and international organizations are set forth in SECNAVINST 5510.34A and the DoN Foreign Disclosure Handbook. If technical information proposed for release to a foreign government or international organization is export controlled, it is CUI and a foreign disclosure determination (FDD) must be made (in addition to compliance with all applicable export control license requirements). Regarding other foreign persons, the Handbook explains: “Foreign Disclosure.[T]he transfer or disclosure of CMI or CUI to a foreign national who is an authorized employee of the U.S. Government or a U.S. contractor is technically not a foreign disclosure, since the disclosure is not made to the person’s government. For contractors, access by such persons will be handled under the provisions of the Arms Export Control Act or the Export Administration Act and the National Industrial Security Program Operating Manual (NISPOM).”
16. ***What additional coordination is required for approval of sales to foreign entities?*** Coordination with the U.S. Trade Representative is not required. However, at NRL, the requirement for advance approval from the director of research does apply as part of its due diligence process discussed in Section V-4b. If the proposed transaction involves technology or information that is subject to release restrictions, coordination with the Information Security Section is required to ensure that all security requirements regarding export control and/or foreign disclosure have been met. If the proposed sale will involve release of controlled information (1) to a foreign person anywhere in the world or (2) to a representative of a foreign government (even if that representative is a U.S. citizen), NRL security will coordinate with the Navy International Programs Office (NIPO) to ensure appropriate release approvals are met.

17. **What is the Militarily Critical Technologies List (MCTL) and how is it used?** <http://www.dtic.mil/mctl/> Failure to identify and protect critical technologies makes U.S. military assets vulnerable to cloning, neutralization, or other action that degrades current and anticipated capabilities. To help minimize these risks, DoD's Militarily Critical Technologies Program developed and periodically updates two lists of technologies - the [Militarily Critical Technologies List](#) and the [Developing Science and Technologies List](#).
- a. The MCTL is a compendium of existing goods and technologies that DoD assesses would permit significant advances in the development, production and use of military capabilities of potential adversaries. The DSTL is a compendium of scientific and technological capabilities being developed worldwide that have the potential to significantly enhance or degrade US military capabilities in the future. It includes basic research, applied research and advanced technology development. While the lists are primarily intended to inform U.S. export control decisions, they can also inform counterintelligence activities, research plans, and technology protection programs, making MCTL and DSTL resources for security decisions.
 - b. The MCTL and DSTL are not export control lists. They are used as tools for assessing what technologies should be added to the USML and CCL, and for assessing whether export license applications should be granted. The usefulness of the MCTL and DSTL was questioned in a recent GAO Report. <http://www.gao.gov/new.items/d06793.pdf>.
18. **What else needs to be considered?** All requirements related to Publication Approval and Foreign Visitors must be strictly complied with. Preliminary discussions with foreign persons must be carefully structured to ensure that there is no inadvertent unauthorized export of controlled information. Remember, an export can occur anywhere in the world if the recipient of technical information is a foreign person or a representative of a foreign person. The status of Government IP rights under any agreement should be established in advance in coordination with the laboratory's office of counsel. A nondisclosure agreement (NDA) may also be required to protect Government IP rights (but it is not a substitute for an FDD or an export license).
19. **Are there other ways that Navy scientists and engineers may get involved in the export control process?** When the State Department (Directorate of Defense Trade Controls (DDTC)) reviews export license applications, it frequently requires technical assistance from the DoD and military departments. When this is the case, it may refer an inquiry to the [Defense Technology Security Administration](#) which, in turn, may refer inquires to the military departments (the Navy International Programs Office (NIPO) in the case of the Navy). When additional subject matter expertise is required, the inquiry may be further referred (for example, NIPO may refer an inquiry to a Navy laboratory). In reviewing license applications, various references (including the Militarily Critical Technologies List (MCTL) and the Developing Science and Technologies List (DSTL)) may be used (<http://www.dtic.mil/mctl/>).

20. **What should Navy laboratories do to remind their collaborators about their obligation to comply with export control requirements?** Appropriate clauses may be included in agreements to address the export of technical information generated or delivered under the agreement. A clause similar to the following may be used:

Export Controls.

- a. *Neither Party shall make a disclosure, export, or deemed export of any technical information, articles, or services that result from this Agreement to any foreign location, entity, or person (including its own employees and associates of any type) except in full compliance with all applicable United States Federal laws (including treaties) and departmental regulations that establish and implement export controls. Compliance with all applicable export licensing requirements and restrictions implemented in the International Traffic in Arms Regulation (ITAR) and the Export Administration Regulations (EAR) is required. A “deemed export” is a disclosure of export controlled information in the United States or abroad to a “foreign person” (under the ITAR) or to a “foreign national” (under EAR).*
 - b. *This Agreement does not authorize any disclosure, export, or deemed export of technical information, articles, or services, nor does it authorize or approve the use of any exemption to the export licensing requirements of the ITAR or the EAR.*
 - c. *The Purchaser warrants that, as of the date of its authorized representative’s signature approving this Agreement, it [(does) or (does not)] intend to make a disclosure, export, or deemed export of technical information, articles or services containing or derived from technical information delivered to it by [insert Navy laboratory] under this Agreement.*
21. **Why do some universities resist export control provisions in agreements with the Government?** Universities rely heavily upon the use of foreign students and faculty to perform fundamental research (much of which is performed under funding agreements with the Government); universities also strongly resist limits upon their ability to publish the results of their research. Both the ITAR (22 C.F.R. [§120.11](#)) and the EAR (15 U.S.C. [§734.8](#)) provide exemptions from the export license requirements for fundamental research under specified conditions (thus obviating the need to obtain an export license for their foreign participants). Fundamental research is defined to mean basic and applied research in science and engineering where the resulting information is ordinarily published and shared broadly within the scientific community, as distinguished from research the results of which are restricted for proprietary reasons or specific U.S. Government access and dissemination controls. University research will not be considered fundamental research (and the license exemption will be lost) if: (1) The university or its researchers accept other restrictions on publication of scientific and technical information resulting from the project or activity, or (2) the research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable. For this reason, certain universities do not routinely accept classified funding agreements from the Government. If you would like to delve into this topic more, take a look at: [National Security Decision Directive 189](#) (www.fas.org/irp/offdocs/nsdd/nsdd-189.htm, www.aau.edu/research/AAASIGComm6_27_05.pdf, www.aas.org/news/releases/2005/1012dod.pdf); DoD Instruction Number [5230.27](#); and, www.washington.edu/research/osp/ecr.html).

Section V - 4b

An Example of One Navy Laboratory's Due Diligence Program for Dealing With Foreign Persons, Entities and FOCI

The following describes one Navy laboratory's internal "pre-approval" process for initiating CRADA discussions with Foreign Owned, Controlled or Influenced (FOCI) entities. The process includes a "pre-approval" of the opportunity by the laboratory's director of research following coordination with various internal organizations including the legal organization and the laboratory's security organization. This internal pre-approval process was established by this laboratory as a matter of due diligence in dealing with foreign entities. The pre-approval process is not mandatory, but other laboratories may wish to pursue this or alternative pre-approval processes suited to their circumstances.

(Step 1)

When the ORTA is approached with a CRADA opportunity involving a FOCI, the following correspondence is sent to the principal investigator (PI) that requested the CRADA:

Dear PI:

CRADA proposals involving foreign entities (either directly as the Non-Navy Collaborator or indirectly as a third party to the Non-Navy Collaborator) need to be pre-approved by the laboratory's director of research before the laboratory enters into a negotiating stage. The internal routing is extensive, and it is difficult to predict how long it will take.

CRADA negotiations involving a foreign entity as a party (a Non-Navy Collaborator) or other participant (under agreement with a Non-Navy Collaborator) are exceptions to the laboratory's regular CRADA process, and advance approval of the director of research must be obtained before negotiations may be initiated. Consultation with the US Trade Representative (USTR) is also required prior to negotiations of a CRADA with an entity that is foreign owned or controlled (in accordance with E.O. 12591). In addition, if technology that is export controlled will be involved in the CRADA, coordination with the Office of Naval Research (ONR) and/or the Navy International Programs Office (NIPO) may be required. An export license may also be required.

Responsibilities for CRADA pre-approval process:

- A. The laboratory's principal investigator is responsible for preparing the advance-approval request described here (and identified in Step 1 below).
 - 1) The principal investigator shall contact the ORTA before preparing the request to discuss the proposed CRADA and obtain a sample format. Please see the documents (below) that are a sample format for the principal investigator to use.
 - 2) The principal investigator shall review the export control lists (shown below) to determine whether the technology that will be involved in the proposed CRADA (whether existing or to be developed) is export-controlled (and it is suggested you use the advanced approval request memo format attached here). The attached draft memo includes the type of information that security and the director of research need in order to make a determination on whether to proceed with CRADA negotiations involving a foreign entity.

- 3) The advance-approval request shall contain the following elements:
 - a) Background and purpose of the proposed collaboration;
 - b) Detailed information about any foreign party or participant that will be involved;
 - c) A statement summarizing the results of the principal investigator's review of the export control lists indicating whether the CRADA technology is export-controlled;
 - d) Publication release numbers of related laboratory research, if available; and,
 - e) A summary sheet.
 - 4) Routing. The principal investigator shall route the advance-approval request package as follows:
 - a) PI/Section
 - b) ORTA (Technology Transfer Office)
 - c) PI's Branch Head
 - d) PI's Division Head
 - e) ADOR (Associate Director of Research)
 - f) Office of Counsel
 - g) ORTA (Technology Transfer Office)
 - h) Laboratory's Security Office
 - i) Director of Research
 - k) ORTA (Technology Transfer Office)
- B. The ORTA is responsible for reviewing the advance-approval request (Step 2) for completeness and discussing any special issues with the principal investigator, as well as consulting with the USTR and ONR/NIPO (in coordination with office of counsel and the laboratory's security office) as required.
- C. Principal investigator's branch/division heads and ADORs are responsible for reviewing the request and providing recommendations as to whether the proposed CRADA should be pursued (Steps 3, 4, and 5). Any recommendation against pursuing the CRADA will be immediately sent to the ORTA.
- D. Office of counsel is responsible for reviewing the request for legal sufficiency (Step 6). If the PI determines that the CRADA will involve technology that is export controlled, office of counsel will provide comments and recommendations regarding any requirements for a foreign disclosure determination and/or an export license.
- E. Laboratory's security office is responsible for reviewing the subject matter of the technology involved in the proposed CRADA for public release authorization (Step 8). Laboratory's security office will also coordinate the processing of required foreign disclosure determination requests with ONR/NIPO.
- F. Director of research will approve or disapprove the request (Step 9).
- G. ORTA will take one of the following actions if Code 1001 approves the request (Step 10):
- 1) If the technology is not export-controlled. If director of research approves CRADA negotiations, ORTA will consult with the USTR. ORTA will notify the principal investigator following a positive response from the USTR, and CRADA negotiations may begin.

- 2) If the technology is/may be export-controlled. If director of research approves CRADA negotiations, in addition to consulting with the USTR (above), ORTA, office of counsel, and laboratory's security office will coordinate submission of a request for a foreign disclosure determination to ONR/NIPO as appropriate. ORTA and office of counsel will also determine whether an export license may also be required. When all of the foregoing has been successfully accomplished, ORTA will notify the principal investigator that CRADA negotiations may begin.

Additional Information: The process for obtaining advance-approval to enter into CRADA negotiations when a foreign party or other foreign entity will be involved is in addition to the usual CRADA formation and approval process. If advance-approval to enter into negotiations is granted, the usual CRADA negotiation, review, and approval process will be followed. This includes: negotiation of a draft CRADA by the ORTA with the CRADA Collaborator; review of the draft CRADA by the principal investigator's division and ADOR; and, legal review of the draft CRADA by office of counsel; and, approval and execution of the CRADA by codes the director of research and the commanding officer.

The following guidance is provided to the principal investigator for doing the export control assessment:

CHECKING THE USML AND CCL /PRE-APPROVAL REQUESTS

A determination must be made whether technology (articles, services, or technical information) that is (1) proposed for export to a foreign location or disclosure to a foreign person or entity (anywhere in the world) or (2) that may be developed in collaboration with a foreign person is export controlled. This determination requires making an examination of the U.S. Munitions List (USML) and the Commerce Control List (CCL). Both of the lists are accessible on the Internet, and the Department of State and the Department of Commerce have good websites that explain the requirements and procedures.

- The USML is at 22 C.F.R. Part 121
http://www.pmdtc.state.gov/official_itar_and_amendments.htm
 - The CCL is at 15 C.F.R. Part 774 (and explained in Part 738)
http://www.access.gpo.gov/bis/ear/ear_data.html
1. Start with the USML (if a technology is listed on the USML, there is no need to consult the CCL). There are 21 USML Categories listed in Subpart 121.1. Check your technology against the descriptions for each category. Note the results (including negative results) of your search. If there is a match, note the particular provision. If there is no match, proceed to the CCL (below).
 2. If there is no match on the USML, go to the CCL. Check your technology against the ten categories (Category 0 through Category 9) on the CCL. Note the results (including negative results) of your search.
 3. If the technology to be exchanged is on either list, further analysis will have to be done to determine whether an export license (or, in some cases, a temporary import license) will be required. There are a number of exceptions and exclusions that will have to be considered. The Office of Counsel can assist. Include a summary of the results of your search in the preapproval request to the DOR.

(Step 2)

Advance Internal Approval Memo (Sample) to be used by principal investigator to support internal pre-approval to CRADA negotiations with a FOCl:

Date:

Reply to Attention of: Principal Investigator with contact information

Subject: Proposed CRADA between the Laboratory and XXX Corporation ("XXX")

To: Director of Research

1. The laboratory has been contacted by a FOCl company, XXX, that has expressed interest in pursuing collaborative research, etc. *(Describe here as much detail as you know about the circumstances of the inquiry, whether any intellectual property is jointly owned, etc., what company has expressed interest and what country they are from etc.).*
2. As the laboratory's Principal Investigator of this potential CRADA, I understand that it is my responsibility to check the Commerce Control List (CCL), the U.S. Munitions List (USML), and the Military Critical Technologies List (MCTL) to determine if the technology is controlled. I have consulted online versions of these lists, and to the best of my knowledge, I do (or do not) believe this CRADA technology appears on any of them. In particular, I looked for entries related to *(describe the technology and provide explanation why you believe this CRADA technology does/does not appear on any of the above lists)*.
3. *[Optional: If the technology has been approved for public release, cite applicable laboratory security office release number(s), if known. Providing this information helps the laboratory's security office make a recommendation as to whether or not the technology should have a Foreign Disclosure Determination (FDD). If code the laboratory's security office recommends an FDD following the director of research approval, then office of counsel will prepare the applicable document and forward it to ONR. While the publication release numbers are not mandatory, this information should help expedite the review by the laboratory's security office.]*
4. Please let me know if you need additional information to make a determination concerning the dissemination of technical information to this *(country e.g. United Kingdom)* third party. Attached is a brief summary of the proposed CRADA. I can be reached at (xxx) xxx-xxxx or xxxxx@xxx.

Name, Title

Proposed CRADA between [insert Navy Laboratory] and XXX

CRADA Title:

Summary: *[One or two paragraphs summarizing the proposed research, exchange, etc. Include the laboratory's benefit from working with this entity and why the laboratory wants to /needs to work with this entity; include some description of company's business and R&D expertise that it brings to the CRADA opportunity. Also, identify relevant laboratory inventions relating to the proposed work and identify whether the technology that is the subject of the CRADA is classified or unclassified.]*

Laboratory's Program Manager:

Name, phone, and e-mail

(Step 3)

Sample Information/Letter for U.S. Trade Representative:

Dear (U.S. Trade Representative),

I am providing the following information in accordance with EO 12591, which requires consultation with the US Trade Representative when entering into a CRADA with a foreign Collaborator. In this particular case, the **[insert Navy laboratory's name]** wishes to enter a CRADA with Subsidiary Company XYZ. This company is incorporated in the **[insert State or Commonwealth of ABC]**, but is a FOCl of the **[insert name of country]** company, Parent Company XYZ.

I understand you require the following information:

- A. Name of requestor (laboratory/department)
- B. Entity
- C. Country of Entity
- D. State whether CRADA or patent license agreement
- E. Title or Description
- F. Request documentation from USTR

[Insert Navy laboratory's name] responses to the above are:

- A. **[Insert Navy laboratory's name]**
- B. Subsidiary Company XYZ which is incorporated in the **[insert State or Commonwealth of ABC]** but is a FOCl of Parent Company XYZ.
- C. Subsidiary Company XYZ is a US firm but its parent company, Parent Company XYZ is a **[insert name of country]** firm.
- D. CRADA
- E. The proposed CRADA is entitled "Processing Techniques to Enhance Power Output of Widgets."
- F. Please e-mail me documentation indicating whether **[insert Navy laboratory's name]** may proceed with the proposed CRADA.

Thank you for your assistance.

Section V - 4c

Summary of Foreign Disclosure Determination and Export Control Requirements for Licenses and CRADAs

1. All projects and transactions that are classified (or may involve the transfer or development of classified information) or involve instrumentalities of a foreign government or international organization must be coordinated with the Navy International Programs Office (NIPO) through the laboratory's security office.
2. The most useful and authoritative reference tool for assessing foreign disclosure issues is the Department of the Navy Foreign Disclosure Manual:

(<http://doni.daps.dla.mil/secnavmanuals.aspx>)

It contains an extremely useful list of acronyms, abbreviations, and definitions relevant to foreign disclosure and export control issues. If a transaction (or disclosure) does not involve classified military information (CMI) and is not with an instrumentality of a foreign government or international organization, then coordination with NIPO is not required (although, consulting with NIPO may result in obtaining useful guidance).

3. If a project or transaction does not involve classified information or a foreign government (or international organization), a preliminary determination must be made whether controlled unclassified information (CUI) would have to be disclosed to foreign persons during the negotiation or performance of a project or transaction. CUI is technical information that is FOUO and includes information that is subject to export controls. The export controls generally do not apply to non-technical or administrative information; financial or budget information; human resources information; or, basic marketing information. Determining whether technical information is export controlled requires a review of the U.S. Munitions List (USML) and the Commerce Control List (CCL) by the program/project manager. Questions about coverage can be referred to the Office of Counsel. A Commodity Jurisdiction Determination can be requested from the DDTC (to determine whether the technology is on the USML or the CCL); and, for items on the CCL, a Commodity Classification can be requested from the BIS (to determine which, if any, Export Classification Control Number (ECCN) applies to the technology).
4. If technical information that is listed on the USML or CCL (i.e., export controlled) will be involved in the negotiation or performance of a project or transaction with a foreign person or entity, a preliminary determination must be made whether an export license is required or an exemption from the export license requirement applies before such information may be disclosed to a foreign person anywhere in the world (Deemed Exports occur when technical information is disclosed to a foreign person in the United States).
5. There are numerous exemptions from the export licensing requirements. The most important exception is that for technical information that is "publicly available" or in the "public domain." For example: if a Navy laboratory licenses an invention to a foreign entity, and a patent or patent application for the invention has been published, the technical information in the published patent or application is in fact "publicly available" and an export license is not required for the Navy laboratory to enter into the license or disclose published technical information to the foreign licensee.

6. If an export license is required (which, under the applicable guidelines, would be extremely rare at most Navy laboratories), the Office of Counsel would provide assistance and coordinate the filing of any required export license applications.
7. Depending upon the type of agreement used for the collaboration (i.e., a CRADA, cooperative agreement, license agreement, work for outside parties agreement (WFOPA), etc.), additional outside coordination may be required. For example, all Navy licenses and CRADAs with foreign entities must be coordinated with the U.S. Trade Representative, and certain WFOPAs with U.S. entities who plan to market to foreign entities require coordination with NIPO.
8. Navy laboratories should include a clause in their agreements that cover export of technical information generated or delivered under the agreement. A clause such as the following should be used:

Export Control.

- a. Neither Party shall make a disclosure, export, or deemed export of any technical information, articles, or services that result from this Agreement to any foreign location, entity, or person (including its own employees and associates of any type) except in full compliance with all applicable United States Federal laws (including treaties) and departmental regulations that establish and implement export controls. Compliance with all applicable export licensing requirements and restrictions implemented in the International Traffic in Arms Regulation (ITAR) and the Export Administration Regulations (EAR) is required. A “deemed export” is a disclosure of export controlled information in the United States or abroad to a “foreign person” (under the ITAR) or to a “foreign national” (under EAR).
 - b. This Agreement does not authorize any disclosure, export, or deemed export of technical information, articles, or services, nor does it authorize or approve the use of any exemption to the export licensing requirements of the ITAR or the EAR.
9. The status of Navy IP rights is also established in advance (in coordination with Patent Counsel). A nondisclosure agreement (NDA) may be required (to protect Navy IP rights), but it is not a substitute for obtaining any export license that may be required.
 10. Always obtain a security review to determine if there are any limitations on disclosing the type of information involved in the CRADA to the home country of the potential partner; obtain the approval of laboratory management; coordinate with the sponsor of the work; consult with the U.S. Trade Representative; and, designate and process CRADAs with FOCI as Non-Standard.

Section V - 4d

Tool Kit - Links to Foreign Disclosure and Export Control Laws, Regulations and Other Useful References

Subject	URL	Notes
Bureau of Industry and Security (BIS), Department of Commerce	http://www.bis.doc.gov/	This is the “must” website for the export of “dual use” items on the Commerce Control List (CCL).
Canadian Exceptions (Joint Certification Program (JCP))	http://www.dlis.dla.mil/JCP/	There are special provisions for dealing with Canadian entities (see 22 C.F.R. 126.5).
Code of Federal Regulations (CFR) Electronic Code of Federal Regulations (ECFR)	http://www.gpoaccess.gov/cfr/index.html http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl	The CFR contains the ITAR and EAR and other Government Agency Regulations. The ECFR contains the same content as the CFR but has a more user friendly printing capability.
Commerce Control List (CCL)	http://www.access.gpo.gov/bis/ear/ear_data.html	The CCL is at 15 C.F.R. Part 774 (and explained in Part 738). It lists the items that are export controlled under the Export Administration Regulation.
Commodity Jurisdiction	http://www.pmdtc.state.gov/commodity_jurisdiction.htm	The Commodity Jurisdiction program is administered by the DDTTC to assist in determining which export control list (if any) a particular technology is on.
Deemed Exports	http://www.bis.doc.gov/licensing/index.htm http://www.hhlaw.com/pressroom/newspubs/pubdetail.aspx?publication=441	The BIS website provides an excellent discussion of deemed exports that should be reviewed in its entirety.
Department of the Navy Foreign Disclosure Manual	http://doni.daps.dla.mil/secnavmanuals.aspx	The most useful, authoritative reference tool for assessing foreign disclosure issues. It also contains an extremely useful list of acronyms, abbreviations, and definitions used in foreign disclosure and export control issues.
Defense Security Service (DSS)	https://www.dss.mil/GW/ShowBinary/DSS/index.html	DSS administers the National Industrial Security Program (NISP). Its home page includes links to the NISPOM (a key reference in assessing FOCI and Facility Clearance issues).

Subject	URL	Notes
Defense Technology Security Administration (DTSA)	http://www.defenselink.mil/policy/sections/policy_offices/dtsa/index.html	DTSA administers the development and implementation of Department of Defense (DoD) technology security policies on international transfers of defense-related goods, services and technologies.
Directorate of Defense Trade Controls (DDTC), U.S. Department of State	http://www.pmddtc.state.gov/	This links to the DDTC website and relevant information about the ITAR and USML as well as the Export License process. Go here and look around.
Executive Order 12829	http://www.archives.gov/federal-register/codification/executive-order/12591.html	This EO establishes the National Industrial Security Program (the basis for Facility Clearances for Government Contractors and FOCI assessments).
Executive Order 12591	http://www.archives.gov/federal-register/codification/executive-order/12591.html	This EO, among other things, establishes the requirement for consultation with the U.S. Trade Representative for licenses and CRADAs with foreign entities.
Export Administration Regulations (EAR)	http://www.access.gpo.gov/bis/index.html	This site is maintained by GPO and is up-to-date. You can search and download the full text of the EAR. The Commerce Control List (CCL) is included.
Federal Register	http://www.gpoaccess.gov/fr/index.html	On GPO Access.
Federation of American Scientists (FAS) Arms Sales Monitoring Project	http://www.fas.org/asmp/index.html	Great source for facts and figures, Government documents, issue papers, etc., on arms and export control.
Fundamental Research Exceptions	www.fas.org/irp/offdocs/nsdd/nsdd-189.htm , www.aau.edu/research/AAA/SIGComm6_27_05.pdf , www.aaas.org/news/releases/2005/1012dod.pdf); DoD Instruction Number 5230.27 ; and, www.washington.edu/research/osp/ecr.html	The URLs link to several references related to the fundamental research exception to export control requirements under the ITAR and EAR.

Subject	URL	Notes
Links	http://www.dtic.mil/mct/LINKS.html http://pmddtc.state.gov/links_to_other_websites.htm http://www.bis.doc.gov/about/reslinks.htm	The URLs provide links to related websites that are useful in addressing foreign disclosure and export control issues.
International Traffic in Arms Regulations (ITAR)	http://pmddtc.state.gov/itar_index.htm	This edition of the ITAR is up-to-date. The U.S. Munitions List (USML) is included.
Military Critical Technologies List (MCTL)	http://www.dtic.mil/mct/	A reminder - The MCTL is not an export control list. The U.S. Munitions List (USML) and the Commerce Control List (CCL) are the U.S.G. control lists. It is used as a tool for assessing what technologies should be added to the USML and CCL, and for assessing whether export license applications should be granted.
Navy International Programs Office (NIPO)	https://www.nipo.navy.mil/niipo/	Among other responsibilities, NIPO manages the Navy's foreign disclosure program.
NASA Export Control Program	http://www.hq.nasa.gov/office/codei/nasaecp/ain.html	
National Security Industrial Program Operating Manual (NISPOM)	http://nsi.org/Library/Govt/Nispom.html	The NISPOM is the DSS Manual that implements Facility Clearance Procedures for Government Contractors (a good FOIC reference).
NISPOM FOIC Provisions	http://nsi.org/Library/Govt/Nispom.html#link2	This provision is a key reference for assessing FOIC.
SECNAVINST 5510.34A	http://doni.daps.dla.mil/allinstructions.aspx	Disclosure of classified military information and controlled unclassified information to foreign governments, international organizations, and foreign representatives.
U.S. Munitions List (USML)	http://www.pmddtc.state.gov/official_itar_and_amendments.htm	
Wassenaar Arrangement	http://www.wassenaar.org/	
Wassenaar Arrangement List of Dual-Use Goods and Technologies & Munition List	http://www.wassenaar.org/controls/index.html	

Section V - 5

Release Issues for CRADAS - Explanation

This section provides guidance for release of information of work related to a CRADA. Requests for such information may require a general public release by either of the Collaborators announcing the CRADA partnership, a Freedom of Information Act (FOIA) request, or a request provided for these cases. General guidance is provided for these cases.

Section V - 5a

Public Release Issues for CRADAs

Article 10.5 of the Navy Standard CRADA, (Revision 1, dated 1 May 2002) addresses public release of the Agreement:

“This Agreement, without funding information (Article 5) and Appendices, may be released to the public.”

This simple statement is a clue in writing the agreement and protecting it after its completion.

The document is a business agreement between the Navy and a non-Navy entity and should be protected as business sensitive. All Navy personnel with responsibility for the CRADA, need to be advised of these sensitivities ensuring that any copies of the CRADA are not freely given out to unauthorized personnel. Further, the Non-Navy Collaborator may not wish the relationship to be publicly known. To the extent allowed by law, this desire should be honored.

If either of the Collaborators desires to make a press release announcing the CRADA partnership, both need to agree on its content. The Navy Collaborator needs to have official release according to the rules and regulations of that laboratory. As a matter of practice, copies of any press releases dealing with the CRADA should be sent to the Office of Naval Research, Code 03TSB, attention Dottie Vincent.

The operative word in Article 10.5 is “may”. The CRADA may be distributed within the Navy for the purpose of conducting official business. It may be released to the public under a Freedom of Information Act request (see FOIA section of the Handbook).

In registering the CRADA in the Defense Technology Transfer Information System (DTTIS), the information entered is only available to those within the Navy who have been given authorization for its use.

Section V - 5b

Dealing with Freedom of Information Act (FOIA) Requests

It is Navy policy to include in its Cooperative Research and Development Agreements an Article describing how CRADA information may be released under a FOIA request. The following is extracted from the NSCRADA, Article 7.1.1.5.

Release of Data Under the Freedom of Information Act:

Data in the possession of **[Navy Collaborator]** that are not marked CUI, Proprietary Information of **[Non-Navy Collaborator]** or Restricted Access Information must be released by **[Navy Collaborator]** where such release is required pursuant to a request under the Freedom of Information Act (FOIA) (5 USC 552). **[Navy Collaborator]** shall protect Data that are properly marked CUI, Proprietary Information of **[Non-Navy Collaborator]** or Restricted Access Information from release under the FOIA for as long as the marked Data meet the definition of CUI, Proprietary Information or Restricted Access Information. Prior to release of any Data, **[Navy Collaborator]** shall promptly notify **[Non-Navy Collaborator]** of any request for Data of **[Non-Navy Collaborator]** regardless of whether the requested Data are marked Proprietary Information.

The classes of marked data that will not be released under a FOIA request are clearly stated: Controlled Unclassified Information (CUI), Proprietary Information, and Restricted Access Information. Generally speaking, the CRADA document will rarely have CUI or Restricted Access Information included in the text. However, it may contain information that is Proprietary Information.

Best Practice:

If a FOIA request is received for the CRADA and/or data generated by the CRADA, immediate notification by phone and in writing is to be made Non-Navy Collaborator when the FOIA request is received by the ORTA. Such review should be made within fifteen calendar days from notification to the Non-Navy Collaborator (the local Navy point of contact in charge of answering the FOIA request may grant you a longer time period if justified).

During the review process, a distinction should be made among the text of the legal requirements of the CRADA, the Statement of Work, and the appendices. The Appendices can be protected from release in a manner similar to Restricted Access Information for a period not to exceed five years from date of creation. The legal text, except for financial or business sensitive information, should be open for public view. For data that are part of the CRADA, the Collaborators should review all data generated for proper markings in accordance with the CRADA instruction. Only data that meet the FOIA requirements above will be released.

Section V - 5c

Release of a CRADA to Other Federal Agencies or Department

To ensure protection of sensitive business information discussed in a CRADA, it is recommended that each page of the CRADA be marked with the statement, "For Official Use Only" before releasing to any Federal Agency or Department requesting a copy of a Navy Laboratory CRADA.

Section V - 6

Patent Rights and CRADAs with Government Contractors

The Bayh-Dole Act (P.L. 96-517) defines the respective rights of the Government and small business or non-profit contractors in inventions made by employees of the contractor while performing under the work statement of a Government funding agreement such as a contract ("Subject Inventions"). This statute is implemented by regulation in the form of patent rights clause FAR 52.227-11 and implementing guidance found in FAR Part 27 of the Federal Acquisition Regulations. Government policy requires that essentially similar rights be extended to big business contractors under the patent rights clause FAR 52.227-12. These clauses are required to be in certain types of contracts as defined in FAR Part 27. The patent rights clauses are to be used without modification, and no other clause in the contract may have the effect of imposing modifications on the patent rights clauses. Absent a patent rights clause, the Government obtains no rights in any invention made by the contractor under a contract. The patent rights clause defines a "subject invention" as any invention "conceived" or "first actually reduced to practice" by an employee of the company working on the contract. Under the patent rights clause, the contractor is permitted to retain title (own) any subject invention so long as the contractor: (a) elects to retain title to the invention within a specified time period; (b) files a patent application in the U.S. Patent and Trademark Office (PTO) to protect the invention; (c) provides the Government with a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention throughout the world; and (d) provides the Government with an appropriate document suitable for filing in the PTO that confirms the Government's rights in the invention. Under certain circumstances, the Government may cover the contractor's costs for protecting a subject invention (See FAR 31.205-30).

Federal laboratories are not authorized to fund the participation of a private party collaborator under a CRADA (15 USC 3710a(b)(3)(A)). However, there is no prohibition to the collaborating party receiving funding from other Government activities. Thus, a laboratory may enter into a CRADA with a contractor of another Government activity to assist the contractor in performing tasks under the contract so long as all the other requirements of a CRADA are met.

The Bayh-Dole Act and the implementing contractual patent rights clause as well as the big business patent rights clause are consistent with the invention rights disposition of a CRADA. What differs is the time frames for taking action imposed on the parties by the patent rights clauses and the Navy Standard CRADA model. While different, these time requirements are not totally inconsistent and, thus, meeting the earliest time requirements in either agreement will satisfy the requirements of the other agreement so long as the reporting/electing requirements of each agreement are met. As a result, the contractor/CRADA collaborator is subject to an increased administrative burden. See also Section III - 7, License Grantback Agreement.

Section V - 7

U.S. Competitiveness

“Manufactured Substantially in the U.S.”

The preference for manufacturing in the United States originates in 35 USC 204, Section 204. The relevant clause is reproduced below:

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee 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.

Article 10.4, U.S. Competitiveness of the Navy Standard CRADA is currently required by Navy policy. The Article as currently written is shown below:

[Non-Navy Collaborator] agrees that any product, process, or service using Intellectual Property arising from the performance of this Agreement shall be manufactured substantially in the United States.

If the U.S. Competitiveness clause becomes a point in negotiation with your Non-Navy Collaborator, please contact your laboratory legal office for advice. Three examples of alternative language as used in U.S. Army CRADAs are provided as reference.

From the U.S. Army CRADA:

ARTICLE 4.7

Preference for U.S. Industry. Company X agrees that any product used or sold by Company X, or any licensee or sublicensee of Company X, which embodies inventions or technologies resulting from work performed under this Agreement shall be manufactured substantially in the United States. **Company X, or its licensee or sublicensee, may request waiver of this requirement from ARL upon a showing that under the circumstances domestic manufacture is not commercially feasible.**

From ARDEC:

ARTICLE 13.7

Manufacture. The parties agree that a purpose of this Agreement is to provide substantial benefit to the U.S. economy. To the extent feasible, the parties agree to exercise reasonable efforts to manufacture substantially in the United States products embodying intellectual property developed under this Agreement.

From the U.S. Army Research, Development and Engineering Command, Aviation and Missile Research, Development and Engineering Center:

Article XIII Competitiveness

To the extent feasible, the PARTNER shall exercise reasonable efforts to manufacture substantially in the United States of America any product embodying intellectual property developed under this Agreement.

Section V - 8

Small Business Innovation Research (SBIRs) and CRADAs

The Small Business Innovation Program (SBIR) promotes partnerships with federal laboratories. However, there are restrictions placed on the SBIR award funds that are received by a small business. Current guidelines from the Small Business Administration (SBA) state that funds that are received from an SBIR award cannot be transferred to a federal laboratory for conducting a portion of the work proposed under the SBIR award unless a waiver is granted. A federal contracting officer is not permitted to sign an SBIR award that transfers funds to a federal laboratory unless a waiver is granted.

The use of waivers is discussed in the current SBIR policy directive.

[see: <http://www.sba.gov/SBIR/SBIR-PolicyDirective.pdf>]

The following is extracted from the SBA Policy Direction, Section 9(f)(3):

(f) Limitation of participation and use of funds.

(3) An agency must not issue an SBIR funding agreement that includes a Provision for subcontracting any portion of that agreement back to the issuing agency, to any other Federal Government agency, or to other units of the Federal Government. SBA may issue a case-by- case waiver to this provision after review of an agency's written justification that includes the following information:

- (i) An explanation of why the SBIR research project requires the use of the Federal facility or personnel, including data that verifies the absence of non-federal facilities or personnel capable of supporting the research effort.
- (ii) Why the Agency will not and can not fund the use of the Federal facility or personnel for the SBIR project with non-SBIR money.
- (iii) The concurrence of the SBC's chief business official to use the Federal facility or personnel.

SBIR companies may use non-SBIR funds to enter into CRADAs. If the SBIR award winning company has an Internal Research and Development (IR&D) Program, those funds may be legally used to fund a CRADA with any federal laboratory.

Section 9 (c) of the SBA Policy Directive permits agencies to hire vendors to provide discretionary technical assistance to SBIR awardees. The following is extracted from the policy directive:

(c)The Act allows discretionary technical assistance to SBIR awardees.

- (1) Agencies may enter into agreements with vendors to provide technical assistance to SBIR awardees, which may include access to a network of scientists and engineers engaged in a wide range of technologies or access to technical and business literature available through on-line data bases. Each agency may select a vendor for a term not to exceed 5 years. The vendor must be selected using competitive and merit-based criteria. The purpose of this technical assistance is to assist SBIR awardees in:

- (i) making better technical decisions on SBIR projects;
 - (ii) solving technical problems that arise during SBIR projects;
 - (iii) minimizing technical risks associated with SBIR projects; and
 - (iv) commercializing the SBIR product or process.
- (2) Phase I awards: Each agency may provide up to \$4,000 of SBIR funds for the technical assistance described above in (c) (1). The amount will be in addition to the award and will count as part of the agency's SBIR funding.
- (3) Phase II awards: Each agency may allow awardees to expend up to \$4,000 of SBIR funds per year, using funds available from the SBIR award, for the technical assistance described above in (c) (1). Intellectual Property Rights under SBIR awards may have a strong influence on the terms and conditions contained with an SBIR award winner.

If you enter into a CRADA with an SBIR award winner and that company's pre-existing data was generated under an SBIR award, you should be familiar with the policies under the SBA SBIR Act. The following is extracted from Section 8 of the Policy Directive:

TERMS OF AGREEMENT UNDER SBIR AWARDS

- (a) **Proprietary Information Contained in Proposals.** The standardized SBIR Program solicitation will include provisions requiring the confidential treatment of any proprietary information to the extent permitted by law. Agencies will discourage SBCs from submitting information considered proprietary unless the information is deemed essential for proper evaluation of the proposal. The solicitation will require that all proprietary information be identified clearly and marked with a prescribed legend. Agencies may elect to require SBCs to limit proprietary information to that essential to the proposal and to have such information submitted on a separate page or pages keyed to the text. The Government, except for proposal review purposes, protects all proprietary information, regardless of type, submitted in a contract proposal or grant application for a funding agreement under the SBIR Program, from disclosure.
- (b) **Rights in Data Developed Under SBIR Funding Agreement.** The Act provides for "retention by an SBC of the rights to data generated by the concern in the performance of an SBIR award."
- (1) Each agency must refrain from disclosing SBIR technical data to outside the Government (except reviewers) and especially to competitors of the SBC, or from using the information to produce future technical procurement specifications that could harm the SBC that discovered and developed the innovation.
 - (2) SBIR agencies must protect from disclosure and non-governmental use all SBIR technical data developed from work performed under an SBIR funding agreement for a period of not less than four years from delivery of the last deliverable under that agreement (either Phase I, Phase II, or federally-funded SBIR Phase III) unless, subject to (b) (3) of this section, the agency obtains permission to disclose such SBIR technical data from the awardee or SBIR applicant. Agencies are released from obligation to protect SBIR data upon expiration of the protection period except that any such data that is also protected and referenced under a subsequent SBIR award must remain protected through the protection period of that subsequent SBIR award. For example, if a Phase III award is issued within or after the Phase II data rights protection period and the Phase III award refers to and protects data developed and protected under the

Phase II award, then that data must continue to be protected through the Phase III protection period. Agencies have discretion to adopt a protection period longer than four years. The Government retains a royalty-free license for Government use of any technical data delivered under an SBIR award, whether patented or not. This section does not apply to program evaluation.

- (3) SBIR technical data rights apply to all SBIR awards, including subcontracts to such awards, that fall within the statutory definition of Phase I, II, or III of the SBIR Program, as described in Section 4 of this Policy Directive. The scope and extent of the SBIR technical data rights applicable to federally-funded Phase III awards is identical to the SBIR data rights applicable to Phases I and II SBIR awards. The data rights protection period lapses only: (i) upon expiration of the protection period applicable to the SBIR award, or (ii) by agreement between the awardee and the agency.
 - (4) Agencies must insert the provisions of (b) (1), (2), and (3) immediately above as SBIR data rights clauses into all SBIR Phase I, Phase II, and Phase III awards. These data rights clauses are non-negotiable and must not be the subject of negotiations pertaining to an SBIR Phase III award, or diminished or removed during award administration. An agency must not, in any way, make issuance of an SBIR Phase III award conditional on data rights. If the SBIR awardee wishes to transfer its SBIR data rights to the awarding agency or to a third party, it must do so in writing under a separate agreement. A decision by the awardee to relinquish, transfer, or modify in any way its SBIR data rights must be made without pressure or coercion by the agency or any other party. Following issuance of an SBIR Phase III award, the awardee may enter into an agreement with the awarding agency to transfer or modify the data rights contained in that SBIR Phase III award. Such a bilateral data rights agreement must be entered into only after the SBIR Phase III award, which includes the appropriate SBIR data rights clause has been signed. SBA must immediately report to the Congress any attempt or action by an agency to condition an SBIR award on data rights, to exclude the appropriate data rights clause from the award, or to diminish such rights.
- (c) **Title Transfer of Agency-Provided Property.** Under the Act, the Government may transfer title to equipment provided by the SBIR agency to the awardee where such transfer would be more cost effective than recovery of the property.
 - (d) **Continued Use of Government Equipment.** The Act directs that an agency allow an SBIR awardee participating in the third phase of the SBIR Program continued use, as a directed bailment, of any property transferred by the agency to the Phase II awardee. The Phase II awardee may use the property for a period of not less than 2 years, beginning on the initial date of the concern's participation in the third phase of the SBIR Program.
 - (e) **Grant Authority.** The Act does not, in and of itself, convey grant authority. Each agency must secure grant authority in accordance with its normal procedures.
 - (f) **Conflicts of Interest.** SBA cautions SBIR agencies that awards made to SBCs owned by or employing current or previous Federal Government employees may create conflicts of interest in violation of FAR Part 3 and the Ethics in Government Act of 1978, as amended. Each SBIR agency should refer to the standards of conduct review procedures currently in effect for its agency to ensure that such conflicts of interest do not arise.

(g) **American-Made Equipment and Products.** Congress intends that the awardee of a funding agreement under the SBIR Program should, when purchasing any equipment or a product with funds provided through the funding agreement, purchase only American-made equipment and products, to the extent possible, in keeping with the overall purposes of this program. Each SBIR agency must provide to each awardee a notice of this requirement.

Approved standard language for working with SBIR contractors can be found in Section I, Instructions, of this document under Approved Alternative Articles.

SECTION VI

APPENDICES

The following are highlights of Technology Transfer Legislation and Executive Orders. For more detail please see either www.USASearch.gov or the Federal Laboratory Consortium's publication, *Federal Technology Transfer Legislation and Policy (The Green Book)*.

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Section VI - 1a

Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480)

The Stevenson-Wydler Technology Innovation Act of 1980 was the first law to define and promote technology transfer from federal laboratories to nonfederal parties.

Details of the Stevenson-Wydler Act and its amendments are found in 15 U.S. Code 3701-3716.

Highlights of the original include the following:

- Focused on dissemination of information
- Required federal laboratories to take an active role in technical cooperation
- Established Offices of Research and Technology Applications (ORTAs) at major federal laboratories
- Established the Center for the Utilization of Federal Technology in the National Technology Information Service

Section VI - 1b

Bayh-Dole Act of 1980 (P.L. 96-517)

The Bayh-Dole Act and the Patent and Trademark Clarification Act of 1984 placed new limitations on patents and licenses for federally funded research and development.

- Permitted universities, not-for-profit organizations, and small businesses to obtain title to inventions developed with Government support
- Provided early on intellectual property rights protection of invention descriptions from public dissemination and Freedom of Information Act (FOIA)
- Allowed Government owned and Government operated (GOGO) laboratories to grant exclusive licenses to patents

Section VI - 1c

Federal Technology Transfer Act of 1986 (P.L. 99-502)

This was the second major technology transfer legislation. Highlights of the law are as follows:

- Made technology transfer a responsibility of all federal laboratory scientists and engineers
- Mandated that technology transfer responsibility be considered in employee performance evaluations
- Established principle of royalty sharing for federal inventors (15% minimum) and set up a reward system for other innovators
- Legislated a charter for the Federal Laboratory Consortium for Technology Transfer and provided a funding mechanism for that organization to carry out its work
- Provided for the exchange of personnel, services, and equipment among the laboratories and nonfederal partners

- Permitted current and former Government employees to participate in commercial development, to the extent there is no conflict of interest
- Allowed laboratories to make advance agreements with large and small companies on title and license to inventions resulting from CRADAs with Government laboratories

Section VI - 1d

Executive Orders 12591 and 12618 (1987) Facilitating Access to Science and Technology

Purpose

To ensure that Federal agencies and laboratories assist universities and the private sector in broadening the U.S. technology base by moving new knowledge from the research laboratory into the development of new products and processes.

Content and Outline

Section 1. Transfer of Federally Funded Technology

- Delegated CRADA authority to GOGO laboratories
- GOGO laboratories authorized to license, assign, or waive rights to intellectual property developed by the laboratory under a CRADA
- Promoted the commercialization of science and technology

Section 2. Establishment of the Technology Share Program

- Restricted to the Departments of Agriculture, Commerce, Energy, Health and Human Services, and NASA

Section 3. Technology Exchange – Scientists and Engineers

- Authorized a personnel exchange program between federal laboratories and the private sector

Section 4. International Science and Technology

- Permits agencies to enter into CRADAs with FOCl in consultations with the U.S. Trade Representative with appropriate consideration to
 - Reciprocity
 - Policies by foreign governments to protect U.S. intellectual property
 - Processes by foreign governments that prevent the transfer of strategic technologies to destinations prohibited under U.S.

Section 5. Technology Transfer from the Department of Defense

- Required the Secretary of Defense to identify a list of funded technologies with potential use to U.S. industry and academia

Section 6. Basic Science and Technology Centers

- Allowed Agency to examine the potential for establishing university centers, funded by the Federal Government, the private sector, and the States, on technology areas that contribute to the Nation's long-term economic competitiveness

Section 7. Reporting Requirements

- Required the Director of the Office of Science and Technology policy to convene an interagency task force to identify and disseminate creative approaches to technology transfer from federal laboratories

Section VI - 1e

National Technology Transfer and Advancement Act of 1995 (P.L. 104-113)

This is the third major technology transfer legislation. It amended the Stevenson-Wydler Act and made technology transfer more attractive to both federal laboratories and scientists and to private industry.

- Assures to U.S. companies that they will be granted sufficient intellectual property rights to justify prompt commercialization of inventions arising from a CRADA with a federal laboratory
- Gives collaborating party in a CRADA the right to choose an exclusive or nonexclusive license for a pre-negotiated field of use for an invention resulting from a joint research under a CRADA
- CRADA partner may also retain title to an invention made solely by its employees in exchange for granting the Government a worldwide license to use the invention
- Revised financial rewards for federal scientists who develop marketable technology under a CRADA to \$150,000 per person
- Provided for permanent funding of the Federal Laboratory Consortium from the agencies

Section VI - 1f

Technology Transfer Commercialization Act of 2000 (P.L. 106-404)

This is the most recent amendment to the Stevenson - Wydler Technology Transfer Act and is often referred to as the Morella Bill. The Morella Bill also made changes to U.S. Code 35 Section 209 (Licensing Federally Owned Inventions) and the Bayh - Dole Act.

- Permits Government laboratories under a CRADA to grant licenses of federally owned inventions for which a patent application was filed before the signing of the agreement, and directly within the scope of work under such agreement
- Requires a license applicant to make a commitment to achieve practical application of the invention within a reasonable time
- Prohibits an agency from granting an exclusive license on a federally owned invention unless it has provided a 15-day public notice and considered all comments received (exempts from such requirements the licensing of any inventions made under a CRADA)

- Provides that an agency may grant a license on a federally owned invention only if the licensee has supplied a basic business plan for development or marketing the invention; such business plans are not subject to FOIA
- Provides that a federal agency, employing a co-inventor with a non-profit organization or small business may consolidate rights in the invention to ease commercialization of the invention
- Requires each federal agency with a federally funded laboratory that has one or more CRADAs to report to the Committee on National Security of the National Science and Technology Council and Congress, with respect to major proposed CRADAs that involve critical national security technology or that may have a significant impact on domestic or international competitiveness
- Authorized federal laboratories to enter into contracts with partnership intermediaries to perform services that increase the likelihood of successes in the conduct of cooperative or joint activities with institutions of higher education
- Requires that each Federal agency which operates or directs one or more federal laboratories or which conducts activities under Sections 207 and 209 of Title 35 U.S. Code, shall report annually to the Office of Management and Budget, as part of the agency's annual budget submission, on the activities performed by that agency and its federal laboratories

Section VI - 2

Public Laws (Hyperlinks)

Clicking on the blue title will take you directly to that website.

FEDERAL ACQUISITION

[FARS/DFARS](#)

The Federal Acquisition Regulations System is established for the codification and publication of uniform policies and procedures for acquisition by all executive agencies. The Federal Acquisition Regulations System consists of the Federal Acquisition Regulation (FAR), which is the primary document, and agency acquisition regulations that implement or supplement the FAR.

The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) also apply to purchases and contracts by DoD contracting activities made in support of foreign military sales or North Atlantic Treaty Organization cooperative projects without regard to the nature or sources of funds obligated, unless otherwise specified in this regulation.

MONEY AND FINANCE

31 USC 1341

[MONEY AND FINANCE](#)

Limitations on expending and obligating amounts

(a)(1) An officer or employee of the United States Government or of the District of Columbia government may not:

- (A) make or authorize an expenditure or obligation exceeding an amount available in an appropriation or fund for the expenditure or obligation;
- (B) involve either Government in a contract or obligation for the payment of money before an appropriation is made unless authorized by law;
- (C) make or authorize an expenditure or obligation of funds required to be sequestered under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985; or
- (D) involve either Government in a contract or obligation for the payment of money required to be sequestered under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985.

(a)(2) This subsection does not apply to a corporation getting amounts to make loans (except paid in capital amounts) without legal liability of the United States Government.

(b) An article to be used by an executive department in the District of Columbia that could be bought out of an appropriation made to a regular contingent fund of the department may not be bought out of another amount available for obligation.

SMALL BUSINESS

13 CFR 121.101

[CHAPTER I--SMALL BUSINESS ADMINISTRATION PART 121--SMALL BUSINESS SIZE REGULATIONS-](#)

GENERAL TECHNOLOGY TRANSFER

PUBLIC LAW 99-502, 20 October 86

FEDERAL TECHNOLOGY TRANSFER ACT

A bill to amend the Stevenson-Wydler Technology Innovation Act of 1980. It promotes technology transfer by authorizing Government-operated laboratories to enter into cooperative research agreements and by establishing a Federal Laboratory Consortium for Technology Transfer within the National Science Foundation, and for other purposes.

DoD DIRECTIVE 5535.3

DoD Domestic Technology Transfer (T2) Program

DoD INSTRUCTION 5535.8

DoD Technology Transfer (T2) Program

Implements Policy, assigns responsibilities, and prescribes procedures under DoD Directive 5535.3 "Department of Defense Technology Transfer (T2) Program" May 21, 1999 for implementation of T2 programs.

SECNAVINST 5700.16A *(Note: No current link is available; Instruction is being rewritten)*

Implement, establish policy, and assign responsibility for the Department of the Navy (DON) domestic technology transfer (T2).

COMMERCE AND TRADE

15 USC 632

COMMERCE AND TRADE

Small-business concern

A small business concern shall be deemed to be one which is independently owned and operated and which is not dominant in its field of operation: Provided, that notwithstanding any other provision of law, an agricultural enterprise shall be deemed to be a small business concern if it (including its affiliates) has annual receipts not in excess of \$750,000.

15 USC 3703(9)

15 USC 3703(10)

COMMERCE AND TRADE
TECHNOLOGY INNOVATION

Definitions

(9) “Invention” means any invention or discovery which is or may be patentable or otherwise protected under title 35 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.).

(10) “Made” when used in conjunction with any invention means the conception or first actual reduction to practice of such invention.

15 USC 3710a

15 USC 3710a(c)(7)(B)

15 USC 3710a(d)(2)(A)

15 USC 3710a(e)

COMMERCE AND TRADE
TECHNOLOGY INNOVATION

Cooperative research and development agreements

(B) The director, or in the case of a contractor-operated laboratory, the agency, for a period of up to 5 years after development of information that results from research and development activities conducted under this chapter and that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party participating in a cooperative research and development agreement, may provide appropriate protections against the dissemination of such information, including exemption from subchapter II of chapter 5 of title 5.

(2) the term “laboratory” means:

(A) a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government;

(e) Determination of laboratory missions. For purposes of this section, an agency shall make separate determinations of the mission or missions of each of its laboratories.

EXPORT ADMINISTRATION ACT

EXPORT ADMINISTRATION ACT OF 1979

The bill would delegate from Congress to the executive branch its express constitutional authority to regulate foreign commerce. While EAA authorizes the Department of Commerce to regulate U.S. exports of most dual-use commodities in consultation with the Department of Defense and other agencies, several other U.S. Government agencies regulate exports of specified goods and technologies. For example, the Department of State must approve exports of defense articles and defense services that are identified on the U.S. Munitions List, which includes some dual-use items such as commercial communication satellites. See the box below for a list of other Government organizations involved in export administration.

EXECUTIVE ORDERS

EXECUTIVE ORDER 12591

Facilitating Access to Science and Technology

Ensures that Federal agencies and laboratories assist universities and the private sector in broadening our technology base by moving new knowledge from the research laboratory into the development of new products and processes.

COPYRIGHTS

17 USC COPYRIGHTS

Table of Contents for Copyright information

17 USC 106 COPYRIGHTS

Exclusive rights in copyrighted works

Subject to sections 107 through 121, the owner of copyright under this title has the exclusive rights to do and to authorize any of the following:

- (1) to reproduce the copyrighted work in copies or phonorecords;
- (2) to prepare derivative works based upon the copyrighted work;
- (3) to distribute copies or phonorecords of the copyrighted work to the public by sale or other transfer of ownership, or by rental, lease, or lending;
- (4) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and motion picture and other audiovisual works, to perform the copyrighted work publicly;
- (5) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and pictorial, graphic, or sculptural works, including the individual images of a motion picture or other audiovisual work, to display the copyrighted work publicly; and
- (6) in the case of sound recordings, to perform the copyrighted work publicly by means of a digital audio transmission.

42 USC 7261 THE PUBLIC HEALTH AND WELFARE

Acquisition of copyrights, patents, etc.

The Secretary is authorized to acquire any of the following described rights if the property acquired thereby is for use by or for, or useful to, the Department:

- (1) copyrights, patents, and applications for patents, designs, processes, and manufacturing data;
- (2) licenses under copyrights, patents, and applications for patents; and
- (3) releases, before suit is brought, for past infringement of patents or copyrights.

PATENTS

TITLE 35 PATENTS

35 USC 205

PATENTS

PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

Confidentiality

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark office or with any foreign patent office.

TITLE 37

--PATENTS, TRADEMARKS, AND COPYRIGHTS CHAPTER IV--ASSISTANT SECRETARY FOR TECHNOLOGY POLICY, DEPARTMENT OF COMMERCE PART 404--LICENSING OF GOVERNMENT OWNED INVENTIONS

This part prescribes the terms, conditions, and procedures upon which a federally owned invention, other than an invention in the custody of the Tennessee Valley Authority, may be licensed. It supersedes the regulations at 41 CFR Subpart 101-4.1. This part does not affect licenses which (a) were in effect prior to July 1, 1981; (b) may exist at the time of the Government's acquisition of title to the invention, including those resulting from the allocation of rights to inventions made under Government research and development contracts; (c) are the result of an authorized exchange of rights in the settlement of patent disputes; or (d) are otherwise authorized by law or treaty.

FOIA

5 USC 552 FOIA

GOVERNMENT ORGANIZATION AND EMPLOYEES

Public information; agency rules, opinions, orders, records, and proceedings

Regulates the information that is to be made available to the public.

TORT CLAIMS PROCEDURE

28 USC 2671

JUDICIARY AND JUDICIAL PROCEDURE **TORT CLAIMS PROCEDURE**

Definitions

DTIC ANNOUNCES MCTL WEBSITE TO ITS USERS

Through cooperation with the Defense Threat Reduction Agency (DTRA) and the Institute for Defense Analyses (IDA), DTIC now offers the latest update to the Militarily Critical Technologies List (MCTL). The MCTL is available in two versions - The Unclassified Unlimited (U2) version available from our Public Website, and the new Unclassified Limited (UL) version available via Secure STINET. The Secure STINET site is free. Users interested in the MCTL UL version and our other limited collections need only contact DTIC's Registration Branch for access privileges.

The DTIC Registration Branch can be contacted at: (703) 767-8272 or DSN 427-8272.

The U2 version can be found at:

<http://www.dtic.mil/mctl/>

The UL version (available to Registered Secure STINET Users) can be found at:

<https://ca-stinet.dtic.mil/mctl/>

Section VI - 2a

Laws, Executive Orders, U.S. Code

Policy and Guidance Documents

Federal Laws:

Stevenson-Wydler Technology Innovation Act of 1980
(PL-96-480) [15 USC 3701-3714]

Bayh-Dole Act of 1980
(PL-96-517)

Small Business Innovation Development Act of 1982
(PL 97-219)

Cooperative Research Act of 1984
(PL 98-462)

Trademark Clarification Act of 1984
(PL 98-620)

Federal Technology Transfer Act of 1986
(PL 99-502)

Executive Order 12591 and 12618 (10987): Facilitating Access to Science and Technology

Omnibus Trade and Competitiveness Act of 1988
(PL 100-418)

National Institute of Standards and Technology Authorization Act for FY 1989
(PL 100-519)

National Competitiveness Technology Transfer Act of 1989
(PL 101-189)
[included as Section 3131 *et. seq.* of DoD Authorization Act for FY 1990)

Defense Authorization Act for FY 1991
(PL 101-510)

American Preeminence Act 1991
(PL 102-245)

Small Business Technology Transfer (STTR) Program 1992
(PL 102-564)

National Department of Defense Authorization Act for 1993
(PL 102-25)

National Department of Defense Authorization Act for FY 1993
(PL 102-484)

National Department of Defense Authorization Act for 1994
(PL 103-160)

National Technology Transfer and Advancement Act of 1995
(PL 104-113)

Defense Authorization Act for 1997
(PL 104-201)

Technology Transfer Commercialization Act of 2000
(PL 106-404)

Department of Defense:

DoD Domestic Technology Transfer (DT2) Program Directive (DoDD 5535.3)
May 21, 1999

DoD Technology Transfer (DT2) Program Instruction (DoDI 5535.8)
May 14, 1999

Interim Guidance on the use of Certain authorities Granted Under: 10 U.S.C. Section 2194, "Educational Partnerships", 15 U.S.C. Section 3710(i), Utilization of Federal Technology" aka "Stevenson-Wydler Act", and 15 U.S.C. Section 3710a, "Cooperative Research and Development Agreements"
DDRE MEMORANDUM 22 June 2001

Department of Navy:

Domestic Technology Transfer (T2) SECNAVINST 5700.16, ONR 362, 7 March 2000

Section VI - 3

DoD Directives and Instructions - Explanation

These DoD Directives and Instructions are currently under review and scheduled for dissemination during 2008. The material that follows is to be considered current policy until new Directives and Instructions are issued.



Section VI - 3a
Department of Defense
DIRECTIVE

NUMBER 5535.3
May 21, 1999

DDR&E

SUBJECT: DoD Domestic Technology Transfer (T2) Program

- References: (a) DoD Directive 5535.3, "Licensing of Government-Owned Inventions by the Department of Defense," November 2, 1973 (hereby canceled)
(b) Secretary of Defense Memorandum, "DoD Domestic Technology Transfer/Dual Use Technology Development," June 2, 1995 (hereby canceled)
(c) DoD 3200.12-R-4, "Domestic Technology Transfer Program Regulation," December 1988, (hereby canceled)
(d) Sections 3702, 3703, 3705, 3706, 3710, 3712, 3715 of title 15, United States Code
(e) through (k), see enclosure 1

1. REISSUANCE AND PURPOSE

This Directive:

- 1.1. Reissues reference (a) and supersedes references (b) and (c).
- 1.2. Implements, establishes policy, and assigns responsibility for DoD domestic T2 activities under reference (d), as they apply to the Department of Defense, and under 10 U.S.C. (reference (e)), as they apply to the T2 activities of the Department of Defense.

2. APPLICABILITY

This Directive applies to the Office of the Secretary of Defense (OSD), the Military Departments, the Defense Agencies, and the DoD Field Activities (hereafter referred to collectively as "the DoD Components").

3. DEFINITIONS

The following terms, used in this Directive, are defined in DoD Instruction 5535.8 (reference (f)):

- 3.1. Cooperative Research and Development Agreement (CRADA).
- 3.2. Laboratory (as broadly defined in 15 U.S.C. 3710a(d)(2)(A), reference (d), for this Directive).
- 3.3. Nonprofit institution (Sections 3703 and 3710(i) of reference (d) and E.O. 12999 (reference (g)) for this Directive).

3.4. Technical assistance.

3.5. T2.

4. POLICY

It is DoD policy that:

- 4.1. Consistent with national security objectives under 10 U.S.C. 2501 (reference (e)), domestic T2 activities are integral elements of DoD pursuit of the DoD national security mission and concurrently improve the economic, environmental, and social wellbeing of U.S. citizens (Section 3702 of reference (d)). Concurrently, T2 supports a strong industrial base that the Department of Defense may utilize to supply DoD needs. Those activities must have a high-priority role in all DoD acquisition programs and are recognized as a key activity of the DoD laboratories and all other DoD activities (such as test, logistics, and product centers and depots and arsenals) that may make use of or contribute to domestic T2.
- 4.2. Domestic T2 programs, including spin-off, dual-use, and spin-on activities, make the best possible use of national scientific and technical capabilities to enhance the effectiveness of DoD forces and systems.
- 4.3. It is further DoD policy to:
 - 4.3.1. Promote domestic T2 through a variety of activities, such as CRADAs, cooperative agreements, other transactions, education partnerships, State and local government partnerships, exchange of personnel, presentation of technical papers, and other ongoing DoD activities.
 - 4.3.2. Promote domestic T2 through U.S. and foreign patenting, patent licensing, and protecting other intellectual property rights. DoD inventions applicable for licensing shall be publicized to accelerate transfer of technology to the domestic economy. T2 is of the greatest benefit when the patented invention is commercialized (35 U.S.C. 200 and 207, reference (h)).
 - 4.3.3. Allow non-Federal entities to use independent research and development funding as a part of their contributions to domestic T2 activities, including CRADAs, cooperative arrangements, and other transactions (Subpart 31.205-18(e) of the FAR, reference (i)).
 - 4.3.4. Include domestic T2 as a duty and responsibility in position descriptions for applicable scientific, engineering, management, and executive positions.
 - 4.3.5. Allow CRADAs between a DoD Component and DoD contractors, in accordance with DoD conflict of interest rules (DoD Directive 5500.7, reference (j)) and export control laws and regulations.
 - 4.3.6. Ensure that domestic transfers of technology are accomplished without actual or apparent personal or organizational conflicts of interest or violations of ethics standards.

- 4.3.7. Allow conduct of T2 activity with foreign persons, industrial organizations, or government R&D activities, in accordance with export control laws, regulations, and policies and laws, regulations and policies governing foreign military sales (FMS). Consideration should be given to whether or not the government of such persons or industrial organization allows similar relationships and whether such activities benefit the U.S. industrial base and are consistent with the U.S. export control and FMS frameworks (E.O. 12591, reference (k)).
- 4.3.8. Encourage domestic T2 by giving preference to U.S. small business firms, consortia involving U.S. small business firms, and firms located in the United States.

5. RESPONSIBILITIES

- 5.1. The Under Secretary of Defense for Acquisition and Technology shall ensure that the Director, Defense Research and Engineering, shall:
 - 5.1.1. Implement 10 U.S.C. 2515 (reference (e)) to monitor all DoD R&D activities; identify DoD R&D activities using technologies and technology advancements that have potential non-DoD commercial application; serve as a clearinghouse for, coordinate, and otherwise help the transfer of technology to the U.S. private sector; assist private firms to resolve policy issues involved with the transfer of technology from the Department of Defense; and consult and coordinate with other Federal Departments on matters involving T2.
 - 5.1.2. Serve as oversight authority for execution of all domestic T2 science and technology (S&T) matters and coordination with, as applicable, other DoD officials for matters under their oversight. As part of that oversight, the Director, Defense Research and Engineering, (DDR&E) shall define core domestic T2 S&T mechanisms and provide policy guidance for DoD Component investments in such mechanisms.
 - 5.1.3. Develop policy for DoD Component participation in, and support of, Federal S&T domestic T2 programs.
 - 5.1.4. Develop guidance for implementation of domestic T2 policy, to include coordination with other DoD officials for matters under their cognizance.
 - 5.1.5. Coordinate input from the DoD Components and prepare reports to the Congress, as required by 15 U.S.C. (reference (d)) and reference (e), the Office of Management and Budget, and others, as may be imposed by higher authority.
 - 5.1.6. Ensure that the DoD Components establish T2 awards programs and make applicable T2 awards.
 - 5.1.7. Ensure that the Administrator, Defense Technical Information Center (DTIC), maintains and provides development support for T2 databases useful to the Office of the DDR&E (ODDR&E) and the DoD Components.

- 5.2. The Secretaries of the Military Departments and the Heads of the other DoD Components, including the Directors of the Defense Agencies, under the OSD Principal Staff Assistants, shall:
 - 5.2.1. Ensure that domestic T2 is a high priority in their organizations. That includes establishing processes to promote T2 and developing plans for improving T2 for matters under their oversight, to include specific objectives and milestones.
 - 5.2.2. Provide inputs for reports, as required by the ODDR&E, including T2 transaction and program investment data to the DTIC.
 - 5.2.3. Develop personnel policies for R&D executives, managers, laboratory directors, scientists, and engineers that make domestic T2 a critical factor for consideration in promotions, a critical element in performance appraisals, and a duty and responsibility in position descriptions where applicable. Those policies also shall ensure that members of the Office of Research and Technology Applications (ORTA) staff are included in the overall laboratory and/or Agency and/or DoD Field Activity management development programs.
 - 5.2.4. Execute a T2 education and training program for scientists and engineers and other personnel who may be involved in domestic T2.
 - 5.2.5. Establish an awards program, including cash awards, to recognize domestic T2 accomplishments.
 - 5.2.6. Institute policies for protecting inventions and other intellectual property arising from federally supported R&D. That includes policies for patenting inventions, licensing the patented inventions, and maintaining the patents with commercial potential. Costs and expenses to acquire and maintain those patents shall be funded by the DoD Components. That shall not preclude collaborating parties from paying costs and expenses associated with protecting intellectual property rights.
 - 5.2.7. Institute policies under which laboratories may be authorized to license, assign, or waive rights to intellectual property and distribute royalties and other payments, in accordance with DoD Instruction 5535.8 (reference (f)).
 - 5.2.8. Implement marketing and outreach programs.
 - 5.2.9. Provide support of mission-related domestic T2 activities with mission program element funds and ensure that domestic T2 programs have adequate staff and resources, giving particular attention to payment of salaries and travel expenses of scientific, engineering, legal, and ORTA personnel involved in T2. That includes costs and expenses associated with initiation and/or negotiation of CRADAs and other agreements.
 - 5.2.10. Ensure implementation of all T2 functions, as required in 15 U.S.C. 3710(c) (reference (d)), by the ORTA or other domestic T2 focal points.

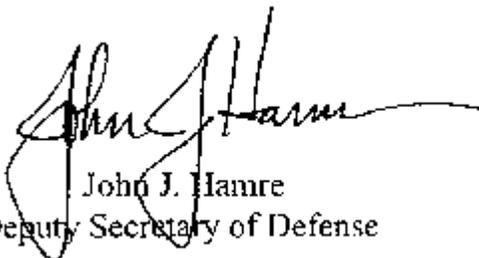
- 5.2.11. Allow use of partnership intermediaries to obtain domestic T2 support. Approval authority may be redelegated to the heads of the DoD laboratories.
 - 5.2.12. Ensure that the directors and/or the commanders of laboratories make domestic T2 a high-priority element of their S&T programs by plan, budget, and execution.
 - 5.2.13. Ensure that laboratories and other activities prepare applications assessments for selected R&D projects that may have commercial applications.
 - 5.2.14. Encourage laboratories to provide technical assistance services, including help by technical volunteers, to State and local governments, school systems, and other organizations, where applicable.
- 5.3. The Heads of the DoD Components (other than the Secretaries of the Military Departments), including the Directors of the Defense Agencies, under the OSD Principal Staff Assistants, are delegated the authority of the Secretary of Defense to:
- 5.3.1. Loan, lease, or give research equipment or educationally useful Federal equipment, consistent with export control laws and regulations, which is excess to the needs of the laboratory to an educational institution or nonprofit institution for the conduct of technical and scientific education and research activities (Section 3710(i) of reference (d), and E.O. 12999 and 10 U.S.C. 2194, references (g) and (e)). That authority may be further delegated.
 - 5.3.2. Enter into CRADAs with entities other than foreign governmental entities (Section 3710a of reference (d)). That authority may be further delegated.

6. INFORMATION REQUIREMENTS

The Secretaries of the Military Departments and the Heads of the other DoD Components shall provide inputs for reports, as required by the ODDR&E in subparagraph 5.2.2., above, including T2 transaction and program investment data to the DTIC under Reports Control Symbol DDA&T(A)2020.

7. EFFECTIVE DATE

This Directive is effective immediately.



John J. Hamre
Deputy Secretary of Defense

Enclosures - 1
E1. References, continued

E1. ENCLOSURE 1
REFERENCES

- (e) Sections 2501, 2506, 2514-2516, 2358, 2371, 2194, 2195 of title 10, United States Code
- (f) DoD Instruction 5535.8, "DoD Technology Transfer Program Procedures," May 14, 1999
- (g) Executive Order 12999, "Educational Technology: Ensuring Opportunity for All Children in the Next Century," April 17, 1996
- (h) Sections 200 and 207-209 of title 35, United States Code
- (i) Federal Acquisition Regulation, Subpart 31.205-18(e), "Independent Research and Development and Bid and Proposal Costs," current edition
- (j) DoD Directive 5500.7, "Standards of Conduct," August 30, 1993
- (k) Executive Order 12591, "Facilitating Access to Science and Technology," April 10, 1987



Section VI - 3b
Department of Defense
INSTRUCTION

NUMBER 5535.8
May 14, 1999

DDR&E

SUBJECT: DoD Technology Transfer (T2) Program

- References:**
- (a) DoD Directive 5535.3, "Department of Defense Technology Transfer (T2) Program," May 21, 1999
 - (b) DoD 5025.1-M, "DoD Directives System Procedures," August 1994, authorized by DoD Directive 5025.1, June 24, 1994
 - (c) Sections 2501, 2506, 2514, 2516, 2358, 2371, 2194, 2195 of title 10, United States Code
 - (d) Sections 3702, 3703, 3705, 3706, 3710, 3712, 3715 of title 15, United States Code
 - (e) through (o), see enclosure 1

1. PURPOSE

This Instruction:

- 1.1. Implements policy, assigns responsibilities, and prescribes procedures under reference (a) for implementation of T2 programs.
- 1.2. Authorizes issuance of DoD 5535.8-H, in accordance with reference (b).

2. APPLICABILITY

This Instruction applies to the Office of the Secretary of Defense (OSD), the Military Departments, the Defense Agencies, and the DoD Field Activities (hereafter referred to collectively as "the DoD Components").

3. DEFINITIONS

Terms used in this Instruction are defined in enclosure 2.

4. POLICY

It is DoD policy under DoD Directive 5535.3 (reference (a)) that, consistent with U.S. security objectives set out at 10 U.S.C. 2501 (reference (c)), T2 activities shall be an integral element of the DoD national security mission, a high-priority role in all DoD acquisition programs, and recognized as a key activity of the DoD laboratories and/or technical activities and all other DoD activities that may make use of or contribute to T2.

5. RESPONSIBILITIES

- 5.1. The Director, Defense Research and Engineering, under the Under Secretary of Defense for Acquisition and Technology, shall monitor compliance with this Instruction and DoD Directive 5535.3 (reference (a)).
- 5.2. The Deputy Director, Defense Research and Engineering, Technology Transition, shall:
 - 5.2.1. Fulfill requirements in 10 U.S.C. 2515 (reference (c)), to:
 - 5.2.1.1. Monitor all DoD research and development (R&D) activities.
 - 5.2.1.2. Identify R&D activities using technologies and technology advancements that have potential non-DoD commercial application.
 - 5.2.1.3. Serve as a clearinghouse for, coordinate, and otherwise facilitate T2 to the private sector.
 - 5.2.1.4. Assist private firms to resolve problems involved with the transfer of technology from the Department of Defense.
 - 5.2.1.5. Consult and coordinate with the other Federal Departments on matters involving T2.
 - 5.2.2. Circumscribe core T2 science and technology (S&T) mechanisms for DoD Component investment. That procedure is prescribed in section 6., below.
 - 5.2.3. Ensure effective and consistent application of U.S. and DoD guidance impacting the participation of foreign individuals and organizations in DoD T2 transactions.
 - 5.2.4. Issue DoD 5535.8-H to provide common practices, procedures, and processes necessary to promote a uniform DoD approach to T2 between the Department of Defense and its partners.
- 5.3. The Secretaries of the Military Departments and the Heads of the Other DoD Components, including the Directors of the Defense Agencies, under the OSD Principal Staff Assistants, shall be responsible for:
 - 5.3.1. Accomplishing T2 in their organizations, as defined in DoD Directive 5535.3, subsection 5.2. (reference (a)).
 - 5.3.2. Ensuring that all DoD laboratories and/or technical activities, as defined in 15 U.S.C. 3710a(d)(2) (reference (d)), and all other organizations capable of supporting or making use of T2, shall make T2 a high priority in accomplishing their programs.

6. PROCEDURES

- 6.1. The DoD Components may participate in, and shall support, Federal S&T T2 programs. That includes, but is not limited to, the following:
 - 6.1.1. Each DoD Component shall transfer funds to the National Institute of Standards and Technology to support the Federal Laboratory Consortium (FLC), as required in 15 U.S.C. 3710e(7)(A)-3710e(7)(C) (reference (d)).
 - 6.1.2. Federal resources such as the National Technology Transfer Center and the Regional Technology Transfer Centers managed through the National Aeronautics and Space Administration and the National Technical Information Service may be used, when applicable.
 - 6.1.3. Ongoing programs or projects supporting U.S. initiatives such as the Partnership for a New Generation Vehicle are encouraged.
 - 6.1.4. Laboratory personnel are encouraged to participate in conferences, seminars, workshops, and other mission-related technical activities of interest due to the mission of the particular laboratory.
 - 6.1.5. Collaborative efforts between the DoD laboratories and/or technical activities or between DoD laboratories and other Federal Agency activities are encouraged.
- 6.2. The DoD Components are encouraged to use any combinations of spin-off, dual-use, and spin-on mechanisms that are most effective for accomplishment of T2 objectives.
 - 6.2.1. T2 ensures DoD programs make the best possible use of national scientific and technical capabilities to enhance the effectiveness of DoD forces and systems. Commercial availability of DoD-developed technologies can be expected to lower the costs of acquiring military equipment by providing the opportunity to take advantage of economies of scale and buy from a larger commercial industrial base. The following mechanisms are core DoD T2 mechanisms and as such should be part of DoD Components' investment strategies. The list, while extensive, is not meant to be exclusive of other mechanisms.
 - 6.2.1.1. Cooperative Research and Development Agreements - CRADAs should be used whenever possible to expand capabilities for R&D and to transfer technology developed jointly or independently to enhance both defense capabilities and the civilian economy. The cost and expense of development, negotiation, and implementation of CRADAs should be funded from laboratory resources.
 - 6.2.1.2. Other core T2 mechanisms include, alphabetically: contracts, cooperative agreements, education partnerships, exchange of personnel, exchange of technical data, grants, other transactions, partnerships with universities, patenting, patent license agreements and other intellectual property licensing agreements, presentations of technical papers, technical assistance, and technology assessments.

- 6.2.2. That recommendation aligns DoD T2 with other elements in the DoD new acquisition strategy, which gives greater emphasis to dual-use technology development and spin-on from the private sector. Several considerations, which are also relevant for T2, have prompted that new strategy. Affordability is a key consideration in weapon system acquisition and sustainment, where the commercial acquisition of products provides economies of scale and resulting cost savings. The Department of Defense frequently will benefit from making DoD-developed technologies available to the commercial sector so that subsequent DoD acquisitions may benefit from such economies of scale.
 - 6.2.3. Dual-use and spin-on also take advantage of the strategic advantages inherent in the U.S. civilian economy and technology base. A DoD-unique acquisition strategy may result in the fielding of obsolescent systems.
 - 6.2.4. The increased attention being given to dual-use and spin-on does not mean that there is no longer an important role for in-house research, development, test, and evaluation (RDT&E) in the DoD Components. Some technologies are unique to the DoD missions. Some technological capabilities may be adapted to make them fully suitable for DoD applications. Despite those considerations, there has been a change in emphasis. The DoD Components are encouraged to experiment with new dual-use and spin-on mechanisms in T2.
- 6.3. The Heads of the DoD laboratories and/or technical activities, as defined in enclosure 2, shall prepare, with the business planning processes of their organizations, a T2 business plan that describes how the responsibilities prescribed in the DoD Directive 5535.3, paragraphs 5.2.1. through 5.2.14. (reference (a)), have been addressed for the current year. Those plans shall identify the activities for the year ahead and describe efforts to make improvements in that program.
 - 6.4. To accomplish its role, the Director, Defense Research and Engineering (DDR&E), as the central authority and clearinghouse for DoD T2, requires various reports from the DoD Components. Those reports include, but are not limited to, the OMB Circular A-11 (reference (e)) report, the Defense T2 Information System (DTTIS) reports, and the DoD Component business plans. Those reports also help the DDR&E highlight DoD T2 successes as part of the reporting requirements to the Congress. Details on the DTTIS and other reporting requirements are in section 7., below, and in separate DDR&E issuances.
 - 6.5. DoD Directive 5535.3 (reference (a)) requires that the Heads of the DoD Components shall develop personnel policies for R&D executives, managers, laboratory directors, scientists, and engineers that make T2 a critical element for position descriptions, job performance appraisals, and promotions. They are also required to ensure that members of the Office of Research and Technology Applications (ORTA) staff are included in the overall laboratory and/or Agency and/or DoD Field Activity management development programs. Procedures to accomplish that include, but are not limited to, the following:
 - 6.5.1. Including statements in personnel position descriptions similar to those found in enclosure 3.

- 6.5.2. Including identification of critical factors for consideration in promotions for T2 personnel in the T2 business plans of the DoD Components.
 - 6.5.3. Providing incentives for ORTA personnel such as training or future job assignments, as an incentive to attract the best people to those positions.
 - 6.5.4. Making knowledge of T2 a required knowledge, skill, and ability for all laboratory scientific or engineering job announcements.
- 6.6. The implementation and execution of a viable T2 program requires education and training of personnel, including all scientists and engineers, and other personnel who may be involved in T2. All the DoD Components are encouraged to institute applicable organization-wide T2 training programs that provide personnel with the requisite knowledge base and skills. Some sources of training include the FLC, the NTTC, the Technology Transfer Society, the Association of University Technology Managers, colleges and universities, and other professional organizations.
- 6.7. Under the authorities of 15 U.S.C. 3710b and DoD 1400.25-M (references (d) and (f)), the Deputy DDR&E, recognizes S&T T2 achievements through a variety of mechanisms, including monetary rewards to DoD winners of FLC awards.
- 6.7.1. DoD recipients of FLC awards may receive a cash award. The amount may be provided to one Federal employee or appropriately divided if there is more than one Federal employee for each organization. When notified, the DoD Components shall provide the names of their FLC award recipient(s) to the ODDR&E. If cash awards are available, they shall be provided through personnel pay system disbursements.
 - 6.7.2. Letters of appreciation and other forms of recognition may be issued for specific T2 accomplishments. Such honorary awards may be presented to individuals and teams, which may include Federal employees as well as non-Federal employees, who shall have made exceptional achievements in T2.
- 6.8. Patents are one of the original instruments of T2 and represent one of the clearest means to characterize an innovation and to describe how it may be of benefit to the user. Procedures for protecting intellectual property shall include the following:
- 6.8.1. Evaluation of inventions arising from R&D efforts.
 - 6.8.2. Filing and prosecuting patent applications for those inventions selected as having sufficient benefit to justify obtaining patent protection.
 - 6.8.3. Determination of which patents shall remain enforceable through payment of required maintenance fees.

- 6.8.4. Providing for payment of costs and expenses to acquire and maintain patents and other intellectual property from the program elements funds, overhead accounts, royalties or other payments, or other sources, as applicable, of the DoD Components. That does not preclude collaborating parties from paying costs and expenses associated with intellectual property rights.
- 6.9. Distribution of royalties and other payments received by the DoD Components.
 - 6.9.1. Royalties or other payments received on account of any invention licensed by a DoD Component shall be payable to the inventor or each co-inventor, as prescribed in the remainder of this paragraph. The DoD Component shall pay to the inventor or each co-inventor each year, at least \$2,000 plus equal shares of at least 20 percent of the remainder of the royalties or other payments. In the absence of extrinsic evidence that co-inventors made unequal contributions to the invention, subject to review and approval by the concerned legal counsel for the DoD Component, it shall be presumed that the co-inventors made equal contributions to the invention and are entitled to equal shares of the 20 percent remainder of the royalties or other payments. If the royalties or other payments received in any given year are less than or equal to \$2,000, or for co-inventors, less than or equal to \$2,000 times the number of inventors, the entire amount is paid to the inventor, or for co-inventors, the entire amount is divided equally among the co-inventors. The inventor or co-inventors shall receive their prescribed share of any royalties or other payments, as received by the Government on an annualized basis.
 - 6.9.2. Royalties or other payments from inventions to any one person shall not exceed \$150,000 for each year without Presidential approval, as in 5 U.S.C. 4504 (reference (g)).
 - 6.9.3. A DoD Component or subordinate laboratory, when authority is delegated, may provide applicable incentives from royalties or other payments, to laboratory employees who are not inventors or co-inventors of such inventions, but who substantially increase the technical value of such inventions. When the incentive is in the form of a monetary payment, such payments may be at any level subject to the authority of the DoD Component or activity that approved the payment, but such payments shall not exceed the limits established in paragraphs 6.9.1. and 6.9.2., above. Payments may be on a one-time or annual basis, and they shall cease when the employee is no longer employed by that DoD Component.
 - 6.9.4. Inventors shall be entitled to royalties or other payments income, as discussed in subsection 6.1. through paragraph 6.9.3., above, and paragraph 6.9.4. through subparagraph 6.9.5.3., below, regardless of the date of the invention.
 - 6.9.5. Assignment and use of royalties or other payments income shall be applied, in accordance with the following schedule:
 - 6.9.5.1. Royalties or other payments shall be used by the end of the second fiscal year (FY) succeeding the FY in which the royalties and other payments were received.

- 6.9.5.2. After assignment of royalties and other payments to inventors under paragraph 6.9.1., above, any remainder may be used for the following:
 - 6.9.5.2.1. Payment of expenses incidental to administration and licensing of inventions and other intellectual property.
 - 6.9.5.2.2. Other activities of the DoD Component that increase the licensing potential for transfer of DoD technology.
 - 6.9.5.2.3. Scientific R&D consistent with the R&D mission and objectives of activities of the DoD Component.
 - 6.9.5.2.4. Reward of scientific, engineering, and technical employees of activities of the DoD Component.
 - 6.9.5.2.5. Promotion of scientific exchange among other activities in the DoD Component.
 - 6.9.5.2.6. Education and training of employees consistent with the R&D mission and objectives of the Department of Defense.
 - 6.9.5.3. Each DoD Component shall prescribe its own regulations as to whether inventors or co-inventors, whose whereabouts are unknown for 1 year, or more, are entitled to further royalty payments.
- 6.10. U.S. and DoD initiatives to stimulate economic competitiveness, reform the acquisition process, and integrate the civilian and defense industrial bases, all stress the need for improved interaction between the laboratories and/or technical activities and the industrial and academic sectors. Laboratories and/or technical activities shall have formal programs to stimulate "spin-off" and "spin-on" to eliminate the perception that the laboratories and/or technical activities compete with the private sector, and to develop new partnerships with broad segments of industry and academia. The implementation and execution of a viable T2 program also shall require applicable forms of marketing and outreach. The intent of marketing and outreach activities is to communicate, inform, or collaborate with stakeholders, in the T2 community.
- 6.10.1. The cost and expenses associated with establishing and operating a T2 Office or an ORTA shall come from the program element funds, overhead accounts, royalties or other payments, or other sources, as applicable, of the DoD Components. Subsection 3710(b) of 15 U.S.C. (reference (d)), requires that the DoD Components shall make available sufficient funding to support the T2 functions. An office (ORTA), that provides coordination, administration, and management of DoD T2, shall function at all DoD laboratories and/or technical activities with 200 or more scientific, engineering, or related technical positions regardless of individual laboratory and/or technical activity funding issues.

- 6.10.2. The Heads of DoD laboratories and/or technical activities shall develop procedures to provide support to mission-related T2 activities and shall ensure that T2 programs are adequately staffed and resourced. For example, program element funds may be used to pay the costs and expenses of initiation and negotiation of CRADAs and other agreements. Those procedures shall give particular attention to payment of salaries and travel expenses of scientific, engineering, and legal personnel and ORTA personnel involved in T2.
- 6.10.3. Marketing and outreach activities are part of the functions of the ORTA. The DoD Components are encouraged to utilize multiple means to conduct marketing and outreach programs, such as the following:
 - 6.10.3.1. Advanced information technologies (including websites, search and/or retrieval tools, webcasting, and collaboration applications).
 - 6.10.3.2. Personal and professional contacts.
 - 6.10.3.3. Advertising.
 - 6.10.3.4. Joint technical publications.
 - 6.10.3.5. Requests for collaborations in the Commerce Business Daily.
 - 6.10.3.6. Use of Advanced Planning Briefing for Industry.
 - 6.10.3.7. Press releases for relevant industrial publications.
 - 6.10.3.8. Use of the North American Industrial Classification System for targeted mailings to industry.
 - 6.10.3.9. Education partnerships.
 - 6.10.3.10. Symposia and conferences.
 - 6.10.3.11. Alliances with local, regional, and U.S. T2 networks and organizations (i.e., State and local business development organizations).

- 6.10.4. Some DoD laboratories and/or technical activities have unique technical and other capabilities that may be of benefit to non-Federal organizations. It is applicable for laboratories and/or technical activities to advertise and demonstrate such capabilities to promote fee-for-service use. The Heads of the DoD Components and laboratory managers shall develop and implement policies to ensure that such advertising and use of laboratory facilities is consistent with U.S. and DoD policy for such matters. Particular attention shall be given to the objective of avoiding situations in which a DoD laboratory is competing with or providing services available from other domestic sources. Special emphasis shall be given to development and implementation of policies to ensure that fee-for-service use of DoD facilities does not degrade performance of primary mission activities in the laboratories and/or technical activities.
- 6.11. Intermediaries affiliated with State or local governments may ease communication and understanding between defense laboratories and/or technical activities and non-Federal entities. Intermediaries normally conduct a number of functions for the laboratory that a laboratory cannot perform due to lack of skills or expertise. The goal of the intermediaries is to assist the laboratory in forming and maintaining productive technology partnerships. The DoD Components are encouraged to delegate authority, to the maximum extent possible, for entering into partnerships with intermediaries.
 - 6.11.1. The intermediaries shall provide a number of services, including consulting services, strategic planning, military and commercial technology assessments, integration with Federal core research and/or focus and/or outreach areas, and technology marketing. They also may provide coordinated media and legislative interface and assistance with DoD conversion activities. One of their attributes is their ability to interface with small business and regional economies interested in commercializing Federal technology.
 - 6.11.2. Intermediaries normally shall provide services to the affiliated defense lab and/or center typically under a contract, CRADA, educational partnership agreement, or memorandum of understanding and/or memorandum of agreement. Intermediaries may be professional societies; industry and trade associations; economic development associations; DoD conversion and/or technology development Agencies; academic institutions; State, regional, or local governments; and for-profit consultants and/or firms under competed procurement contracts. A specific type of intermediary, a "Federal Partnership Intermediary," is described in 15 U.S.C. 3715(c) (reference (d)). The DoD Components are encouraged to delegate authority for such decisions to the maximum extent possible.

- 6.12. Technology assessment is an important part of the T2 process. Technology assessments shall be conducted to determine the potential commercial value of a laboratory and/or the intellectual property of a technical activity. Technology assessment shall be a continuous process in DoD laboratories and/or technical activities to enable development of a portfolio of marketable technologies that may be used to respond to inquiries and unanticipated application opportunities defined by potential clients. Assessment includes identifying candidate products and/or processes and evaluating potential to validate feasibility, suitability, and marketability.
- 6.13. Besides intermediaries, use of consultants and contractors to support T2 activities by conducting assessments of marketing opportunities, applications, and technologies is among the mechanisms that the DoD Components may use to promote T2. That may involve contracts with for-profit or nonprofit organizations. It also may involve purchasing commercial products and services dealing with markets, applications, and technologies. Consideration shall be given to potential conflict-of-interest issues in making decisions on the use of consultants and contractors to perform assessments supporting T2.
- 6.14. Laboratories and/or technical activities may provide technical assistance services, including help by technical volunteers, to State and local governments, school systems, and nonprofit organizations. Those services may include problem analysis, assistance in the development and interpretation of technical information, hands-on technical help from laboratory volunteers, and limited projects in a laboratory where that does not compete with available services in the private sector. In making decisions on such technical assistance services, mission activities necessarily shall have first priority. It is applicable to consider U.S. and DoD policies that promote educational and technical activities. It is also applicable to give consideration to potential payoffs to the laboratory; e.g., the benefits for recruitment of technical staff that may be associated with providing technical assistance services to educational institutions.
- 6.15. The Heads of the DoD laboratories and/or technical activities (see enclosure 2, definition E2.1.3.) may loan, lease, or give research equipment that is excess to the needs of the laboratory to an educational institution or nonprofit organization for the conduct of technical and scientific education and research activities. Title of ownership shall transfer to the recipient when the excess research equipment is transferred as a gift. Research equipment provided to a recipient under 15 U.S.C. 3710(i) (reference (d)) is not subject to existing Federal property disposal regulations implementing separate authorities. Federal laboratories and/or technical activities that transfer their excess research equipment directly to the recipient shall report the transfer to the General Services Administration (GSA). That is clarification of 15 U.S.C. 3710(i) (reference (d)) and E.O. 12999 (reference (h)) to allow laboratories and/or technical activities, Agencies, or Departments to give, loan, or lease excess research equipment to public and private schools and nonprofit institutions without the administrative burden of existing Federal property disposal laws. That is an alternative and free-standing method of distribution of excess research equipment. Under this E.O. (reference (h)), Federal laboratories and/or technical activities may donate their excess research equipment directly to the recipient or report excess research equipment to the GSA for transfer under existing Federal property disposal laws.

- 6.16. One objective of DoD T2 is to improve the domestic U.S. economy and standard of living. That does not mean that T2 may be accomplished only by working with U.S.-owned and U.S.-based companies. There may be situations in which working with a foreign organization, individual, or government R&D facility is the best way to accomplish the T2 goal. The foreign individual, organization, or government R&D facility may have the best technology for a given application, or a foreign company may provide for manufacture mostly in the United States.
 - 6.16.1. It is DoD policy to allow foreign persons and organizations to be involved in DoD T2 transactions when it is in the judgment of the laboratory or other DoD Component personnel responsible for making such decisions, the best option for achieving their objectives, only if such foreign participation is consistent with U.S. and DoD policy. That is done without any intention of inhibiting such foreign participation; the goal, rather, is to ensure that actions are consistent with U.S. and DoD policy.
 - 6.16.2. The Heads of the DoD Components shall consider the criteria in paragraph 6.16.3., below, when developing guidance for their laboratories and/or technical activities on U.S. and DoD policies impacting the participation of foreign individuals and organizations in T2 transactions. Such guidance shall be developed in forms that help decision-making in DoD laboratories and/or technical activities, which are not anticipated to have expertise in trade policy. That guidance shall encompass all of the types of T2 transactions and mechanisms addressed in this Instruction.
 - 6.16.3. It is expected that criteria shall include special consideration such as the following:
 - 6.16.3.1. Whether such foreign companies or governments shall permit and encourage U.S. Agencies, organizations, or persons to enter into cooperative R&D agreements and licensing arrangements on a comparable basis.
 - 6.16.3.2. Whether those foreign governments shall have policies to protect U.S. intellectual property rights.
 - 6.16.3.3. Where cooperative research shall involve data, technologies, or products subject to U.S. security export controls under the laws of the United States, whether those foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such U.S. security export controls or by international agreements to which the United States and such foreign governments are signatories.
- 6.17. Guidance and factors to consider when using a CRADA:

- 6.17.1. CRADAs are agreements that allow one or more Federal laboratories and/or technical activities and one or more non-Federal parties to conduct specified R&D efforts that are related to and consistent with the mission of the DoD laboratory. CRADAs are instruments that may be used in all aspects of a product and/or system life cycle where RDT&E activities occur.
- 6.17.2. CRADAs are not subject to terms for procurement contracts and other instruments that are defined by 31 U.S.C. 6303-6305 (reference (i)), but they are contracts in the sense that are legally enforceable documents. CRADAs shall not be viewed as an alternative to normal procurement procedures.
- 6.17.3. Special consideration shall be given to small businesses or consortia involving small businesses.
- 6.17.4. Preference shall be given to businesses located in the United States or those that agree that products embodying inventions made under the CRADA or produced through the use of such inventions shall be manufactured substantially in the United States (consistent with subsection 6.16., above).
- 6.17.5. CRADAs shall contain provisions for a variety of intellectual property issues including data rights, property ownership, and the allocation of rights to future inventions and/or intellectual property.
- 6.17.6. DoD laboratories and/or technical activities may protect from public access certain commercially valuable information resulting from work under a CRADA for a period of up to 5 years. Doing so provides the collaborating entity sufficient time to capitalize on the inventions and/or intellectual property created under the CRADA.
- 6.17.7. DoD laboratories and/or technical activities may commit resources such as personnel, services, facilities, equipment, intellectual property or other resources with or without reimbursement, but shall not provide funds to the non-Federal partner as part of the agreement. Non-Federal parties may commit funds to the Federal partner to the agreement.
- 6.17.8. DoD laboratories and/or technical activities receiving funds under a CRADA shall maintain separate and distinct accounts, records, and other evidence supporting expenditures under the CRADA.
- 6.17.9. When licensing intellectual property under a CRADA, the DoD laboratory and/or activity shall retain a nonexclusive, nontransferable, irrevocable, and paid-up license for use by the Government.
- 6.17.10. The private non-Federal partner shall be given the option to choose an exclusive license for a pre-negotiated field of use for any invention made in whole or part by a laboratory employee.
- 6.17.11. CRADAs shall be accomplished without actual or apparent personal or organizational conflicts of interest or violations of ethics standards.

7. INFORMATION REQUIREMENTS

7.1. The Defense Technical Information Center (DTIC) shall, under the direction of the DDR&E, develop, maintain, and operate databases to collect, store, and disseminate information about DoD T2 program activities. Elements or segments of those databases shall be accessible to applicable levels of DoD and external users (non-DoD activities) in a manner consistent with the constraints of the data, as specified in DoD Directive 5535.3, the Secretary of Defense Memorandum, and 15 U.S.C. (references (a), (j), and (d)). The DTIC shall develop, maintain, and operate those computer databases in support of DoD T2 policies and concepts with the coordinated and approved requirements of the DoD Components to include the following:

7.1.1. Preparation; coordination with the DoD Components; and issuance of uniform procedures, codes, data elements, and formats for submitting records to, and obtaining records from, the computer databases. The data elements and codes shall comply with DoD 8320.1-M-1 (reference (k)) or be developed, in accordance with DoD Directive 8320.1 (reference (l)).

7.1.2. Providing and operating a system for database input, output, access, and retrieval.

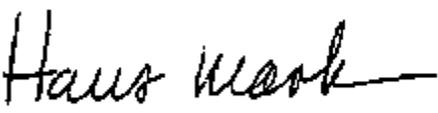
7.1.3. Providing to each of the DoD Components and activity focal points, a quarterly report that summarizes quantity and quality of input from the activities of that DoD Component. A complete summary of those reports shall be provided to the ODDR&E (Technology Transfer Directorate).

7.1.4. Incorporation of applicable security requirements, in accordance with DoD 5200.28-M (reference (m)).

7.2. Other scientific and technical information needs may be addressed in DoD Directive 3200.12 and DoD Instruction 5230.27 (references (n) and (o)), and other policy issuances.

8. EFFECTIVE DATE

This Instruction is effective immediately.


Director, Defense Research and Engineering

Enclosures - 3

E1. References, continued

E2. Definitions

E3. Starting Point for Position Descriptions, Work Plans, and Performance Standards

E1. ENCLOSURE 1
REFERENCES

- (e) Office of Management and Budget, Circular No. A-11, "Preparation and Submission of Budget Estimates," June 23, 1997
- (f) DoD 1400.25-M, "DoD Civilian Personnel Manual System," December 1996, authorized by DoD Directive 1400.25, "DoD Civilian Personnel Management System," November 25, 1996
- (g) Sections 2105 and 4504 of title 5, United States Code
- (h) Executive Order 12999, "Educational Technology: Ensuring Opportunity for All Children in the Next Century," April 17, 1996
- (i) Sections 6303-6305 of title 31, United States Code
- (j) Secretary of Defense Memorandum, "DoD Domestic Technology Transfer/Dual Use Technology Development," June 2, 1995
- (k) DoD 8320.1-M-1, "Data Element Standardization Procedures," January 1993, authorized by DoD Directive 8320.1, September 26, 1991
- (l) DoD Directive 8320.1, "DoD Data Administration," September 26, 1991
- (m) DoD 5200.28-M, "ADP Security Manual," January 1973, authorized by DoD Directive 5200.28, March 21, 1988
- (n) DoD Directive 3200.12, "DoD Scientific and Technical Information Program," February 15, 1983
- (o) DoD Instruction 5230.27, "Presentation of DoD-Related Scientific and Technical Papers at Meetings," October 6, 1987

E2. ENCLOSURE 2
DEFINITIONS

E2.1.1. Cooperative Research and Development Agreement (CRADA). An agreement between one or more Federal laboratories and/or technical activities and one or more non-Federal parties. Under a CRADA, the Government laboratories and/or technical activities shall provide personnel, services, facilities, equipment or other resources with or without reimbursement (but not funds to the non-Federal parties). CRADAs are instruments that may be used in all aspects of a product and/or system life cycle where RDT&E activities occur. The non-Federal parties shall provide funds, personnel, services, facilities, equipment or other resources toward the conduct of specified R&D efforts that are consistent with the missions of the laboratory. The CRADA partners shall share in the intellectual property developed under the effort. The terms of a CRADA may not conform to a procurement contract or cooperative agreement as those terms are used in Sections 6303-6305 of 31 U.S.C. (reference (i)). Besides that definition, two types of CRADAs are, as follows:

E2.1.1.1. Technical Assistance CRADA. That allows a Federal laboratory and a non-Federal partner to work jointly to assist local businesses by providing limited (4-day maximum) free technical consulting. Preference is given to non-Federal partners that are State organizations, universities, non-profit entities, or business incubators that shall publicize availability of Federal assistance, receive and assess requests for cooperative research, ensure that the laboratory and/or technical activity shall not compete with private organizations, and coordinate work of the laboratory and/or technical activity with the requester companies. The laboratory and/or technical activity shall provide the required assistance and reports to the CRADA partner and the requester company. The requester company only shall provide a problem statement and sign a short 2-page "mini-CRADA" agreement, "sub-agreement," or "CRADA amendment."

E2.1.1.2. Military-Use CRADA. A CRADA between a DoD laboratory and/or technical activity and an industrial partner to utilize existing unique capabilities and facilities at the DoD laboratory in a product or process intended primarily for DoD or other military use. Each participant recognizes that it cannot support the research alone nor duplicate existing research or facilities. The technology is incorporated in new DoD systems or products as well as in other commercial opportunities. Specific concerns to be addressed in each military-use CRADA include the following:

- E2.1.1.2.1. A CRADA may be the proper vehicle (work is not a contract).
- E2.1.1.2.2. Government rights are maintained (not establishing a sole source).
- E2.1.1.2.3. Equal opportunity shall be provided to other qualified companies.
- E2.1.1.2.4. The laboratory shall not compete with private sector.
- E2.1.1.2.5. Preferably, the funds for the laboratory shall not go through industry.

E2.1.2. Federal Employee. That is defined in U.S.C. 2105 (reference (g)).

E2.1.3. Laboratory and/or Technical Activity. For the Instruction, that term is, as broadly defined, in 15 U.S.C. 3710a(d)(2)(A) (reference (d)), and shall include the following:

E2.1.3.1. "A facility or group of facilities owned, leased, or otherwise used by a Federal Agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government."

E2.1.3.2. Use of this broad definition, in subdefinition E2.1.3.1., above, is deliberate. That definition is not confined to those DoD Components that are formally titled "laboratories." The intent of that definition is to encompass the wide range of organizations and arrangements that function as laboratories and/or technical activities in DoD research, development, and engineering programs. It shall include laboratories and/or technical activities and reference more diverse arrangements that shall provide a virtual laboratory capability. For example, a DoD Component may have a virtual lab involving a management function accomplished in a Defense Agency activity, plus a dispersed set of research activities to be accomplished by a variety of organizations outside of the sponsoring and/or managing activity. Those capabilities are included in test, logistics, and product centers; depots; arsenals; program offices; and all DoD offices providing for RDT&E. That is consistent with 15 U.S.C. 3710a(d)(2)(A) (reference (d)), which uses such encompassing terms as "facility." That broad definition is in accordance with new DoD practices.

E2.1.3.3. While the definition cited in Subsection 3710a(d)(2)(A) of reference (d) occurs in a Section of the U.S.C. dealing with CRADAs, the use of that broad definition in the Instruction (and DoD Directive 5535.3, reference (a)) shall not be limited to matters involving CRADAs. The broad definition applies to all citations of laboratories and/or technical activities in the Instruction and reference (a).

E2.1.4. Nonprofit Institution. That is an organization owned and operated exclusively for scientific or educational purposes, the net earnings of which shall not benefit any private shareholder or individual.

E2.1.5. Technical Assistance. Allows a Federal laboratory and a non-Federal partner to work jointly to assist local businesses by providing limited (up to 4-day maximum) free technical consulting. Preference shall be given to non-Federal partners that are State organizations, universities, or non-profit entities, including the FLC, which shall publicize availability of Federal assistance, ensure that the laboratory and/or technical activity shall not compete with private organizations, and coordinate the work of the laboratory and/or technical activity with the requester companies. The laboratory and/or technical activity shall provide the required assistance in the form of technical information, lessons, learned, problem solving, or further advice. At no time are technical assistance activities or technical assistance CRADAs to be used to accomplish R&D.

E2.1.6. Technology Transfer (T2). The intentional communication (sharing) of knowledge, expertise, facilities, equipment, and other resources for application to military and nonmilitary systems. Domestic T2 activities shall include the following:

E2.1.6.1. Spin-off activities that shall demonstrate DoD technology; e.g., commercial viability of technologies already developed or presently being developed for U.S. security purposes. The primary purpose of those activities, which encompass T2, shall be to promote and make available existing DoD-owned or -developed technologies and technical infrastructure to a broad spectrum of non-DoD applications.

E2.1.6.2. Dual-use science and technology and other activities that develop technologies that have both DoD and non-DoD applications.

E2.6.3 Spin-on promotion activities that shall demonstrate the U.S. security utility of technologies developed outside of the Department of Defense. That goal shall be to incorporate the innovative technology into military systems to meet mission needs at a lower acquisition cost by taking advantage of the economies of scale by purchasing from a larger industrial base.

E3. ENCLOSURE 3
STARTING POINTS FOR DEVELOPMENT OF POSITION DESCRIPTIONS,
WORK PLANS, AND PERFORMANCE STANDARDS

E3.1. POSITION DESCRIPTION

E3.1.1 Duties and Responsibilities. Transfers, where applicable, Federally owned or originated technology and technical capabilities to State and local governments and to the private sector. Develops technologies having both DoD and non-DoD applications. Promotes the use of technologies developed outside the Department of Defense.

E3.2. WORK PLAN

E3.2.1. Performance Element (Critical) T2. Assesses the availability and applicability of technologies and technical capabilities of their projects and programs. Transfers those technologies and technical capabilities to State and local government and the private sector in compliance with public laws and applicable DoD Directives, Instructions, and Regulations, and Component directives, instructions, and regulations. Obtains assistance from the local ORTA. Works with the T2 partner after formal agreements are in effect (CRADAs, cooperative agreements, other transactions, and patent license agreements, etc.).

E3.2.2. Dual-Use Technology. That technology shall identify industrial technology requirements and shall take those requirements into consideration when developing in-house technology.

E3.2.3. Spin-on Technology. When seeking solutions to DoD requirements, shall consider technologies developed outside Department of Defense on an equal basis with those developed inside the Department of Defense.

E3.3. PERFORMANCE STANDARD

E3.3.1. T2. Performance is satisfactory when the incumbent shall demonstrate an active knowledge of the program requirements, take positive action to assess technologies and technical capabilities, and start actions to formally transfer those technologies and technical capabilities to State and local government and the private sector. The incumbent shall maintain an active working relationship with the local ORTA in developing, negotiating, and getting approval for T2 instruments (CRADAs, cooperative agreements and other transactions, patent license agreements, etc.). It actively shall work with the T2 partners to satisfy effectively the Component obligations in the T2 instruments.

E3.3.2. Dual-Use Technology and Spin-on. Performance is satisfactory when the incumbent shall consider industrial requirements when developing in-house technologies and non-DoD technologies when seeking solutions to DoD requirements.



Section VI - 4

Department of the Navy INSTRUCTION

SECNAVINST 5700.16A
ONR 362
7 March 2000

SECNAV INSTRUCTION 5700.16A

From: Secretary of the Navy

Subj: DOMESTIC TECHNOLOGY TRANSFER (T2)

Ref: (a) Sections 3702, 3703, 3705, 3706, 3710, 3712, 3715 of title 15, United States Code
(b) Sections 2501, 2506, 2514, 2515, 2358, 2371, 2194, 2195 of Title 10, United States Code
(c) DoD Directive 5535.3 of 21 May 99, DoD Domestic Technology Transfer (T2) Program (NOTAL)
(d) DoD Instruction 5535.8 of 14 May 99, DoD Technology Transfer (T2) Program (NOTAL)
(e) Federal Acquisition Regulation, Subpart 31.205-18(e), Independent Research and Development and Bid and Proposal Costs, 62 FR 64932, 9 Dec 97; FAC 97-03
(f) Executive Order 12591, Facilitating Access to Science and Technology, 10 Apr 87
(g) Executive Order 12999, Educational Technology: Ensuring Opportunity for All Children in the Next Century, 17 Apr 96

1. Purpose. To implement, establish policy, and assign responsibility for the Department of the Navy (DON) domestic technology transfer (T2), under references (a), (b), (c) and (d). This is a complete revision and should be read in its entirety.
2. Cancellation. SECNAVINST 5700.16 and OCNRINST 5700.1.
3. Scope. This instruction is applicable to all commands and activities within DON responsible for the sponsorship, management, administration, and execution of domestic T2.
4. Definitions. The following terms, used in this instruction, are defined in reference (d):
 - a. Cooperative Research and Development Agreement (CRADA).
 - b. Laboratory and/or Technical Activity (including the Marine Corps).
 - c. Military-Use CRADA.
 - d. Technical Assistance CRADA.
 - e. Technology Transfer (T2).

5. Policy. It is DON policy that domestic T2 activities, as integral elements of the DON national security mission, concurrently improve the economic, environmental, and social well-being of United States citizens, and shall be carried out per references (a) through (g).
6. Responsibilities
 - a. The Chief of Naval Research, in conjunction with the Chief Technology Officer, will be responsible for all domestic T2 policy and guidance matters within the DON.
 - b. The Chief Technology Officer (CTO) shall:
 - (1) Ensure that domestic T2 policy and guidance within DON promotes the transition of technology into the industrial base that DON acquisition programs may utilize to supply DON needs.
 - (2) Promote technologies available within DON laboratories and technical activities to the interested companies.
 - c. The Chief of Naval Research (CNR) shall:
 - (1) Serve as oversight authority for execution of all DON domestic T2 science and technology (S&T) matters.
 - (2) Execute an awards program, including cash awards, to recognize domestic T2 accomplishments.
 - (3) Institute policies under which laboratories and/or technical activities may be authorized to enter into CRADAs and to license, assign, or waive rights to intellectual property and distribute royalties and other payments per reference (d).
 - (4) Name a DON program manager for domestic T2. This manager shall:
 - (a) Coordinate, direct, and manage Navy domestic T2 per established policies, this directive, and the directions of higher authority.
 - (b) Provide inputs for reports, as required by the Office of the Director, Defense Research and Engineering in references (c) and (d).
 - (c) Represent the DON in the Federal Laboratory Consortium (FLC), interagency meetings with other Federal departments, and internally with the DON activities.
 - (d) Encourage participation in and promote the results of DON domestic T2.
 - (5) Direct the DON Research, Development, Test and Evaluation Fiscal Director, as required in 15 U.S.C. 3710e(7)(A)- 3710e(7)(C), to determine the amount of Navy funding support to the FLC, collect the determined amount of funds from the Research, Development, Test and Evaluation, Navy allocation holders, and transfer the funds to the National Institute of Standards and Technology, for use by the FLC.

- (c) Heads of DON activities are responsible for reviewing the definition of a Laboratory/Technical Activity (reference (d) paragraph E2.3.) and determining whether the activity may be considered a Laboratory/Technical Activity for the purposes of this instruction.
- (d) Heads of DON laboratories and/or technical activities: shall manage, budget, and implement the procedures mandated for Department of Defense (DoD) laboratories and/or technical activities in reference (d).
- (e) All DON laboratories and/or technical activities are delegated the authority to:
 - (1) Enter into CRADAs, including technical assistance and military-use CRADAs, and licenses of Navy inventions provided that:
 - (a) The following qualifications are met:
 - 1 Procedures are established for entering into CRADAs and patent licenses.
 - 2 Personnel with training or experience in technology transfer are designated to be responsible for implementing the procedures.
 - 3 A single point of contact for interface with the Office of Naval Research (ONR) is sent to ONR.
 - 4 Personnel responsible for implementing the procedures receive at least eight hours of training in technology transfer every year.
 - (b) Legal review is obtained prior to entering into an agreement to ensure that the CRADA or license conforms to all statutes, regulations, Executive Orders, and binding instructions issued within DoD.
 - (c) Reports and executed copies of CRADAs and licenses are submitted as directed by ONR per reference (a).
 - (d) A CRADA or license normally conforms to Navy policy. If a deviation from Navy policy is deemed warranted by unusual circumstances, a written explanation of the reasons for the deviation is prepared and legal review is obtained prior to entering into the CRADA or license. A copy of the written explanation and legal review is attached to the copy of the CRADA or license that is sent to ONR.
 - (e) Review and approval are obtained from the United States Trade Representative for all CRADAs and licenses with foreign persons or industrial organizations that are directly or indirectly controlled by a foreign company or government per reference (f).

- (f) All payments due under a license are made payable to DFAS-CH DSSN 8347 and mailed to:

Office of Naval Research
Patent Counsel of the Navy (ONR 00CC)
875 North Randolph Street
Arlington, VA 22203-1995

- (2) Loan, lease, or give research equipment or educationally useful Federal equipment, consistent with export control laws and regulations, which is excess to the needs of the laboratory and/or technical activity, to an educational institution or nonprofit institution for the conduct of technical and scientific education and research activities (Section 3710(i) of reference (a) and 10 U.S.C. 2194 and Executive Order 12999, references (b) and (g)). That authority may be further delegated.

7. Action

- a. Responsible entities shall take the necessary steps to implement DON domestic T2 as outlined in this instruction.
- b. Heads of DON laboratories and/or technical activities shall designate to CNR, within 60 days of receipt of this instruction, points of contact responsible for domestic T2 Office of Research and Technology Applications duties and compliance with this instruction.

8. Reports. The reporting requirement contained in paragraph 6a(4)(b) is assigned symbol DD-A&T(A)2020(5700).

Richard Danzig

Distribution:

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A6 (Headquarters, U.S. Marine Corps (MARCORSYSCOM AW))
B1 (SECDEF Offices)
C4L (Director of Navy Laboratories)
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(Continued on page 5)

(Continued from page 4)

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FKP4A (Coastal Systems Station Dahlgren Division)
FKP4E (Naval Surface Warfare Center)
FKP6C (SEASPARROW Project Support Office)
FKP6D (Experimental Diving Unit)
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FKP16 (Ship Systems Engineering Station)
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FT1 (CNET)
Chief Technology Officer

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21A (Fleet Commanders in Chief and Detachment)

Director, Defense Research and Engineering (OSD)
Defense Advanced Research Projects Agency
Ballistic Missile Defense Organization
Department of the Army
Department of the Air Force

Section VI - 5

Acronym List

AIS	Automated Information System
ARDEC	Army Research and Development Command
BIS	Bureau of Industry and Security
BXA	Bureau of Export Administration
CAGE	Commercial and Government Entity
CCAL	Certified Contractor Access List
CCL	Commerce Control List
CCR	Central Contractor Registration
CFR	Code of Federal Regulations
CLA	Confirmatory License Agreement
CMI	Classified Military Information
CNR	Chief of Naval Research
COCOM	Coordinating Committee for Multilateral Export Controls
COMSEC	Communications Security
COR	Contracting Officer Representative
COTS	Commercial Off-the-Shelf (Equipment and Materials)
CRADA	Cooperative Research and Development Agreement
CSA	Commercial Service Agreement
CUI	Controlled Unclassified Information
DDL	Delegation of Disclosure Authority Letter
DDR&E	Department of Defense Research and Engineering
DEA	Drug Enforcement Administration
DFARS	Defense Federal Acquisition Regulation Supplement
DLIS	Defense Logistics Information Service

DOC	Department of Commerce
DoD	Department of Defense
DoDD	Department of Defense Directive
DOE	Department of Energy
DON	Department of Navy
DOS	Department of State
DSS	Defense Security Service
DTIC	Defense Technical Information Center
DTRA	Defense Threat Reduction Agency
DTTIS	Defense Technology Transfer Information System
DT2	Department of Defense Domestic Technology Transfer
EAA	Export Administration Act
EAR	Export Administration Regulations
ECCN	Export Control Classification Number
EKMS	Electronic Key Management System
EO	Executive Order
EPA	Educational Partnership Agreement
FAR	Federal Acquisition Regulations
FAS	Federation of American Scientists
FDA	Federal Drug Administration
FDD	Foreign Disclosure Determination
FDO	Foreign Disclosure Official
FFRDCs	Federally Funded Research and Development Centers
FLC	Federal Lab Consortium
FN	Foreign National
FOCI	Foreign Owned, Controlled or Influenced

FOIA	Freedom of Information Act
FOUO	For Official Use Only
FSC	Facility Security Clearance
FSO	Facility Security Officer
FTCA	Federal Tort Claims Act
FY	Fiscal Year
GOCO	Government-Owned, Commercial-Operated
GOGO	Government-Owned, Government-Operated
GSA	General Services Administration
IDA	Institute for Defense Analyses
IEC	Independent Ethics Committee
IP	Intellectual Property
IPA	Intergovernmental Personnel Assignment
IPO	International Programs Office
IR&D	Internal Research and Development
IRB	Institutional Review Board
ITAR	International Trade in Arms Regulations
LES	Law Enforcement Sensitive
LP	Limited Purpose
MCT	Military (Militarily) Critical Technology
MCTL	Militarily Critical Technologies List
MOU	Memorandum of Understanding
NDA	Non-Disclosure Agreement
NIPO	Navy International Programs Office
NISPOM	National Industrial Security Program Operating Manual
NLR	No License Required

NMCI	Navy Marine Corps Intranet
NNC	Non-Navy Collaborator
NSCRADA	Navy Standard Cooperative Research and Development Agreement
NSTISSI	National Security Telecommunications and Information Systems Security
NTIS	National Technical Information Service
NTTC	Naval Technical Training Center
ODDR&E	Office of the Department of Defense Research and Engineering
OMD	Office of Management and Budget
ONR	Office of Naval Research
OPRR	Office for Protection from Research Risks
OPSEC	Operations Security
ORTA	Office of Research and Technology Application
OSD	Office of the Secretary of Defense
PAO	Public Affairs Office
PI	Principal Investigator
PIA	Partnership Intermediary Agreement
PL	Public Law
PLA	Patent License Agreement
POC	Point of Contact
PTO	Patent Trademark Office
R&D	Research and Development
RAI	Restricted Access Information
RDT&E	(In-House) Research, Development, Test and Evaluation
S&T	Science and Technology
SBA	Small Business Administration

SBC	Small Business Concern
SBIR	Small Business Innovation Research
SBU	Sensitive But Unclassified
SECNAV	Secretary of the Navy
SECNAVINST	Secretary of the Navy Instruction
SOW	Statement of Work
SSA	Special Security Agreement
STINET	Scientific and Technical Information Network
STTR	Small Business Technology Transfer
T2	Technology Transfer
TT	Technology Transfer
TTO	Technology Transfer Office
UCNI	Unclassified Nuclear Information
UL	Unclassified Limited
USC	United States Code
USML	United States Munitions List
USPQ	United States Patents Quarterly
USTR	United States Trade Representative
U2	Unclassified Unlimited
WFOPA	Work for Outside Parties Agreement
WWPP	Work With Private Parties