

**OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)**

BETWEEN

**CONSORTIUM**

Name and address

AND

**THE UNITED STATES OF AMERICA**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

330 INDEPENDENCE AVENUE, SW G640

WASHSINGTON, DC 20201

CONCERNING

(INSERT RESEARCH AND DEVELOPMENT TITLE)

Agreement No.:

PR No.:

Total Amount of the Agreement: \$(INCLUDES CONSORTIUM AND GOVERNMENT FUNDING)

Total Estimated Government Funding of the Agreement: \$

Funds Obligated: \$

Authority: 10 USC 2371 and Sections 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Appropriation:

AA

\$

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by the Department of Health and Human Services (HHS) and the (INSERT CONSORTIUM NAME) pursuant to and under U.S. Federal law.

FOR (INSERT CONSORTIUM NAME)

FOR THE UNITED STATES OF AMERICA

THE DEFENSE ADVANCED RESEARCH

\_\_\_\_\_

(Signature)

\_\_\_\_\_

(Signature)

\_\_\_\_\_

(Name, Title)

(Date)

\_\_\_\_\_

(Name, Title)

(Date)

## TABLE OF CONTENTS

### ARTICLES

### PAGE

<a href="#">ARTICLE I</a>	<a href="#">Scope of the Agreement</a>
<a href="#">ARTICLE II</a>	<a href="#">Term</a>
<a href="#">ARTICLE III</a>	<a href="#">Management of the Project</a>
<a href="#">ARTICLE IV</a>	<a href="#">Agreement Administration</a>
<a href="#">ARTICLE V</a>	<a href="#">Obligation and Payment</a>
<a href="#">ARTICLE VI</a>	<a href="#">Disputes</a>
<a href="#">ARTICLE VII</a>	<a href="#">Patent Rights</a>
<a href="#">ARTICLE VIII</a>	<a href="#">Data Rights</a>
<a href="#">ARTICLE IX</a>	<a href="#">Foreign Access to Technology</a>
<a href="#">ARTICLE X</a>	<a href="#">Title to and Disposition of Property</a>
<a href="#">ARTICLE XI</a>	<a href="#">Subcontracting</a>
<a href="#">ARTICLE XII</a>	<a href="#">Civil Rights Act</a>
<a href="#">ARTICLE XIII</a>	<a href="#">Execution</a>
<a href="#">ARTICLE XIV</a>	<a href="#">Special Clauses</a>

### ATTACHMENTS

<a href="#">ATTACHMENT 1</a>	<a href="#">Statement of Work</a>
<a href="#">ATTACHMENT 2</a>	<a href="#">Report Requirements</a>
<a href="#">ATTACHMENT 3</a>	<a href="#">Schedule of Payments and Payable Milestones</a>
<a href="#">ATTACHMENT 4</a>	<a href="#">Funding Schedule</a>

Insert more or delete as necessary.

**ARTICLE I: SCOPE OF THE AGREEMENT**

**A. Background**

*THIS PARAGRAPH(S) DESCRIBES THE VISION OF THE PROGRAM*

**B. Definitions (MODIFY AS NEEDED. PARTICULAR ATTENTION TO IP TERMS IS REQUIRED)**

**Agreement:** The body of this Agreement and Attachments 1 – 4, which are expressly incorporated in and made a part of the Agreement.

**Consortium:** The group of companies and universities collaborating to accomplish the objectives of the Agreement.

**Consortium Member:** A single company or university operating under the Articles of Collaboration referred to in this Agreement.

**Data:** Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, and trade secrets. The term does not include financial, administrative, cost, pricing or management information and does not include subject inventions, included in Article VII.

**Foreign Firm or Institution:** A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

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

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

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

**Know-How:** All information including, but not limited to discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus and machines.

**Made:** Relates to any invention means the conception or first actual reduction to practice of such invention.

**OT for Advanced Research (OTAR)** means: A legally binding, non-acquisition instrument (generally called "an agreement") used in instances where the principal purpose is the stimulation and/or support of advanced research and development (as defined below), where a non-traditional Government Awardee participates to significant extent in the work.

**Other Transaction Agreement Office (OTAO):** Is the responsible government official authorized to bind the government by signing this agreement and bilateral modifications

**Practical application:** To manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

**Program:** Research and development being conducted by CONSORTIUM, as set forth in Article I., paragraph C.

**Property:** Any tangible personal property other than property actually consumed during the execution of work under this agreement. For purposes of this article, "property" does not include the deliverable prototype which is the (*INSERT DELIVERABLE*).

**Subject invention:** Any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

**Technology:** Discoveries, innovations, Know-How and inventions, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights developed under this Agreement.

**Unlimited Rights:** Rights to use, duplicate, release, or disclose, Data in whole or in part, in any manner and for any purposes whatsoever, and to have or permit others to do so.

### **C. Scope**

1. Consortium shall perform an advanced research and development program (AR&D Program) designed to develop (*INSERT AR&D EFFORT*). The research shall be carried out in accordance with the Statement of Work incorporated in this Agreement as Attachment 1. CONSORTIUM shall submit or otherwise provide all documentation required by Attachment 2, Report Requirements.

2. CONSORTIUM shall be paid for each Payable Milestone accomplished in accordance with the Schedule of Payments and Payable Milestones set forth in Attachment 3 and the procedures of Article V. Both the Schedule of Payments and the Funding Schedule set forth in Attachments 3 and 4 respectively may be revised or updated in accordance with Article III. The agreement payments will be based upon accumulation of expenses incurred by the consortium.

3. The Government and CONSORTIUM (Parties) estimate that the Statement of Work of this Agreement can only be accomplished with an CONSORTIUM aggregate resource contribution of \$ (*INSERT DOLLAR AMOUNT*) from the effective date of this Agreement through (*INSERT NUMBER OF MONTHS*) ( ) months thereafter. CONSORTIUM intends and, by entering into this Agreement, undertakes to cause these funds to be provided. CONSORTIUM contributions will be provided as detailed in the Funding Schedule set forth in Attachment 4. If either HHS or CONSORTIUM is unable to provide its respective total contribution, the other Party may reduce its project funding by a proportional amount.

4. The Government will have continuous involvement with CONSORTIUM. The Government will also obtain access to research results and certain rights in data and patents pursuant to Articles VII and VIII. HHS and CONSORTIUM are bound to each other by a duty of good faith and best research effort in achieving the goals of the Program.

5. This Agreement is an “other transaction” pursuant to 10 U.S.C. § 2371 and Sections 319L(c)(4)(B) and 319L(c)(4)(D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417. The Parties agree that the principal purpose of this Agreement is for the Government to support and stimulate CONSORTIUM to provide its best efforts in advanced research and technology development and not for the acquisition of property or services for the direct benefit or use of the Government.

## **ARTICLE II: TERM**

### **A. Term of this Agreement**

The Program commences upon the date of the last signature hereon and continues for (*INSERT NUMBER OF MONTHS*) months. If all funds are expended prior to the (*INSERT NUMBER OF MONTHS*) month duration, the Parties have no obligation to continue performance and may elect to cease development at that point. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified herein, shall be given effect, notwithstanding this Article.

### **B. Termination Provisions**

Subject to a reasonable determination that the program will not produce beneficial results commensurate with the expenditure of resources, either Party may terminate this Agreement by written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement, shall be in accordance with the provisions set forth in Article VIII, Data Rights. The Government and CONSORTIUM will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VI, Disputes. The Government has no obligation to pay CONSORTIUM beyond the last completed and paid milestone if CONSORTIUM decides to terminate.

**C. Extending the Term**

The Parties may extend by mutual written agreement the term of this Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the OTAO and the CONSORTIUM Administrator.

**ARTICLE III: MANAGEMENT OF THE PROJECT** (NOTE: THIS ARTICLE MAY BE SUBSTANTIALLY REVISED DEPENDING ON THE FACTS OF EACH AGREEMENT.)

**A. Consortium Members**

Consortium Members, as set forth in the Articles of Collaboration of the Consortium, are:

*(LIST CONSORTIUM MEMBERS)*

**B. Consortium Management Committee (CMC)**

1. The CMC shall be comprised of one voting representative from each Consortium Member, and in accordance with the Consortium Articles of Collaboration, bind the Consortium Members. The following CMC decisions are subject to HHS approval:

(a) Changes to the Articles of Collaboration if such changes substantially alter the relationship of the Parties as originally agreed upon when the Agreement was executed;

(b) Changes to, or elimination of, any HHS funding allocation to any Consortium Member as technically and/or financially justified;

(c) Technical revisions to the Agreement; and

(d) Admission of additional or replacement Consortium Members.

2. The CMC is responsible for establishing a schedule of regular technical meetings to be held on a quarterly basis. The CMC shall notify all Consortium Members and the OTTR of the established meeting schedule and, in the event of changes to this schedule, shall notify all Consortium Members and the OTTR thirty (30) calendar days prior to the next scheduled meeting.

3. A quorum is required of the Program Managers (or The OTTR or designee) at quarterly technical meetings. All technical decisions shall be made by (*MAJORITY/CONSENSUS/ETC.*) vote of the CMC and the OTTR

### **C. Management and Program Structure**

Technical and program management of the coordinated research program established under this Agreement shall be accomplished through the management structures and processes detailed in this Article.

1. The CMC shall be responsible for the overall management of the Consortium including technical, programmatic, reporting, financial and administrative matters.

2. The OTTR shall fully participate in all meetings of the CMC. Other Government personnel as deemed appropriate by the OTTR may also participate in the technical portion of these meetings.

### **D. Program Management Planning Process**

The program management and planning process shall be subject to quarterly and annual reviews with inputs and review from the CMC and the OTTR.

1. Initial Program Plan: The Consortium will follow the initial program plan that is contained in the Statement of Work (Attachment 1), and the Schedule of Payments and Payable Milestones Exit Criteria (Attachment 3).

2. Overall Program Plan Annual Review

(a) The CMC, with The OTTR participation and review, will prepare an overall Annual Program Plan in the first quarter of each Agreement year. (For this purpose, each consecutive twelve (12) month period from (and including) the month of execution of this Agreement during which this Agreement shall remain in effect shall be considered an "Agreement Year.") The Annual Program Plan will be presented and reviewed at an annual site review concurrent with the appropriate quarterly meeting of the CMC which will be attended by the Consortium Members, the OTTR, Senior HHS ASPR management or other HHS program managers and personnel as appropriate. The CMC, with HHS participation and review, will prepare a final Annual Program Plan.

(b) The Annual Program Plan provides a detailed schedule of research activities commits the Consortium to meet specific performance objectives and describes the Payable Milestones. The Annual Program Plan will consolidate all prior adjustments in the research schedule, including revisions/modifications to prospective payable milestones. Recommendations for changes and technical revisions or modifications to the Agreement which result from the Annual Review shall be made in accordance with the provisions of Article III, Section E.

## **E. Modifications**

1. As a result of quarterly meetings, annual reviews, or at any time during the term of the Agreement, research progress or results may indicate that a change in the Statement of Work and/or the Payable Milestones would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the Statement of Work and/or the Payable Milestones, will be documented in a letter and submitted by CONSORTIUM to the OTTR with a copy to the HHS OTA. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the research program. CONSORTIUM shall approve any Agreement modification. The Government is not obligated to pay for additional or revised Payable Milestones until the Payable Milestones Schedule (Attachment 3) is formally revised by the OTA and made part of this Agreement.

2. The OTTR shall be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement Statement of Work, Schedule of Payments or Payable Milestones, or other proposed changes to the terms and conditions of this Agreement.

3. For minor or administrative Agreement modifications (e.g. changes in the paying office or appropriation data, changes to Government or CONSORTIUM personnel identified in the Agreement, etc.) no signature is required by CONSORTIUM.

#### **ARTICLE IV: AGREEMENT ADMINISTRATION**

Unless otherwise provided in this Agreement, approvals permitted or required to be made by HHS may be made only by the HHS OTA. Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

A. Government Points of Contact:

OTA

(NAME)

(TITLE)

(PHONE NUMBER)

(EMAIL)

HHS Program Manager:

(NAME)

(TITLE)

(PHONE NUMBER)

(EMAIL)

OTA's Representative (OTAOR):

(NAME)

(TITLE)

(PHONE NUMBER)

(EMAIL)

Administrative OTA (AOTA):

(NAME)

(ADDRESS)

(TITLE)

(PHONE NUMBER)

(EMAIL)

B. Consortium Points of Contact

CONSORTIUM Administrative/Contracting:

(NAME)

(TITLE)

(PHONE NUMBER)

(EMAIL)

CONSORTIUM Program Manager:

(NAME)

(TITLE)

(PHONE NUMBER)

(EMAIL)

## ARTICLE V: OBLIGATION AND PAYMENT

### A. Obligation

1. The Government's liability to make payments to CONSORTIUM is limited to only those funds obligated under the Agreement or by modification to the Agreement. HHS may obligate funds to the Agreement incrementally.

2. If modification becomes necessary in performance of this Agreement, pursuant to Article III, paragraph B, the HHS OTAO and CONSORTIUM Administrator shall execute a revised Schedule of Payable Milestones consistent with the then current Program Plan.

### B. Payments

1. CONSORTIUM has an established and agrees to maintain an established accounting system which complies with Generally Accepted Accounting Principles and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds. An acceptable accounting system is one in which all cash receipts and disbursements are controlled and documented properly.

#### Samples

2. Payments Type: Accumulation of Company expenses. If the company is a traditional government consortium with established and approved accounting system, the same requirements that apply to their cost reimbursement type contracts apply to this agreement. *Include treatment of IR&D expenses.*

or

2. Payments Type: Accumulation of Company expenses. If the company is a non-traditional government consortium and does not have an established and approved accounting system, the parties have determined that following hourly rate, which includes all direct and indirect costs, but not fee or profit, will be used to determine costs accumulation: \$XXX.XX.

The government has the right to examine the time records to verify that part any expenses incurred.

Or

2. Limited cost principles or limits on percentages of mark-up over costs of goods sold.

3. CONSORTIUM shall document the accomplishments of each Payable Milestone by submitting or otherwise providing the Payable Milestones Report required by Attachment 2, Part D. CONSORTIUM shall submit an original and one (1) copy of all invoices to the OTAO for payment approval. After written verification of the accomplishment of the Payable Milestone by the OTTR, and approval by the OTAO, the invoices will be forwarded to the payment office within fifteen (15) calendar days of receipt of the invoices at HHS. Payment approval for the final Payable Milestone will be made after reconciliation of HHS funding with actual CONSORTIUM contributions. Payments will be made XXXXXXX within fifteen (15) calendar days of HHS's transmittal. Subject to change only through written Agreement modification, payment shall be made to the address of the CONSORTIUM Administrator set forth below.

Address of Payee: *(INSERT NAME AND ADDRESS OF PAYEE)*

4. Government funds shall be maintained in an interest-bearing account prior to disbursement. This account shall not be in U. S. Treasury Notes. Any interest earned shall be remitted annually to the HHS OTAO, or designee. Interest payments shall be made payable to the U. S. Treasury. Interest amounts less than \$250 per year may be retained by CONSORTIUM for administrative expenses.

5. Payments shall be made in the amounts set forth in Attachment No. 3, provided the OTTR has verified the accomplishment of the Payable Milestones. It is recognized that the quarterly accounting of current expenditures reported in the "Quarterly Business Status Report" submitted in accordance with Attachment No. 2 is not necessarily intended or required to match the Payable Milestones until submission of the Final Report; however, payable milestones may be revised during the course of the program to reflect current and revised projected expenditures.

6. Financial Records and Reports: CONSORTIUM shall maintain adequate records to account for all funding under this Agreement and shall maintain adequate records to account for CONSORTIUM funding provided under this Agreement. Upon completion or termination of this Agreement, whichever occurs earlier, the CONSORTIUM Administrator shall furnish to the OTAO a copy of the Final Report required by Attachment 2, Part E. CONSORTIUM's relevant financial records are subject to examination or audit on behalf of HHS by the Government for a period not to exceed three (3)

years after expiration of the term of this Agreement. The OTAO or designee shall have direct access to sufficient records and information of CONSORTIUM, to ensure full accountability for all funding under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party.

**If the amount of the OT is expected to exceed \$5M, include the following:**

**7. Comptroller General Access to Records**

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

**ARTICLE VI: DISPUTES**

**A. General**

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

**B. Dispute Resolution Procedures**

1. Any disagreement, claim or dispute between HHS and CONSORTIUM concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under subparagraph B.3 of this article constitute the basis for relief under this article unless the Director of HHS in the interests of justice waives this requirement.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the OTA0 or CONSORTIUM's Administrator, as the case may be) in writing of the relevant facts, identify unresolved issues, and specify the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the HHS Senior Procurement Executive, and senior executive (no lower than *(INSERT EXECUTIVE)* level) appointed by CONSORTIUM. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The HHS Senior Procurement Executive and the senior executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, upon written request to the HHS, made within thirty (30) calendar days of the expiration of the time for a decision under subparagraph B.3 above, the dispute shall be further reviewed. The Assistant Secretary for Preparedness and Response (ASPR) HHS may elect to conduct this review personally or through a designee or jointly with a senior executive (no lower than *(INSERT EXECUTIVE)* level) appointed by CONSORTIUM. Following the review, the Secretary of HHS or designee will resolve the issue(s) and notify the Parties in writing. Such resolution is not subject to further administrative review and, to the extent permitted by law, shall be final and binding.

### **C. Limitation of Damages**

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of HHS funding disbursed as of the time the dispute arises. In no event shall HHS be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, or other indirect damages.

## **ARTICLE VII: PATENT RIGHTS.**

***(NOTE: This article and Article VIII are fluid and negotiable. The government will consider present and future government and industry needs in exercising good business judgment in negotiating IP.)***

### **A. Allocation of Principal Rights**

Unless CONSORTIUM shall have notified HHS (in accordance with subparagraph C.2 below) that CONSORTIUM does not intend to retain title, CONSORTIUM shall retain the entire right, title, and interest throughout the world to each subject invention consistent with the provisions of this Article and

35 U.S. § 202. With respect to any subject invention in which CONSORTIUM retains title, HHS shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the subject invention throughout the world.

**B. Invention Disclosure, Election of Title, and Filing of Patent Application**

1. CONSORTIUM shall disclose each subject invention to HHS within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to HHS shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. CONSORTIUM shall also submit to HHS an annual listing of subject inventions.

2. If CONSORTIUM determines that it does not intend to retain title to any such invention, CONSORTIUM shall notify HHS, in writing, within eight (8) months of disclosure to HHS. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by HHS to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

3. CONSORTIUM shall file its initial patent application on a subject invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. CONSORTIUM may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

4. Requests for extension of the time for disclosure election, and filing under Article VII, paragraph C, may, at the discretion of HHS, and after considering the position of CONSORTIUM, be granted.

### **C. Conditions When the Government May Obtain Title**

Upon HHS's written request, CONSORTIUM shall convey title to any subject invention to HHS under any of the following conditions:

1. If CONSORTIUM fails to disclose or elects not to retain title to the subject invention within the times specified in paragraph C of this Article; provided, that HHS may only request title within sixty (60) calendar days after learning of the failure of CONSORTIUM to disclose or elect within the specified times.
2. In those countries in which CONSORTIUM fails to file patent applications within the times specified in paragraph C of this Article; provided, that if CONSORTIUM has filed a patent application in a country after the times specified in paragraph C of this Article, but prior to its receipt of the written request by HHS, CONSORTIUM shall continue to retain title in that country; or
3. In any country in which CONSORTIUM decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a subject invention.

### **D. Minimum Rights to CONSORTIUM and Protection of CONSORTIUM's Right to File**

1. CONSORTIUM shall retain a nonexclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title, except if CONSORTIUM fails to disclose the invention within the times specified in paragraph C of this Article. The CONSORTIUM license extends to the domestic (including Canada) subsidiaries and affiliates, if any, within the corporate structure of which CONSORTIUM is a party and includes the right to grant licenses of the same scope to the extent that CONSORTIUM was legally obligated to do so at the time the Agreement was awarded. The license is transferable only with the approval of HHS, except when transferred to the successor of that part of the business to which the invention pertains. HHS approval for license transfer shall not be unreasonably withheld.
2. The CONSORTIUM domestic license may be revoked or modified by HHS to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which CONSORTIUM has achieved practical application and continues to make the benefits of the invention reasonably accessible

to the public. The license in any foreign country may be revoked or modified at the discretion of HHS to the extent CONSORTIUM, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

3. Before revocation or modification of the license, HHS shall furnish CONSORTIUM a written notice of its intention to revoke or modify the license, and CONSORTIUM shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

#### **E. Action to Protect the Government's Interest**

1. CONSORTIUM agrees to execute or to have executed and promptly deliver to HHS all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which CONSORTIUM elects to retain title, and (ii) convey title to HHS when requested under paragraph D of this Article and to enable the Government to obtain patent protection throughout the world in that subject invention.

2. CONSORTIUM agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by CONSORTIUM each subject invention made under this Agreement in order that CONSORTIUM can comply with the disclosure provisions of paragraph C of this Article. CONSORTIUM shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U. S. or foreign statutory bars.

3. CONSORTIUM shall notify HHS of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

4. CONSORTIUM shall include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made with Government support under Agreement XXXXX-XX-3-XXXX, awarded by HHS. The Government has certain rights in the invention."

## **F. Lower Tier Agreements**

CONSORTIUM shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

## **G. Reporting on Utilization of Subject Inventions**

1. CONSORTIUM agrees to submit, during the term of the Agreement, an annual report on the utilization of a subject invention or on efforts at obtaining such utilization that is being made by CONSORTIUM or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by CONSORTIUM, and such other data and information as the agency may reasonably specify. CONSORTIUM also agrees to provide additional reports as may be requested by HHS in connection with any march-in proceedings undertaken by HHS in accordance with paragraph J of this Article. Consistent with 35 U.S.C. § 202(c) (5), HHS agrees it shall not disclose such information to persons outside the Government without permission of CONSORTIUM.
2. All required reporting shall be accomplished, to the extent possible, using the i-Edison reporting website: <https://s-edison.info.nih.gov/iEdison/>. To the extent any such reporting cannot be carried out by use of i-Edison, reports and communications shall be submitted to the OTA and Administrative OTA.

## **H. Preference for American Industry**

Notwithstanding any other provision of this clause, CONSORTIUM agrees that it shall not grant to any person the exclusive right to use or sell any subject invention in the United States or Canada unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by HHS upon a showing by CONSORTIUM that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

## **I. March-in Rights**

CONSORTIUM agrees that, with respect to any subject invention in which it has retained title, HHS has the right to require CONSORTIUM, an assignee, or exclusive licensee of a subject invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if CONSORTIUM, assignee, or exclusive licensee refuses such a request, HHS has the right to grant such a license itself if HHS determines that:

1. Such action is necessary because CONSORTIUM or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the subject invention;
2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by CONSORTIUM, assignee, or their licensees;
3. Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by CONSORTIUM, assignee, or licensees; or
4. Such action is necessary because the agreement required by paragraph (I) of this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such Agreement.

#### **ARTICLE VIII: DATA RIGHTS**

***(NOTE: This article and Article VII are fluid and negotiable. The government will consider present and future government and industry needs in exercising good business judgment in negotiating IP.)***

##### **A. Allocation of Principal Rights**

1. This Agreement shall be performed with mixed Government and CONSORTIUM funding. The Parties agree that in consideration for Government funding, CONSORTIUM intends to reduce to practical application items, components and processes developed under this Agreement.

2. CONSORTIUM agrees to retain and maintain in good condition until (INSERT NUMBER OF YEAR) ( ) years after completion or termination of this Agreement, all Data necessary to achieve practical application. In the event of exercise of the Government's March-in Rights as set forth under Article VII or subparagraph B.3 of this article, CONSORTIUM agrees, upon written request from the Government, to deliver at no additional cost to the Government, all Data necessary to achieve practical application within sixty (60) calendar days from the date of the written request. The Government shall retain Unlimited Rights, as defined in Article I above, to this delivered Data.

3. CONSORTIUM agrees that, with respect to Data necessary to achieve practical application, HHS has the right to require CONSORTIUM to deliver all such Data to HHS in accordance with its reasonable directions if HHS determines that:

(a) Such action is necessary because CONSORTIUM or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the technology developed during the performance of this Agreement;

(b) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by CONSORTIUM, assignee, or their licensees; or

(c) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by CONSORTIUM, assignee, or licensees.

4. With respect to Data delivered pursuant to Attachment 2 (**and listed below**), the Government shall receive Government Purpose Rights, as defined in paragraph A above. With respect to all Data delivered, in the event of the Government's exercise of its right under subparagraph A.3 of this article, the Government shall receive Unlimited Rights.

## **B. IDENTIFICATION AND DISPOSITION OF DATA**

The consortium shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this agreement for the time specified by the FDA and provide such data to OIAO. HHS reserves the right to review any other data determined by HHS to be relevant to this agreement.

## **C. Marking of Data**

Pursuant to paragraph B above, any Data delivered under this Agreement shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in Agreement XX-3-XXXX between the Government and CONSORTIUM.

**D. Lower Tier Agreements**

CONSORTIUM shall include this Article, suitably modified to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

**ARTICLE IX: FOREIGN ACCESS TO TECHNOLOGY (IF NECESSARY)**

This Article shall remain in effect during the term of the Agreement and for (INSERT NUMBER OF YEARS) ( ) years thereafter.

**A. General**

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national security, and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. The controls contemplated in this Article are in addition to, and are not intended to change or supersede, the provisions of the International Traffic in Arms Regulation (22 CFR pt. 121 et seq.), the DoD Industrial Security Regulation (DoD 5220.22-R) and the Department of Commerce Export Regulation (15 CFR pt. 770 et seq.)

**B. Restrictions on Sale or Transfer of Technology to Foreign Firms or Institutions**

1. In order to promote the national security and economic interests of the United States and to effectuate the policies that underlie the regulations cited above, the procedures stated in subparagraphs B.2, B.3, and B.4 below shall apply to any transfer of technology. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology.
2. Transfers do not include:
  - (a) sales of products or components, or

(b) licenses of software or documentation related to sales of products or components, or

(c) transfer to foreign subsidiaries of CONSORTIUM for purposes related to this Agreement, or

(d) transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the conduct of research under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

3. CONSORTIUM shall provide timely notice to HHS of any proposed transfers from CONSORTIUM of Technology developed under this Agreement to Foreign Firms or Institutions. If HHS determines that the transfer may have adverse consequences to the national security interests of the United States, CONSORTIUM, its vendors, and HHS shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to CONSORTIUM.

4. In any event, CONSORTIUM shall provide written notice to the OTAO's Representative and OTAO of any proposed transfer to a foreign firm or institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within thirty (30) calendar days of receipt of CONSORTIUM's written notification, the OTAO shall advise CONSORTIUM whether it consents to the proposed transfer. In cases where the OTAO does not concur or sixty (60) calendar days after receipt and HHS provides no decision, CONSORTIUM may utilize the procedures under Article VI, Disputes. However, **no transfer shall take place until a decision is rendered.**

5. In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by HHS takes place, CONSORTIUM shall (a) refund to HHS funds paid for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government, the CONSORTIUM shall provide written confirmation of such licenses.

### **C. Lower Tier Agreements**

CONSORTIUM shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work.

## **ARTICLE X: TITLE TO AND DISPOSITION OF PROPERTY (IF NECESSARY – SUBJECT TO NEGOTIATION)**

### **A. Title to Property**

Title to each item of property acquired under this Agreement with an acquisition value of \$50,000 or less shall vest in CONSORTIUM upon acquisition with no further obligation of the Parties unless otherwise determined by the OTAO. Should any item of property with an acquisition value greater than \$50,000 be required, CONSORTIUM shall obtain prior written approval of the OTAO. Title to this property shall also vest in CONSORTIUM upon acquisition. CONSORTIUM shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense.

### **B. Disposition of Property**

At the completion of the term of this Agreement, items of property with an acquisition value greater than \$50,000 shall be disposed of in the following manner:

1. Purchased by CONSORTIUM at an agreed-upon price, or the price that the parties agree represent fair market value property at the completion of the agreement, with the proceeds of the sale being returned to HHS in accordance with its cost share ratio; or
2. Transferred to a Government research facility with title and ownership being transferred to the Government; or
3. Donated to a mutually agreed University or technical learning center for research purposes; or
4. Any other HHS-approved disposition procedure.

## **ARTICLE XI: SUBCONTRACTING**

## **ARTICLE XII: CIVIL RIGHTS ACT**

This Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. CONSORTIUM has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

## **ARTICLE XIII: EXECUTION**

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of CONSORTIUM and the HHS OIAO. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

## **ARTICLE XIV: SPECIAL CLAUSES (as necessary)**

### **A. PROTECTION OF HUMAN SUBJECTS**

1. The Consortium agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Consortium's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Consortium further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Consortium shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Consortium retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Consortium or any sub consortium, agent or employee of the Consortium, or any other person, organization, institution, or group of any kind whatsoever, as the agent or

employee of the Government. The Consortium agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent consortium without imputing liability on the part of the Government for the acts of the Consortium or its employees.

**3.** If at any time during the performance of this contract, the HHS OTAO's determines, in consultation with the OHRP, OPHS, ASH, that the Consortium is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this contract until the Consortium corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Consortium fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the HHS OTAO's may, in consultation with OHRP, OPHS, ASH, terminate this contract in a whole or in part, and the Consortium's name may be removed from the list of those consortiums with approved Health and Human Services Human Subject Assurances.

## **B. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)**

**1.** The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Consortium in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

**2.** The Consortium shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by sub consortiums identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Consortium.

**3.** Provision by the Consortium to the HHS OTAO's of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

Investigational Research Board Number \_\_\_\_\_ (FILL IN)

**C. RESEARCH INVOLVING HUMAN FETAL TISSUE**

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing [regulations and guidance for conducting research on human fetal tissue](#) may be found at 45 CFR 46, Subpart B and <http://grants1.nih.gov/grants/guide/notice-files/not93-235.html> and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice. The Consortium shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Consortium.

**D. NEEDLE EXCHANGE**

The Consortium shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

**E. CARE OF LIVE VERTEBRATE ANIMALS**

**1.** Before undertaking performance of any contract involving animal related activities, the Consortium shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Consortium shall furnish evidence of the registration to the Contracting Officer.

**2.** The Consortium shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.

**3.** The Consortium agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture ( see 7 U.S.C. 2131 et seq . and 9

CFR Subchapter A, Parts 1 - 4). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this contract, the HHS OTAO's determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Consortium is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this contract until the Consortium corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Consortium fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the HHS OTAO's may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Consortium's name may be removed from the list of those consortiums with approved PHS Animal Welfare Assurances.

Note: The Consortium may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

Office of Laboratory Animal Welfare Number \_\_\_\_\_ (FILL IN)

#### **F. ANIMAL WELFARE**

All research involving live, vertebrate animals shall be conducted in accordance with the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#). This policy may be accessed at:

<http://grants1.nih.gov/grants/olaw/references/phspol.htm>

#### **G. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES**

All Consortium personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "[Protection of NIH Personnel Who Work with Nonhuman Primates](#)," located at the following URL: <http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/>

## **I. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS**

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the [Animal Welfare Act \(7 U.S.C. 2131 et. seq.\)](#), <http://www.nal.usda.gov/awic/legislat/awa.htm>.

The Public Health Service (PHS) Policy is administered by the [Office of Laboratory Animal Welfare \(OLAW\)](#) <http://grants2.nih.gov/grants/olaw/olaw.htm>. An essential requirement of the [PHS Policy](#) <http://grants2.nih.gov/grants/olaw/references/phspol.htm> is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the [Guide for the Care and Use of Laboratory Animals](#) <http://www.nap.edu/readingroom/books/labrats/> and that they comply with the regulations ([9 CFR, Subchapter A](#)) <http://www.nal.usda.gov/awic/legislat/usdaleg1.htm> issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The [Association for Assessment and Accreditation of Laboratory Animal Care International](#) (AAALAC) <http://www.aaalac.org> is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the Accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the [Federated of Animal Science Societies](#) <http://www.fass.org>.

## **J. APPROVAL OF REQUIRED ASSURANCE BY LAW**

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the consortium for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the consortium under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within

30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the consortium or individual performance sites pending OLAW approval of their respective assurance of compliance with [7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28](#). Additional information regarding OLAW may be obtained via the Internet at <http://grants2.nih.gov/grants/olaw/references/phspol.htm>

**K. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS**

Work involving select biological agents or toxins shall not be conducted under this agreement until the consortium and any affected sub consortium(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in [42 CFR 73](#) (<http://www.cdc.gov/od/sap/docs/42cfr73.pdf>) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The consortium must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the consortium shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the consortium must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the [Select Agent Program](http://www.cdc.gov/od/sap/) Web site at <http://www.cdc.gov/od/sap/>.

#### **L. PRODUCT LICENSURE**

The vaccines purchased, stored and distributed under this agreement shall be manufactured under a current establishment and product licensure issued by the Food and Drug Administration. Offeror shall indicate number below:

Name of Vaccine:

License Number:

The Consortium agrees to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents.

The Consortium agrees to advise the HHS OTAOR and OTAOR immediately of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility. Consortium also agrees to advise the HHS OTAOR's and Contracting Officer's Representative immediately if at any time during the life of the contract, the items under this contract fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483)

#### **M. FINAL DISTRIBUTION**

Prior to expiration or termination of this agreement, the Government may affect final distribution of any vaccines remaining in storage by any one or combination of the following methods:

1. The government may elect to require shipment of the vaccine to US Government facilities or to state and local health agencies and/or other providers.
2. The Government may direct the Consortium to destroy all quantities remaining in storage at a charge to be negotiated between the parties. Such charges shall not exceed the actual

costs incurred by the Consortium, and agreed to by the Government in advance of the destruction and/or disposal.

3. The Consortium cannot reclaim title to product upon acceptance.

#### **N. MANUFACTURING STANDARDS**

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of this contract, the Offeror fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Offeror shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Offeror fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

#### **O. LIABILITY PROTECTION UNDER THE PREP ACT**

The Public Readiness & Emergency Preparedness Act (PREP Act), Pub. L. 109-148, Division C, 119 Stat. 2818 to 2832, amended the Public Health Service Act, 42, U.S.C. 243 et seq., to provide targeted liability protections. The Government agrees that the medical countermeasure manufactured by the consortium under this contract will not be administered in humans, unless the Secretary executes a declaration in accordance with section 319F-3(b) of the Public Health Service Act, 42, U.S.C. 247-d-6d, that the medical countermeasure delivered under this contract is a covered countermeasure to which section 319-F3(a) applies subject to the terms and conditions of the declaration.

**ATTACHMENT 1:**

**TASK DESCRIPTION DOCUMENT (SOW or SOO)**

Task 1:

## **ATTACHMENT 2:**

### **REPORT REQUIREMENTS**

#### **A. QUARTERLY REPORT**

On or before ninety (90) calendar days after the effective date of the Agreement and quarterly thereafter throughout the term of the Agreement, CONSORTIUM shall submit or otherwise provide a quarterly report. Two (2) copies shall be submitted or otherwise provided to the HHS Program Manager (or OTTR), one (1) copy shall be submitted or otherwise provided to the HHS OTAO. The report will have two (2) major sections.

**1. Technical Status Report.** The technical status report will detail technical progress to date and report on all problems, technical issues, major developments, and the status of external collaborations during the reporting period.

**2. Business Status Report.** The business status report shall provide summarized details of the resource status of this Agreement, including the status of CONSORTIUM contributions. This report will include a quarterly accounting of current expenditures as outlined in the Annual Program Plan. Any major deviations, over plus or minus 10%, shall be explained along with discussions of the adjustment actions proposed. The report will also include an accounting of any interest earned on Government funds. CONSORTIUM is reminded that interest in amounts greater than \$250 per year is not expected to accrue under this Agreement. In the event that this interest does accrue on Government funds, CONSORTIUM is required to provide an explanation for the accrual in the business report. Depending on the circumstances, the Payable Milestones may require adjustment.

#### **B. ANNUAL PROGRAM PLAN DOCUMENT, as necessary**

CONSORTIUM shall submit or otherwise provide to the OTTR and OTAO one (1) copy each of a report which describes the Annual Program Plan as described in Article III, Section B. This document shall be submitted not later than thirty (30) calendar days following the Annual Site Review as described in Article III, Section B.

#### **C. SPECIAL TECHNICAL REPORTS**

As agreed to by CONSORTIUM and the OTTR, CONSORTIUM shall submit or otherwise provide to the OTTR and OTAO one (1) copy each of special reports on significant events such as significant target accomplishments by CONSORTIUM, significant tests, experiments, or symposia.

#### **D. PAYABLE MILESTONES REPORTS**

CONSORTIUM shall submit or otherwise provide to the OTTR and OTAO documentation describing the extent of accomplishment of Payable Milestones. This information shall be as required by Article V, paragraph B and shall be sufficient for the OTTR to reasonably verify the accomplishment of the milestone of the event in accordance with the Statement of Work.

**E. FINAL REPORT (NOTE: The Final Report is included in the last Payable Milestone for the completed Agreement)**

1. CONSORTIUM shall submit or otherwise provide a Final Report making full disclosure of all major developments by CONSORTIUM upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement. With the approval of the OTTR, reprints of published articles may be attached to the Final Report. Two (2) copies shall be submitted or otherwise provided to the OTTR; one (1) copy shall be submitted or otherwise provided to the OTAO. One (1) copy shall be submitted to the National Technical Information Center, Attn: DTIC-BCS, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-0944. Does AMCG do this?

2. The Final Report shall be marked with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations. The Final Report shall be marked on the front page in a conspicuous place with the following marking:

“DISTRIBUTION STATEMENT B. Distribution authorized to U.S. Government agencies only to protect information not owned by the U.S. Government and protected by a consortium’s “limited rights” statement, or received with the understanding that it not be routinely transmitted outside the U.S. Government. Other requests for this document shall be referred to HHS/OTAO.”

**F. EXECUTIVE SUMMARY**

CONSORTIUM shall submit a one to two page executive-level summary of the major accomplishments of the Agreement and the benefits of using the “other transactions” authority pursuant to 10 U.S.C. § 2371 and Sections 319L(c)(4)(B) and/or 319L(c)(4)(D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417 upon completion of the Agreement. This summary shall include a discussion of the actual or planned benefits of the technologies for both the military and commercial sectors. Two (2) copies shall be submitted to the HHS OTAO.



## ATTACHMENT 4: FUNDING SCHEDULE

**A. PROJECTED PROGRAM FUNDING COMMITMENTS**

	<u>HHS Funding</u>	<u>CONSORTIUM Contribution</u>
FY XX	\$	\$
FY XX	\$	\$
FY XX	\$	\$
<b>TOTALS</b>	<b>\$ _____</b>	<b>\$ _____</b>

HHS funding shall be applied toward the following expenses: **(list types of expenses)**. (NOTE: For example, for traditional Government consortiums, fully burdened labor “exclusive of cost of money and fee”. Cost of money and fee are not recognized in a cost sharing situation or when investing in the development of technologies. Also, an agreement between the Parties will be required when allowing unusual expenses.)

**B. CONSORTIUM CONTRIBUTION**

<u>Total Contribution</u>	<u>Cash*</u>	<u>In-kind**</u>
\$	\$	\$

\*Cash contributions consist of ... **(list types of contributions)**. (NOTE: If Government Internal Research and Development (IR&D) expenses are included as contributions, then a side agreement or other documentation is required regarding the treatment of these expenses, i.e. whether Government funds are credited to an IR&D cost pool.)

\*\*In-kind contributions consist of ... **(list types of contributions but also include the basis for determining the in-kind value)**.