**NON-STANDARD**

NAVY CLINICAL TRIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

BETWEEN

**[full name of NAVY COLLABORATOR then acronym]**

AND

**[full name of NON-NAVY COLLABORATOR then acronym]**

AGREEMENT TITLE:

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

AGREEMENT ADMINISTRATORS:

**[NAVY COLLABORATOR acronym]**

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

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

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

**[NON-NAVY COLLABORATOR acronym]**

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 full name then acronym]**

AND

**[Non-Navy Collaborator full name then acronym]**

**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 the Navy Collaborator, **[Navy Collaborator name and address]**, and the Non-Navy Collaborator described below agree to and enter into this Cooperative Research and Development Agreement (CRADA).

**[Insert full name of Non-Navy Collaborator followed by acronym and address]**, is 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]**.

***[Note to ORTA: If the Non-Navy Collaborator is a FOCI, please add the following sentence in the above paragraph. Also, state the name of the parent company and the country in which it is incorporated.]***

Further, **[Non-Navy Collaborator]** is directly or indirectly controlled by a foreign company or government [Executive Order 12591], Section 4 (a), specifically, **[insert name of parent company and the country in which it is incorporated]**.

**[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.

**[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.

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*.*”*]

**Article 1. DEFINITIONS**

***[Note to ORTA: 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 “Adverse Drug Experience” means an adverse event as defined under 21 C.F.R. 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 “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.

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

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) and the Protocol (Appendix E).

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 Commercial License” means the grant by the owner of Intellectual Property of the exclusive right to make, use, or sell an Invention for commercial purposes.

1.9 “FDA” means the Food and Drug Administration, U.S. Department of Health and Human Services.

1.10 “For Official Use Only (FOUO)” means a protective marking to be applied to unclassified information when disclosure to the public of that particular record, or portion thereof, would reasonably be expected to cause a foreseeable harm to an interest protected by one or more provisions of the Freedom of Information Act. This includes information that qualifies for protection under the provisions of the Privacy Act of 1974, as amended.

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

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

1.13 “Information” means all Data, trade secrets, and commercial and financial information.

1.14 “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.

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

1.16 “Internal Use License” means the grant by the owner of Intellectual Property of the right to make, have made, use, and import, but not commercially sell, an Invention or a product or service made using an Invention.

1.17 “Invention” means any creation 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.

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

1.19 “Jointly Made Subject Invention” means any Invention Made jointly by the Collaborators.

1.20 “Limited Rights” means that each Collaborator of this Agreement may use, reproduce, and disclose to their employees properly marked Non-Subject Data provided by the other Collaborator(s) for use in support only of this Cooperative Work.

1.21 “Made” when used in conjunction with any Invention means the conception or first actual reduction to practice of such Invention.

1.22 “Nonexclusive Commercial License” means the grant by the owner of Intellectual Property of the nonexclusive right to make, use, or sell an Invention.

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

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

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

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

1.27 “Proprietary Information” means Information that:

(i) 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; or

(ii) has been generated by the Navy Collaborator during the performance of this Agreement, and would have qualified as Proprietary Information under 1.25(i) above if it had been generated by the Non-Navy Collaborator, and that the Collaborators have agreed to treat as Proprietary Information for a term of up to five years from generation.

1.28 “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 C.F.R. Section 164.501.

1.29 “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.

1.30 “Serious Adverse Drug Experiences” is defined by 21 C.F.R. § 310.305 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 Fed. Reg. 25, 692).

1.32 “Study Patient” means an individual who participates in the Cooperative Work, either as a recipient of the Test Article(s) or as a control.

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

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

1.35 “Tangible Property” means personal or real property having or possessing physical form.

1.36 “Technical Data” means recorded Information relating to experimental or engineering works that can be used to define an engineering or manufacturing process or to design, procure, support, maintain, operate, repair or overhaul material, including, but not limited to graphic or pictorial delineations in media.

1.37 “Technical Document” means recorded Information that conveys scientific and Technical Information or Technical Data.

1.38 “Technical Information” means Information relating to research, development, engineering, test, evaluation, production, operation use, and maintenance of military supplies and equipment.

1.39 “Test Article” means a drug biological product or device that is subject to regulation under the Federal Food, Drug and Cosmetic Act, 21 U.S. Code §201, et seq., as amended, as defined in 21 C.F.R. § 56.152(1).

1.40 “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.

1.41 “Unanticipated Adverse Device Effect” is defined by 21 C.F.R. § 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.

1.42 “Unexpected Adverse Drug Experiences” is defined by either 21 C.F.R. § 310.305(b) or C.F.R. § 314.80(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.

1.43 “Unlimited Rights” means the right to use, modify, reproduce, release, disclose, perform, or display Data 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, Appendix A, and the Clinical Trials Protocol, Appendix E are the defining articles for the Cooperative Work to be done by the Collaborators.]***

**Article 3. RESPONSIBILITIES FOR PERSONNEL AND FACILITIES USE**

3.1 Facilities and Supervision

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

The Cooperative Work done by each Collaborator will be performed under the program guidance of itsPI, who has the responsibility for the scientific and technical conduct of the Cooperative Work performed within that Collaborator’s facilities or done on behalf of that Collaborator by third parties in support of this Agreement. Personnel who perform Cooperative Work at the otherCollaborator’s facilities will be supervised by their own PI.

***[Note to ORTA: Refer to the Navy T2 Handbook when third parties are used by the Collaborators as part of this Agreement.]***

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 Test Article 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]**’s 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 PIshall 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 third party 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.

3.2 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.

***[Note to ORTA: This is the place to add any special security requirements for personnel doing Cooperative Work at the Collaborators’ facilities. 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. If Export Control is needed, attach DD Form 2345, called a “Militarily Critical Technology Data Agreement” to this Agreement. If the Cooperative Work covers classified topics and the Non-Navy Collaborator is FOCI, then a FOCI Mitigation Instrument may be required. Refer to the Navy T2 Handbook.]***

3.3 Protection of Human Subjects

By signing this agreement, the Parties agree that they will comply with the Common Federal Policy for the Protection of Human Subjects, codified by the Department of Defense at 45 C.F.R. Part 46 (2018). The Parties also agree that no research involving human subjects covered under 32 C.F.R. § 219 can commence until IRB approval has been obtained.

**Article 4. REPRESENTATIONS AND WARRANTIES**

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

**[Navy Collaborator]** hereby warrants and represents to **[Non-Navy Collaborator]** that 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]**. **[Navy Collaborator]** is a Federal laboratory of the U.S. Department of the Navy, as defined by 15 U.S. Code § 3710a (d)(2)(A) and Department of Defense Instruction 5535.8, dated May 14, 1999.

***[Note to ORTA: The following Article 4.2 is for a single commercial entity. Choose the appropriate alternatives to Article 4.2 from those listed in the Navy T2 Handbook according to the nature of the Non-Navy Collaborator(s): A university, nonprofit entity, State or local government, an entity directly or indirectly foreign owned, controlled, or influenced (FOCI), an entity comprised of multiple Collaborators.]***

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

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

**[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 **[State or Commonwealth**].

**[Non-Navy Collaborator] [is/is not]** a small business as defined in 15 U.S. Code § 632 and implementing regulations (13 C.F.R. 121.101 et seq.) of the Administrator of the Small Business Administration.

***[Note to ORTA: The following paragraph is to be used only if the Non-Navy Collaborator is not a FOCI as of the signature date of this Agreement.]***

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

***[Note to ORTA: If on the signature date of this Agreement the Non-Navy Collaborator is a FOCI, insert the following paragraph. In addition, an Amendment to this CRADA is required – see the Navy T2 Handbook. Otherwise, omit the following paragraph.]***

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 it or its successor or assignee shall promptly notify **[Navy Collaborator]** to that effect.

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.

**[Non-Navy Collaborator]** is not currently 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.

4.3 Joint Representations and Warranties

The Collaborators make the following Representations and Warranties:

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.

***[Note to ORTA: See the Navy T2 Handbook for approved alternative language to the following paragraph.]***

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. The exporting Collaborator is responsible for obtaining any export licenses and/or foreign disclosure reviews that may be required by U.S. Federal law. **[Non-Navy Collaborator]** shall provide written notification to **[Navy Collaborator]** immediately upon their awareness that an export or disclosure has been made without the required export license or disclosure authorization.

The work proposed in the Statement of Work, Appendix A, may require the introduction or generation of Protected Health Information. All Protected Health Information that is introduced or generated in the performance of work under this Agreement shall be properly marked and safeguarded as provided herein and in all applicable U.S. Federal laws and regulations.

**Article 5. FUNDING**

***[Note to ORTA: 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 the following phrase and remove Articles 5.1 through 5.4 below and from the Table of Contents.]***

Each Collaborator will fund its own efforts.

***[Note to ORTA: Consult the Navy T2 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.]***

***[Note to ORTA: 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, herein, as Appendix D and incorporated herein by reference.

***[Note to ORTA: 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.]***

Electronic payment is preferred.

Bank Name: Credit Gateway

RTN: 051036706

A/C: [insert account number]

DFAS Cleveland can receive funds via ACH using the following:

Bank Name: FRB New York/US Treasury

City: New York, NY

Country: USA

RTN: 021030004

Swift: FRNYUS33FX1

Account Name: DFAS-Cleveland

Account Number: [insert account number]

DFAS Cleveland can also receive funds via wire using the following:

When funds are being transferred electronically, please refer to the CRADA number and provide advance notice so we can be on the lookout for the payment. Please provide notice to [insert financial point of contact name, email, and telephone number].

If checks must be used, checks will be payable to U.S. Treasury. Each check and its cover correspondence shall refer to Navy CRADA number “NCRADA-**[Navy Collaborator]**-**[last two digits of FY]**-**[lab CRADA sequence number]**.”

Checks will be payable to U.S. Treasury.

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

Checks will be mailed to:

***[Note to ORTA: Specify address, including the name of the authorized recipient, title, and appropriate organizational code.]***

5.2 Insufficient and Excess Funds

**[Navy Collaborator]** will not start or continue 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 date of notice, **[Navy Collaborator]** may proceed to terminate the Agreementin accordance with Article 11.2, and may cancel any option for an Exclusive Commercial License to a Subject Invention, and may terminate any Exclusive Commercial License granted pursuant to this Agreement.

Excess Funds that **[Non-Navy Collaborator]** provided under Article 5.1 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 financial 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.

**Article 6. REPORTS AND PUBLICATIONS**

6.1 Interim Reports

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

6.2 Final Reports

The PIs shall submit to the **[Navy Collaborator]** Technology Transfer Office and **[Non-Navy Collaborator]** preferred contact 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 of Information

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.

The Collaborators agree to confer and consult prior to any publication or public disclosure of Subject Data to ensure that no Proprietary Information, or Protected Health 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 to exceed thirty (30) days, to review any proposed abstract, publication, presentation, or other document for public disclosure.

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 before the 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, 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, or is no longer covered by U.S. security laws or regulations.

6.4 Public Presentation of Subject Data

Any public presentation that includes Subject Data that are Protected Health Information 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 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.

7.2 Rights in Subject Data

7.2.1 Rights of Both Collaborators

Each Collaborator shall have title to all Subject Data generated by that Collaborator. Each Collaborator agrees to provide all Subject Data to the other Collaborator and hereby grants Unlimited Rights in Subject Data that does not contain Proprietary Information.

7.2.2 Rights of **[Navy Collaborator]**

For Subject Data that contains **[Non-Navy Collaborator]**’s Proprietary Information, the Government has rights to: 1) Use, modify, reproduce, release, perform, display, or disclose Technical Data within the Government without restriction; and 2) Release or disclose Subject 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 Subject Data for any U.S. Government purpose including competitive procurement.

7.2.3 Rights of [**Non-Navy Collaborator**]

For Subject Data that contains **[Navy Collaborator]**’s Proprietary Information, **[Non-Navy Collaborator]** has rights to use, modify, reproduce, release, perform, display, or disclose Technical Data within **[Non-Navy Collaborator]**’s organization, in whole or in part, and in any manner, for any internal purpose excluding commercial purposes. If **[Non-Navy Collaborator]** is subsequently awarded a Government contract that entails deliverables that incorporate the **[Navy Collaborator]**’s Proprietary Information, such deliverables must be delivered with at least Government Purpose Rights, as defined in the DFARS § 252.227-7013.

**[Non-Navy Collaborator]** shall have a Limited Right to use, reproduce, or disclose Subject Data that may describe one or more Inventions in which the Government owns or may own a right, title, or interest, if such Subject Data are provided by **[Navy Collaborator]** under this Agreement. This Limited Right does not grant the **[Non-Navy Collaborator]** any License to any Invention in which the Government owns or may own a right, title, or interest. In accordance with Article 7.5 below, such Subject Data are to be held in confidence.

7.3 Rights in Non-Subject Data

7.3.1 Rights of Both Collaborators

The Collaborators shall have Unlimited Rights in any Non-Subject Data that are not Proprietary Information or protected under 35 U.S. Code § 205 provided under this Agreement.

7.3.2 Rights of **[Navy Collaborator]**

**[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 written consent to other use or disclosure is obtained from **[Non-Navy Collaborator]**.

7.3.3 Rights of **[Non-Navy Collaborator]**

**[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. Such Non-Subject Data shall be properly marked by **[Navy Collaborator]**.

7.4 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 Non-Subject 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.

7.5 Protection of Data

Except for the rights granted in Article 7.1 and Article 7.2, Data shall be protected in accordance with the proper markings of its owner and as provided by, at a minimum, the requirements of 15 U.S. Code § 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 provided, 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. 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.

Data that is provided by **[Non-Navy Collaborator]** in the performance of this Agreement, and is appropriately marked as a trade secret or commercial or financial information that is privileged or confidential under 5 U.S. Code § 552(b)(4), shall not be disclosed by **[Navy Collaborator]**. **[Non-Navy Collaborator]** shall agree not to disclose, for five (5) years, Data that is produced by the **[Navy Collaborator]** and that would have been considered a trade secret, business commercial, or financial information that is privileged or confidential if it had been produced by the **[Non-Navy Collaborator]**.

Protected Health Information shall be protected in accordance with the security laws of the U.S.

7.6 Release of Data Under the Freedom of Information Act

**[Navy Collaborator]** will comply with the Freedom of Information Act and Executive Order 12600.

7.7 Marking of Data

7.7.1 Markings Required for Both Collaborators

7.7.1.1 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.

7.7.1.2 For Official Use Only (FOUO) Marking

FOUO is the marking used for documents/products containing material that qualifies as exempt from release under FOIA. This includes Technical Information and Technical Data.

Use of the FOUO marking is the responsibility of the originator of the Information. Use of the FOUO marking does not automatically qualify for FOIA exemption.

Technical Documents which contain Technical Information and/or Technical Data are considered FOUO documents and must be appropriately marked.

***[Note to ORTA: For further information associated with FOUO markings see the Navy T2 Handbook.]***

7.7.2 Markings Required for **[Navy Collaborator]**

7.7.2.1 Data that are Subject to 35 U.S. Code § 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 U.S. Code § 205. Such Data shall be marked:

“**[Navy Collaborator]** DATA PROTECTED FROM RELEASE OR DISCLOSURE UNDER 35 U.S. Code § 205.”

7.7.2.2 Data Protected Under Article 7.5

**[Navy Collaborator]** shall place a proprietary marking on each medium used for recording Data that **[Navy Collaborator]** provides to **[Non-Navy Collaborator]**, where the Collaborators have agreed, under second paragraph of Article 7.5 of this Agreement, to protect such Data for up to five (5) years. The marking shall state:

“**[Navy Collaborator]** DATA SHALL BE PROTECTED BY THE **[Non-Navy Collaborator]** FOR A PERIOD OF **[state a number up to** **five years]** FROM **[state the date of generation]**.”

7.7.3 Markings Required for **[Non-Navy Collaborator]**

7.7.3.1 Data that are Proprietary Information

**[Non-Navy Collaborator]** shall place a proprietary marking on each medium used for recording Data that **[Non-Navy Collaborator]** provides to **[Navy Collaborator]** under this Agreement that **[Non-Navy Collaborator]** asserts is Proprietary Information.

For Non-Subject Data that are Proprietary Information the Marking shall state:

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

For Subject Data that are Proprietary Information the Marking shall state:

“PROPRIETARY INFORMATION OF **[Non-Navy Collaborator]** – GOVERNMENT HAS CERTAIN RIGHTS UNDER CRADA NUMBER NCRADA – **[Navy Collaborator]** – [last two digits of FY] – [lab CRADA sequence number].”

7.8 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.

7.9 Subject Inventions

7.9.1 Reporting of Subject Inventions

Within sixty (60) days of Making a Subject Invention, and prior to disclosure of the Invention to any third parties, unless a shorter time period is required by circumstances, the inventor(s) shall submit an Invention Disclosure to their employer. In the case of a Jointly Made Subject Invention, the inventors of each Collaborator shall submit an Invention Disclosure to their respective employer. 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).

7.9.2 Determination of Subject Inventions

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

7.9.3 Title to and Ownership of Subject Inventions

Each Collaborator shall be entitled to solely own the Subject Inventions Made solely by its employees. For any Jointly Made Subject Invention, each Collaborator shall have ownership of the Subject Invention in the form of an undivided interest, without a right of accounting.

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.

7.10 Non-Subject Inventions

7.10.1 Ownership of Non-Subject Inventions

Each Collaborator owns its Non-Subject Inventions.

***[Note to ORTA: Article 7.10.2 is optional. It should be used only if Navy Collaborator and/or Non-Navy Collaborator have preexisting Non-Subject Inventions that are pertinent to this Cooperative Work.]***

7.10.2 Preexisting Non-Subject Inventions Pertinent to the Cooperative Work

Non-Subject Inventions Made prior to the Effective Date of this Agreement 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 of this Agreement 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 attorneys docket number if an Invention Disclosure, or Patent Application serial number, and date of issue (for patents only).]***

7.11 Filing of Patent Applications

By mutual agreement, the Collaborators shall identify which Collaborator shall file a Patent Application on any Subject Invention. 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 and prior to publication, or one year from the date the Invention Disclosure was received, whichever comes first. In the case of a Jointly Made Subject Invention, if no Patent Application is filed within the specified time period by the responsible Collaborator, the other Collaborator may assume control of filing the Patent Application and take title to the Jointly Made 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 Jointly Made Subject Invention or have the Jointly Made Subject Invention practiced throughout the world by or on its behalf.

7.11.1 Patent Filing

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 7.11, 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 has the right to take action if the filing Collaborator declines.

7.11.2 Copies and Inspection

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 request. The filing Collaborator shall give the other Collaborator a limited power to inspect, with authorization to access the Patent Application, make copies, and, in the event that the filing Collaborator declines continued prosecution of the Patent Application, do all that is necessary to secure patent protection for the Jointly Made Subject Invention.

7.11.3 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.

7.12 Licenses to Subject Inventions

7.12.1 Internal Use License to **[Non-Navy Collaborator]**

Government grants to the **[Non-Navy Collaborator]** a nonexclusive, irrevocable, paid-up Internal Use License to a Subject Invention Made solely by employees of **[Navy Collaborator]**. No Internal Use License granted under this Agreement shall permit licensee to grant sublicenses. No Internal Use 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.

7.12.2 Government License

Pursuant to 15 U.S. Code § 3710a(b)(2), for Subject Inventions Made solely by an employee of **[Non-Navy Collaborator]**, **[Non-Navy Collaborator]** grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the Subject Invention or have the Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

7.12.3 Option for Commercial License to Subject Inventions

**[Navy Collaborator]** gives **[Non-Navy Collaborator]** the option of acquiring an Exclusive or Nonexclusive Commercial License for the field of **[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 six (6) months of the filing of a Patent Application. **[Non-Navy Collaborator]** must execute an Exclusive Commercial or Nonexclusive Commercial License to the Subject Invention within six (6) months of election to exercise the option, or the Invention shall be made available for licensing by the public in accordance with 37 C.F.R. Part 404.

7.12.4 Termination of Licenses Granted and Cancellation of License Option to Subject Inventions

**[Navy Collaborator]** may cancel the Exclusive or Nonexclusive Commercial License option and terminate any Exclusive or Nonexclusive Commercial Licenses and Internal Use Licenses provided for above made in whole or in part by Government employees 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]** under Article 11.2; 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 is reasonably determined by **[Navy Collaborator]** not to qualify under the requirements of Executive Order 12591, Section 4(a); or

(e) **[Non-Navy Collaborator]** which was a FOCI organization when the Agreement was signed has now become a different FOCI organization that is reasonably determined by **[Navy Collaborator]** not to qualify under the requirements of Executive Order 12591, Section 4(a).

7.13 License to Non-Subject Inventions

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 applications of Non-Subject Inventions, the **[Non-Navy Collaborator]** must obtain a License from the **[Navy Collaborator]**, in accordance with applicable laws and regulations (including, but not limited to, 37 C.F.R. Part 404).

***[Note to ORTA: Article 7.14 is optional.]***

7.14 Copyrights

**[Non-Navy Collaborator]** may copyright works of authorship prepared pursuant to this Agreement if eligible for copyright protection under Title 17, U.S. Code § 106 **[Non-Navy Collaborator]** grants to the Government a nonexclusive, irrevocable, paid-up license in copyrighted works of authorship, including software, prepared pursuant to this Agreement for any purpose that is consistent with the rights in Data described in Article 7.2 and Article 7.3. **[Non-Navy Collaborator]** shall affix the applicable copyright notice of Title 17, U.S. Code §§ 401-403, and an acknowledgment of the scientific and technical contributions of **[Navy Collaborator]**. **[Non-Navy Collaborator]** grants to the U.S. Government a paid-up, non-exclusive, irrevocable, worldwide license to reproduce or have reproduced, prepare or have prepared in derivative form, and distribute or have distributed copies of publications and solely or jointly created Subject Data for Government purposes.

**Article 8. TANGIBLE PROPERTY**

8.1 Ownership of Tangible Property

Each Collaborator shall retain title to its Tangible Property. All Tangible Property owned and provided by one Collaborator shall remain the property of that Collaborator. Tangible Property having any component purchased or supplied by the Government shall be the property of the Government, unless such tangible Government components reasonably can be separated from non-Government components without damage to any of the individual components comprising the Tangible Property. These separated components shall remain the property of the Collaborator that purchased them. After termination of this Agreement the parties may, by mutual consent, separate the Tangible Property into its components and the separated components shall remain the property of the Collaborator that originally owned the property.

8.2 Tangible Property Operational and Disposition Costs

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.

8.3 Disposal of Tangible Property

Unless otherwise agreed, each Collaborator shall take possession of its respective Tangible Property within sixty (60) days of termination of this Agreement. Each Collaborator shall cooperate with the other Collaborator in the recovery or disposition of the other Collaborator's 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 liable for the negligent or wrongful acts of its officers and employees solely to the extent provided for in the Federal Tort Claims Act (28 U.S. Code § 2671 et. seq.) and in other applicable laws and regulations of the U.S. that specifically waive sovereign immunity. Nothing in this Agreement shall be construed as a waiver of the sovereign immunity of the U.S.

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 Collaborator to this Agreement based on actions of **[Non-Navy Collaborator]**, **[Non-Navy Collaborator]** shall not pursue any actions to enter the Government as a Collaborator in such suit, action or claim unless the Government has some liability under the Federal Tort Claims Act. This provision shall survive termination of this Agreement.

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 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.

10.2 Severability

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

10.3 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.

10.4 Governing Laws

U.S. Federal laws shall govern this Agreement for all purposes.

10.5 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.

10.6 Subcontracting

In accordance with Appendix C, 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.

***[Note to ORTA: Refer to the Navy T2 Handbook for a discussion on issues related to the use of contractors during the execution of a CRADA.]***

10.7 Assignment

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.

10.8 Disputes

**[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.

10.9 Use of Name or Endorsements

**[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.

10.10 Public Release Announcements of This Agreement

Information regarding this Agreement, excluding funding information (Article 5), the Statement of Work, and associated Appendices, may be released to the public.

10.11 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.

10.12 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 U.S.

10.13 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.

**Article 11. MODIFICATIONS AND NOTICES**

11.1 Amendments

Any modifications to this Agreement shall be jointly agreed upon and shall not be effective until a written amendment is signed by both executing officials of this Agreement or their successors.

11.2 Unilateral Termination

**[Non-Navy Collaborator]** and **[Navy Collaborator]** each have the right to unilaterally terminate this Agreement upon thirty (30) days written notice to the other Collaborator.

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]**. All such notices shall be delivered in a manner that ensures confirmation of receipt.

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 four (4) years]** after its Effective Date, unless otherwise extended in writing according to the provisions of Article 11.

***[If necessary, write “Signatures for the Agreement follow on next page”.]***

**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 \_\_\_\_\_\_\_\_20 \_\_\_.

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 \_\_\_\_\_\_\_\_20\_\_\_.

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title:

Navy Organization:

**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. 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:

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 C.F.R. §§ 164.501 and 164.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).

*Privacy Rule* means the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, subparts A and E.

*Protected Health Information* has the same meaning as the term “protected health information” in 45 C.F.R. § 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 C.F.R. §§ 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 C.F.R. Parts 160, 162 and 164, subpart C.

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 C.F.R. §§ 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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.