MODULAR MEDICAL COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

**A** *[select appropriate module(s) from the following:]* **CLINICAL TRIAL / FOCI / CONTRACTOR / COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)** BETWEEN [ \_\_\_\_\_\_\_ ] **(COLLABORATOR)** AND [\_\_\_\_\_\_\_\_]  **(LABORATORY)**

*[include the following, as applicable:]* FOR THE INVESTIGATION OF *TEST AGENT* **(TEST ARTICLE)**

AGREEMENT Title:

AGREEMENT NUMBER: NCRADA-LAB-FY-XXXXX

(if applicable) PROTOCOL INFORMATION: \_\_\_\_\_

AGREEMENT ADMINISTRATORS:

**COLLABORATOR**

Preferred Contact: \_\_\_\_\_, phone: \_\_\_\_\_, email: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_, phone: \_\_\_\_\_, email: \_\_\_\_\_

**LABORATORY**

Preferred Contact:\_\_\_\_\_, phone: \_\_\_\_\_, email:\_\_\_\_\_

Principal Investigator: \_\_\_\_\_, phone: \_\_\_\_\_, email:\_\_\_\_\_

**PREAMBLE**

Under authority of 15 U.S.C. §3710a, the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), **COLLABORATOR** and **LABORATORY**, described below, agree to enter into this Cooperative Research and Development Agreement (CRADA) according to the terms and conditions set in this Agreement.

The **COLLABORATOR** is \_\_\_\_\_ with offices at **\_\_\_\_\_**,andis duly organized, validly existing and in good standing under the laws of \_\_\_\_\_. The **COLLABORATOR** **is/is not** a small business as defined in 13 C.F.R. Part 121.101 *et seq.* of the Administrator of the Small Business Administration. Further, the **COLLABORATOR** **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 (FOCI). If **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 then it or its successor or assignee shall notify the **LABORATORY** to that effect.

The **LABORATORY** is the \_\_\_\_\_,located at \_\_\_\_\_, \_\_\_\_\_, and is a Federal laboratory of the United States Department of Defense wholly owned by the U.S. **GOVERNMENT** a substantial purpose of which is the performance of research, development or engineering.

**Article 1. DEFINITIONS:**

**“ADVERSE DRUG EXPERIENCE”** means an adverse event as defined under 21 C.F.R Part 312.32. *[Include for CRADAs involving clinical trial or test article(s), as appropriate.]*

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

“**DATA**” means all recorded information of any kind regardless of the form or method of the recording, including computer software.

“**EXCLUSIVE LICENSE**” means the grant by the owner of Intellectual Property of the exclusive right to make, use, or sell an **INVENTION**.

“**FOCI**” means Foreign Owned, Controlled or Influenced.

“**GOVERNMENT**” means the Government of the United States of America**.**

“**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.

**“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 subject 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 any patients participating in a clinical trial. *[Include for CRADAs involving clinical trial or test article(s), as appropriate.]*

“**INTELLECTUAL PROPERTY**” means the property of ideas, examples of which include, but are not limited to patents, trademarks copyrights, and trade secrets.

“**INVENTION**” means any **INVENTION** or discovery that is or may be patentable under Title 35 of the United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act. (15 U.S.C. §3703(7)).

“**INVENTION DISCLOSURE**” means the document identifying and describing to organizational management the **MAKING** of an **INVENTION**.

“**INVESTIGATOR’S BROCHURE**”means a document containing all the relevant information about the drug or biologic, including animal screening, preclinical toxicology, and detailed pharmaceutical **DATA**. Also included, if available, is a summary of current knowledge about pharmacology and mechanism of action and a full description of the clinical toxicities. *[Include for CRADAs involving clinical trial or test article(s), as appropriate.]*

“**MADE**” when used in conjunction with any **INVENTION** means the conception or first actual reduction to practice of such **INVENTION**. (15 U.S.C. §3703(8)).

“**NON-SUBJECT INVENTION**” means any **INVENTION** that is not a **SUBJECT INVENTION**.

“**PARTY**” means a signatory to this Agreement.

“**PATENT APPLICATION**” means U.S. or foreign **PATENT APPLICATION**, continuation, continuation-in-part, divisional, reissue, and/or reexamination on any **INVENTION**.

“**PROPRIETARY INFORMATION**” means information that: (1) embodies trade secrets developed at private expense or technical, 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 receiving **PARTY** without obligation concerning its confidentiality; and (d) has not been developed independently by persons who have had no access to the information; or (2) has been generated by the **LABORATORY** during the performance of this Agreement, and would have qualified as Proprietary Information under (1) above if it had been generated by **COLLABORATOR**.

**“PROTECTED HEALTH INFORMATION”** means patient-identifying **DATA** from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens that can be linked to individual human subjects, either directly or indirectly through codes. *[Include for CRADAs involving clinical trial or test article(s), as appropriate.]*

**“PROTOCOL”** means **COLLABORATOR’s** **PROTOCOL** [cite PROTOCOL number and give the title of the PROTOCOL] incorporated into this **AGREEMENT** by reference and attached as Appendix [ ]. *[Include for CRADAs involving clinical trial or test article(s), as appropriate.]*

**“SPONSOR”** means, in accordance with the definition in 21 C.F.R. Part 312.3, an organization or individual who assumes legal responsibility for supervising or overseeing Clinical Trials with Test Article, and is sometimes referred to as the “**IND holder**.” *[Include for CRADAs involving clinical trial or test article(s), as appropriate.]*

“**SUBJECT DATA**” means that **DATA** first recorded in the performance of this **AGREEMENT.**

“**SUBJECT INVENTION**” means any INVENTION MADE through research, development, engineering, or other tasks performed under this Agreement pursuant to this **AGREEMENT**.

“**TEST ARTICLE**” means a drug, biological product or device, etc. which is subject to regulation under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq*, as amended, as well as placebo.

**Article 2.** **OBJECTIVE:**

**LABORATORY** and **COLLABORATOR** have shared interests in [ \_\_\_\_\_\_\_\_\_\_ ] (OBJECTIVE). A Statement of Work (Appendix A) detailing tasks for both **LABORATORY** and **COLLABORATOR** is appended to the end of this Agreement. Any inconsistency in this CRADA shall be resolved by giving precedence in the following order: (a) the cited laws and regulations; (b) the body of the CRADA; (c) the Statement of Work; and (d) other documents to or incorporated into the CRADA.

**Article 3. DATA/PROPRIETARY INFORMATION**:

A **PARTY** shall place a marking on the **DATA** that it asserts is **PROPRIETARY**. Each **PARTY** agrees that it will not disclose or use the other **PARTY**’s, marked as **PROPRIETARY INFORMATION**, without prior written consent except as stated in this AGREEMENT. It is **COLLABORATOR**’s and **LABORATORY**’s responsibility to properly identify all **PROPRIETARY INFORMATION**. Under 15 U.S.C. §3710a(c)(7)(B) the **LABORATORY** and **COLLABORATOR** mutually may agree to provide appropriate protection and restricted access to **LABORATORY** produced **SUBJECT DATA** generated under this Agreement 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. **LABORATORY** may provide **DATA** to **COLLABORATOR** that may be the subject of a **PATENT APPLICATION** which is protectable under 35 U.S.C. §205.

**Article 4.** **PUBLICATIONS**:

Publication of **SUBJECT DATA** is of prime interest to the **LABORATORY** and this Agreement shall not be interpreted to prevent or unreasonably delay publication of research resulting from the activities occurring under this Agreement. **COLLABORATOR** and **LABORATORY** agree to confer and consult to provide a reasonable review period, up to 60 days, prior to the publication or presentation of **SUBJECT DATA** regarding the collaboration to assure that no PROPRIETARY INFORMATION is released and that patent rights are protected. Publication and/or presentation will be delayed for a reasonable time to afford protection, if needed. If the research is not published, the **LABORATORY** and **COLLABORATOR** shall provide a report of the research results to the other **PARTY**.

**Article 5**. **REPORTS:**

The **PARTIES** shall submit reports on the progress of the **OBJECTIVE** as mutually agreed; and at minimum, final written reports shall be exchanged within 30 days of the expiration of this Agreement.

*[Under Article 5, add, if required:]*

**Article 5.1**. **TEST ARTICLE, CLINICAL REPORTS AND PROVISIONS:**

**COLLABORATOR** will provide to **LABORATORY** without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of formulated and acceptably labeled, clinical-grade **TEST ARTICLE** (and, as required by the Protocol(s) to complete the clinical trial(s) agreed to and approved under this CRADA. **[COLLABORATOR](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [will provide any documents attesting to manufacturing and control, such as a Certificate of Analysis, to](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[LABORATORY](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [for each lot of the](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[TEST ARTICLE](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [provided, as per 21 C.F.R. Part 312.23. All](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[ADVERSE DRUG EXPERIENCES](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)**[, as defined in 21 C.F.R. Part 310.305, that are either serious or unexpected shall be reported to the](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[SPONSOR](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [as soon as possible following notification of the occurrence and as provided in the Protocol(s). Details about all such](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[ADVERSE DRUG EXPERIENCES](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [shall be communicated to the](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[SPONSOR](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [in writing via the appropriate form and as required by the Protocol(s).](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[LABORATORY](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [and](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[COLLABORATOR](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)**[, or their agents, may each file any required documentation related to](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[TEST ARTICLE](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [with the U.S. Food and Drug Administration (FDA).](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[LABORATORY](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [and](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[COLLABORATOR](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [expressly authorize and consent to allow each other or its authorized agent(s) access to, and/or to cross-reference, any documents filed with the FDA related to the](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[TEST ARTICLE](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)**[.](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)

[The](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[PARTIES](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [shall make all necessary](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[SUBJECT DATA](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [and Source Documents available to a regulatory authority or other governmental authorities, or the IRB for inspection or auditing. A](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[PARTY](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [shall immediately notify the other](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[PARTY](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)**[(ies) should it receive notice of an inspection, investigation or audit examination. The](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[PARTY](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)** [under examination shall share copies of any documents received from or provided to a regulatory authority or other governmental authorities with the other](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article) **[PARTY](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)**[(ies).](#TipArt41" \o "Use for Clinical Trials involving development of a Test Article)

*[Include the following in CRADAs involving the exchange of Protected Health Information.]*

**The PARTIES** are expected to share **PROTECTED HEALTH INFORMATION** among the other **PARTIES to this AGREEMENT**, and each **PARTY** shall comply with all laws and regulations, including without limitation the regulations of the **HIPAA**, governing the privacy and security of health information. **COLLABORATOR** will execute and abide by the terms of the attached Business Associate Agreement (Appendix C) addressing the handling of **PROTECTED HEALTH INFORMATION**. If, in addition, **COLLABORATOR** requires extraction of existing **PROTECTED HEALTH INFORMATION** from an MHS database, **COLLABORATOR** must execute a Data Sharing Agreement with the Defense Health Agency.

**Article 6**. **WARRANTY:**

*[Include the following in CRADAs involving a test article(s).]*

The **PARTY** providing the **TEST ARTICLE** provided has been produced in accordance with the FDA’s current Good Manufacturing Practice set out in 21 C.F.R. Part 210-211 and ICH QA7, and meets the specifications cited in the Certificate of Analysis and **INVESTIGATOR'S BROCHURE** provided. No **PARTY** to this Agreement is presently subject to debarment or suspension by any agency of the **GOVERNMENT**. Should a **PARTY** be debarred or suspended during the term of this Agreement, the other **PARTY**(ies) shall be notified within thirty (30) days of receipt of a final notice. The notified **PARTY**(ies) may then elect to terminate this Agreement and any licenses and options granted under this Agreement. **COLLABORATOR** will provide **LABORATORY** evidence of holding adequate clinical trial insurance. Other than the aforementioned, *[Include the following in ALL CRADAs.]* no **PARTY** makes any representations nor extends any warranty of any kind, either expressed or implied regarding any materials or equipment transferred under this agreement. There are no expressed or implied warranties of merchantability or fitness for a particular purpose or that the use of any materials or equipment transferred under this agreement will not infringe any patent, copyright, trademark or other rights.

**Article 7.** **LIABILITY:**

The **LABORATORY**’s liability for the negligent or wrongful acts of its officers and employees shall be in accordance with the Federal Tort Claims Act (28 U.S.C. §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. **COLLABORATOR** is solely responsible for its actions and the actions of those acting for **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, **COLLABORATOR** agrees that in any suit, action or claim brought by anyone not a party to this Agreement based on actions of **COLLABORATOR**, **COLLABORATOR** shall not pursue any actions to enter the **LABORATORY** as a party in such suit, action or claim unless the **LABORATORY** has some liability under the Federal Tort Claims Act. No **PARTY** shall be liable for the consequences of any *force majeure* that is beyond its reasonable control.

*[Include the following in CRADAs involving a test article(s).]*

Certificate of Insurance: **COLLABORATOR** will provide a Certificate of Insurance or proof of self-insurance covering the risks of the study. The Certificate will be provided prior to initiation of the research activities in Appendix A. The coverage should include sufficient per occurrence and aggregate general liability, professional liability, bodily injury, automobile, and employee workers compensation protection limits adequate to reasonably cover the expected risks of the study in the jurisdiction where any such actions may be brought, and include provisions to defend, indemnify and hold harmless **LABORATORY**. **COLLABORATOR** will maintain this coverage for the duration of this Agreement and, if the policy is claims-made, for {two to five} years thereafter. **COLLABORATOR** will notify **LABORATORY** within 20 days of any notice of cancellation or non-renewal of, or material change in, or claim against, its insurance coverage.

**Article 8. TRANSFER AND DISPOSAL OF EQUIPMENT/MATERIAL:**

The **PARTIES** agree that any materials or equipment transferred under this Agreement and related **PROPRIETARY INFORMATION** received by either **PARTY**, and any copies of information, shall remain the property of the providing **PARTY**. These items will be promptly returned, destroyed, or otherwise disposed of, at the termination of this Agreement in accordance with the directions of the providing **PARTY**. All requests and responses must be in writing. The materials or equipment transferred under this Agreement and information will be returned at no expense to the providing **PARTY**. All tangible property jointly developed under this agreement shall remain the property of the **GOVERNMENT** unless separately negotiated. The obligations of the **PARTIES** to transfer technology to one or more other **PARTIES**, provide technical information and reports to one or more other **PARTIES**, and otherwise perform under this Agreement are contingent upon compliance with applicable United States export control laws and regulations. In addition, where applicable, the **PARTIES** agree to fully comply with all laws, regulations, and guidelines governing biological select agents and toxins.

**Article 9.** **INTELLECTUAL PROPERTY and DATA RIGHTS:**

Each **PARTY** allows the other **PARTY**(ies) to practice its **NON-SUBJECT INVENTION**(s) to accomplish the requirements, as outlined in the Statement of Work of this **AGREEMENT**, during the term of this **AGREEMENT**. Except as expressly provided in this **Agreement**, no additional rights are provided to **LABORATORY** or **COLLABORATOR** under any pre-existing patents, **PATENT APPLICATIONs**, trade secrets or other intellectual property. Each **PARTY** has unlimited rights to the **DATA** generated by that **PARTY**. **LABORATORY** shall minimally have a nonexclusive, non-transferrable, irrevocable, paid-up license to practice the **Subject Invention MADE** under this **AGREEMENT** or have the **Subject Inventions** practiced throughout the world by or on behalf of the Government under this **Agreement**. Each **PARTY** shall have the right to review and receive delivery of **SUBJECT DATA** generated by the other **PARTY**(ies), and **SUBJECT DATA** shall be delivered to the requesting **PARTY** within fifteen (15) days of the request.

**COLLABORATOR** may copyright works of authorship in the prepared pursuant to this Agreement if eligible for copyright protection under 17 U.S.C. §106. **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 Article 9. **COLLABORATOR** shall affix the applicable copyright notice of 17 U.S.C. §§ 401-403, and an acknowledgement of the scientific and technical contributions of the **LABORATORY**. **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.

*[Include the following in situations where DoD has a long-term and sizable investment in the technology’s development.]*

FDA Regulatory Matters. This Agreement involves a product subject to regulation by the FDA for which FDA clearance or approval will be sought. Accordingly, the **PARTIES** agree on the provisions described in Appendix B.

**Article 10.** **SUBJECT** **INVENTION LICENSE OPTION:**

Each **PARTY** shall retain title to any **SUBJECT** **INVENTION** of its employees **MADE** in the performance of this **AGREEMENT**. Each **PARTY** shall notify the other of the receipt of any **INVENTION** **DISCLOSURE** regarding **SUBJECT** **INVENTION.** In the event of a jointly-owned **SUBJECT INVENTION**, the **PARTIES** agree to consult on the options for advancing the technology. **COLLABORATOR** has a non-exclusive, non-commercial, research use license to any **SUBJECT** **INVENTION** **MADE** by **LABORATORY** occurring under this Agreement in performance of the **OBJECTIVE**. **LABORATORY** gives **COLLABORATOR** the option, to be exercised within one hundred eighty (180) days after any filing of any type of **PATENT APPLICATION** claiming the **SUBJECT INVENTION**, of acquiring an **EXCLUSIVE LICENSE** in the **GOVERNMENT**’s rights in any **SUBJECT 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**. Unilateral termination of this Agreement by **COLLABORATOR** may result in the termination of any **EXCLUSIVE LICENSE** or option thereto.

*[Include the following in CRADAs involving a FOCI COLLABORATOR.]*

The option to an **EXCLUSIVE LICENSE**, or a granted license (exclusive or nonexclusive) can be terminated if **COLLABORATOR** becomes a different **FOCI** organization that does not qualify under requirements of Executive Order 12591.

The **PARTIES** will obtain consent must be obtained from all **PARTIES** to this Agreement for third-party contractors to be employed on behalf of either **COLLABORATOR** or **LABORATORY**, in performance of this **AGREEMENT**; the contractors will retain their Bayh-Dole rights (35 U.S.C. §200 *et seq.*) unless otherwise agreed. **COLLABORATOR** consents to **LABORATORY**’s use of contractors in performance of the **OBJECTIVE**.

**Article 11**. **NOTICES and AMENDMENT:**

The **PARTIES** will send all notices to the Agreement Administrators or their successors at the addresses shown in the **PREAMBLE** or other confirmed address. This Agreement can be amended only by a written amendment mutually agreed to and signed by the Agreement signatories or their successors.

**Article 12**. **DURATION:**

This Agreement will terminate on the earliest of the following dates:

(1) Upon thirty (30) days written notice by any **PARTY** to the other(s), or

(2) \_\_\_\_\_months from the effective date of this Agreement.

**Article 13**. **ENTIRE AGREEMENT, ASSIGNMENT, and DISPUTES:**

This Agreement is the entire Agreement between the **PARTIES** concerning the **OBJECTIVE** and supersedes any prior understanding or written or oral agreement related to the **OBJECTIVE**. This Agreement cannot be assigned without the prior written consent of the other **PARTY**(ies). The **PARTIES** agree that disputes shall be resolved by submitting the issue to the Agreement signatories, or designee(s). Unless the **PARTIES** agree otherwise, if the dispute is not resolved within 30 days of submission to the signatories (or designees), it will thereafter be submitted to the Chief of Naval Research or his/her designee for a final agency decision within 60 days of submission. The **PARTIES** may seek resolution in U.S. Federal Court or an alternative dispute resolution mechanism if the dispute remains unresolved after 60 days.

**Article 14**. **RELATIONSHIP OF PARTIES:**

The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners.

Article 15. **FUNDS (if applicable):**

It is agreed and understood that any materials or equipment transferred from **COLLABORATOR** to **LABORATORY** under this Agreement is/are furnished and the Agreement is entered into at no cost to the **LABORATORY**. If **COLLABORATOR** receives and accepts funds from **LABORATORY** in support of the **OBJECTIVE**, this Agreement is terminated and license terms of Article 10 are null and void. **LABORATORY** may discontinue performance under this Agreement if the funds provided by **COLLABORATOR** are insufficient or are not provided as specified. Funds that have not been obligated or expended at the conclusion of this Agreement shall be returned to **COLLABORATOR**.

*[Include the following in CRADAs where the LABORATORY receives funding resources.]*

**COLLABORATOR** agrees to pay **LABORATORY** the following fees/costs according to the schedule below:

The funding amount is: \_\_\_\_\_

Schedule: \_\_\_\_\_

Electronic payment is preferred.

DFAS Cleveland can receive funds via ACH using the following:

Bank Name: Credit Gateway

RTN: 051036706

A/C: 220031

DFAS Cleveland can also receive funds via wire 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: 00008522

Each payment shall refer to **LABORATORY** CRADA number “CRADA -\_\_\_\_\_”

**Article 16**. **TITLE:**

Each **PARTY** shall retain title to all tangible property to which it had title prior to the effective date of this Agreement unless mutually agreed in writing.

**Article 17**. **USE OF NAME OR ENDORSEMENTS:**

Both **LABORATORY** and **COLLABORATOR** shall not use the name, emblem or symbol of the other **PARTY** or any other Government entity on any product or service that is directly or indirectly related to this Agreement without the prior written approval of the associated **PARTY**.

**Article 18**. **PUBLIC RELEASE OF THIS AGREEMENT:**

Other than the funding information in Article 15, this Agreement 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 12.

*[Include the following in all clinical trial CRADAs.]*

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 Health and Human Services at 45 C.F.R. Part 46 and implemented by the Department of Defense at 32 C.F.R. Part 219. The **PARTIES** also agree that no research involving human subjects covered under 32 C.F.R. Part 219 can commence until it is approved by the governing IRB.

**Article 20**. **GOVERNING LAW and SURVIVING PROVISIONS:**

United States Federal Law shall govern this Agreement for all purposes. All the Articles of this Agreement shall survive its termination.

**Article 21**. **SIGNATURES:**

Each **PARTY** shall execute a copy of this Agreement, each of which shall be deemed an original and all of which when delivered, by facsimile transmission, mail, or email delivery, together shall constitute one instrument.

Accepted for\_\_\_\_\_:

I, the undersigned, am duly authorized to bind \_\_\_\_\_ to this Agreement and do so by affixing my signature hereto.

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

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Accepted for the Department of Defense **LABORATORY**:

I, the undersigned, am duly authorized to bind the **LABORATORY** to this Agreement and do so by affixing my signature hereto. Entered under 15 U.S.C. §3710a.

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

Name: \_\_\_\_\_

Title: \_\_\_\_\_

APPENDIX A – STATEMENT OF WORK

**COLLABORATOR** agrees to perform the following tasks:

1.

2.

3.

**LABORATORY** agrees to perform the following tasks:

1.

2.

3.

The **PARTIES** agree to jointly perform the following tasks:

1.

2.

3.

*[Additional appendices, as applicable, found below.]*

*[Include the following appendix in situations where DoD has a long-term and sizable investment in the technology’s development.]*

APPENDIX B

GOVERNMENT RIGHTS TO ENSURE PRODUCT AVAILABILITY

Appendix B only applies in the event that COLLABORATOR is not able or willing to commercialize the subject technology within a reasonable period of time as defined herein from the expiration or termination of the CRADA.

The terms “Regulatory Application,” “sponsor,” and “applicant” are used herein and are defined as follows: “Regulatory Application” means investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing, 510(k), or another regulatory filing submitted to the FDA related to a product or an analogous foreign filing. The related terms, “sponsor” and “applicant,” are used herein consistent with the definitions and/or usage found in 21 C.F.R. Section 3.2(c), 312.3, 600.3(t), 812.3(n), 812 Subpart C, and 814.20. The term “subject technology” is used herein to mean [(NAME)] technology as described U.S. Patent Application number [(##)], as well as any improvements or modifications developed during the term of this CRADA.

The parties to this CRADA further agree as follows:

1. (FEDERAL ENTITY) will be the sponsor of the Regulatory Application described in this Agreement until said application is cleared or approved by the FDA, at which point (FEDERAL ENTITY) will transfer such clearance or approval to COLLABORATOR.

2. During (FEDERAL ENTITY) sponsorship, LABORATORY will provide COLLABORATOR, upon request, all communication, both formal and informal, to or from the FDA regarding the subject technology being developed under this CRADA. In addition, LABORATORY will ensure that COLLABORATOR staff is permitted the opportunity to participate in any sponsor meetings, both formal and informal, in which the subject technology is discussed with the FDA.

3. After any transfer of the Regulatory Application from (FEDERAL ENTITY) to COLLABORATOR, and in the event that COLLABORATOR fails to obtain any additional, required FDA approval or clearance or to satisfy any outstanding regulatory requirement due from the sponsor within 2 years after the expiration or termination of this CRADA, or where the COLLABORATOR fails to commercially market the regulated technology to the point where the U.S Government may purchase the technology within 2 years after the expiration or termination of this CRADA, COLLABORATOR will:

a. Transfer possession, ownership, and sponsorship/holdership of any Regulatory Application, regulatory correspondence, and supporting regulatory information related to the subject technology to (FEDERAL ENTITY);

b. Inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section 3a. above; and

c. Provide the U.S. Government with a non-exclusive, paid-up, irrevocable license to any patent, copyright, data rights, proprietary information (as defined in Article 3), or regulatory information held by the COLLABORATOR, or obtained from the COLLABORATOR by a third party, in order to permit the U.S. Government to pursue commercialization of the subject technology.

4. Survival. The respective rights and obligations of COLLABORATORunder this Appendix shall survive the termination of the CRADA in which it is incorporated.

*[Include the following in situations where there will be an exchange of HIPAA information.]*

APPENDIX C – Business Associate Agreement

**PRIVACY AND SECURITY OF PROTECTED HEALTH INFORMATION**

1. **Introduction**

In accordance with DoD 6025.18-R, “Department of Defense Health Information Privacy Regulation,” January 24, 2003, the COLLABORATOR meets the definition of Business Associate. Therefore, a Business Associate Agreement is required to comply with both the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security regulations. This clause serves as that agreement whereby the COLLABORATOR, referred to hereafter as the “Business Associate,” agrees to abide by all applicable HIPAA Privacy and Security requirements regarding health information as defined in this clause, and in DoD 6025.18-R and DoDI 8580.02, “Security of Individually Identifiable Health Information in DoD Health Care Programs,” August 12, 2015, as amended. Additional requirements will be addressed when implemented.

a. Definitions. As used in this clause generally refer to the Code of Federal Regulations (CFR) definition unless a more specific provision exists in DoD 6025.18-R or DoDI 8580.02.

(1)*HITECH Act*shall mean the Health Information Technology for Economic and Clinical Health Act included in the American Recovery and Reinvestment Act of 2009.

(2) *Individual* has the same meaning as the term “individual” in 45 C.F.R. Part 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. Part 164.502(g).

(3) 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.

(4) Protected Health Information has the same meaning as the term “protected health information” in 45 C.F.R. Part 160.103, limited to the information created or received by the Business Associate from or on behalf of the Government pursuant to the Contract.

(5) Electronic Protected Health Information has the same meaning as the term “electronic protected health information” in 45 C.F.R Part 160.103.

(6)Required by Law has the same meaning as the term “required by law” in 45 C.F.R. Part 164.103.

(7) Secretary means the Secretary of the Department of Health and Human Services or his/her designee.

(8) Security Incident will have the same meaning as the term “security incident” in 45 C.F.R Part 164.304, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(9) Security Rule means the Health Insurance Reform: Security Standards at 45 C.F.R. part 160, 162 and part 164, subpart C.

(10) Terms used, but not otherwise defined, in this Clause shall have the same meaning as those terms in 45 C.F.R. 160.103, 160.502, 164.103, 164.304, and 164.501.

b. The Business Associate shall not use or further disclose Protected Health Information other than as permitted or required by the Contract or as Required by Law.

c. The Business Associate shall use appropriate safeguards to maintain the privacy of the Protected Health Information and to prevent use or disclosure of the Protected Health Information other than as provided for by this Contract.

d. The HIPAA Security administrative, physical, and technical safeguards in 45 C.F.R. parts 164.308, 164.310, and 164.312, and the requirements for policies and procedures and documentation in 45 C.F.R Part 164.316 shall apply to Business Associate. The additional requirements of Title XIII of the HITECH Act that relate to the security and that are made applicable with respect to covered entities shall also be applicable to Business Associate. The Business Associate 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 Contract.

e. The Business Associate shall, at their own expense, take action to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of a use or disclosure of Protected Health Information by the Business Associate in violation of the requirements of this Clause.  These mitigation actions will include as a minimum those listed in the Breach Reporting procedure, which is available at: http://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties

f. The Business Associate shall report to the Government any security incident involving protected health information of which it becomes aware.

g. The Business Associate shall report to the Government any use or disclosure of the Protected Health Information not provided for by this Contract of which the Business Associate becomes aware.

h. The Business Associate shall ensure that any agent, including a sub Business Associate, to whom it provides Protected Health Information received from, or created or received by the Business Associate, on behalf of the Government, agrees to the same restrictions and conditions that apply through this Contract to the Business Associate with respect to such information.

i. The Business Associate shall ensure that any agent, including a sub-Business Associate, to whom it provides electronic Protected Health Information, agrees to implement reasonable and appropriate safeguards to protect it.

j. The Business Associate shall provide access, at the request of the Government, and in the time and manner reasonably 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 Parts 164.524.

k. The Business Associate shall 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 Parts 164.526 at the request of the Government, and in the time and manner reasonably designated by the Government.

l. The Business Associate shall 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, on behalf of the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner reasonably 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 shall 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 Part 164.528.

n. The Business Associate shall provide to the Government or an Individual, in time and manner reasonably designated by the Government, information collected in accordance with this Clause of the Contract, 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. Part 164.528.

2. **General Use and Disclosure Provisions**

Except as otherwise limited in this Clause, the Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, the Government for treatment, payment, or healthcare operations purposes, in accordance with the specific use and disclosure provisions below, if such use or disclosure of Protected Health Information would not violate the HIPAA Privacy Rule, the HIPAA Security Rule, DoD 6025.18-R or DoDI 8580.02 if done by the Government. The additional requirements of Title XIII of the HITECH Act that relate to privacy and that are made applicable with respect to covered entities shall also be applicable to Business Associate.

3. **Specific Use and Disclosure Provisions**

a. Except as otherwise limited in this Clause, the Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

b. Except as otherwise limited in this Clause, the Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or the Business Associate 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 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 Clause, the Business Associate may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 C.F.R. Part 164.504(e)(2)(i)(B).

d. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. Part 164.502(j)(1).

4. **Obligations of the Government**

Provisions for the Government to Inform the Business Associate of Privacy Practices and Restrictions

a. The Government shall provide the Business Associate with the notice of privacy practices that the Government produces in accordance with 45 C.F.R. Part 164.520.

b. The Government shall provide the Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Business Associate’s permitted or required uses and disclosures.

c. The Government shall notify the Business Associate 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. Part 164.522.

5. **Permissible Requests by the Government**

The Government shall not request the Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the HIPAA Privacy Rule, the HIPAA Security Rule, or any applicable Government regulations (including without limitation, DoD 6025.18-R and DoDI 8580.02) if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Business Associate as otherwise permitted by this clause.

6. **Termination**

a. Termination. A breach by the Business Associate of this clause, may subject the Business Associate to termination under any applicable default or termination provision of this Contract.

b. Effect of Termination.

(1) If this contract has records management requirements, the records subject to the Clause should be handled in accordance with the records management requirements. If this contract does not have records management requirements, the records should be handled in accordance with paragraphs (2) and (3) below

(2) If this contract does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this Contract, for any reason, the Business Associate shall return or destroy all Protected Health Information received from the Government, or created or received by the Business Associate on behalf of the Government. This provision shall apply to Protected Health Information that agents of the Business Associate may come in contact. The Business Associate shall retain no copies of the Protected Health Information.

(3) If this contract does not have records management provisions and the Business Associate determines that returning or destroying the Protected Health Information is infeasible, the Business Associate 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 that return or destruction of Protected Health Information is infeasible, the Business Associate shall extend the protections of this Contract 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 maintains such Protected Health Information.

7. **Miscellaneous**

a. Regulatory References. A reference in this Clause to a section in DoD 6025.18-R, DoDI 8580.02, Privacy Rule or Security Rule means the section currently in effect or as amended, and for which compliance is required.

b. Survival. The respective rights and obligations of the Business Associate under the “Effect of Termination” provision of this Clause shall survive the termination of this Contract.

c. Interpretation. Any ambiguity in this Clause shall be resolved in favor of a meaning that permits the Government to comply with DoD 6025.18-R, DoDI 8580.02, the HIPAA Privacy Rule or the HIPAA Security Rule.

For AGENCY:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

NAME of official signing DATE

Title

Name of Institution

Address

City, State, zip code

For Business Associate:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

NAME of official signing DATE

Title

Name of Institution

Address

City, State, zip code