OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

Agreement No.: HHSO100201800012C

BETWEEN

JANSSEN RESEARCH & DEVELOPMENT, LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

RESEARCH AND DEVELOPMENT OF (b) (4) (b) (4)

Modification No. 0001

Effective Date of Amendment: Upon Last Signature in Section III

Total Amount of the Agreement: is (b) (4) (b) (4)

Government Funding of the Agreement: is (b) (4) (b) (4)

Total Estimated Recipient Funding of the Agreement: is (b) (4)

Funds Obligated: is (b) (4)

Period of Performance of CLIN 0027: Effective Date of the Amendment through 31 January 2020.

Authority: Section 319L(c)(5) of the Public Health Service Act, 42 USC 247d-7e(c)(5).

Line of Accounting and Appropriation:

CLIN	(b) (4)
0001	

0027	(b) (4) [redacted]
Total	

I. **AMENDMENT PURPOSE:** The purpose of this modification is to accomplish the following:

a. Revise and replace the Agreement (HHSO100201800012C) in its entirety replacing it with the attached.

b. Changes to the Agreement are focused on clarifying Agreement scope and corresponding definitions to incorporate an (b) (4) [redacted]

II. **AMENDMENT CHANGES**

a. Add CLIN 0027 (b) (4) [redacted] including specific deliverables to CLIN 0027 activities. This addition of CLIN 0027 also corresponds to the (b) (4) [redacted] Government funding as noted on the previous page.

b. Change the Other Transaction Agreement Officer (OTAO) to Joffrey Q. Benford from Francine L. Hemphill.

c. (b) (4) [redacted]

III. **SIGNATURES**

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

(b) (4), (b) (6) [redacted]

DATE: 3 APRIL 2019

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE
BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY

(b) (6) [redacted]

ITS: OTAO

DATE: 4 APRIL 2019

Table of Contents

ARTICLE I: SCOPE OF THE AGREEMENT 2

ARTICLE II: TERM 8

ARTICLE III: AMENDMENTS 10

ARTICLE IV: MANAGEMENT OF THE PROGRAM 11

ARTICLE V: AGREEMENT ADMINISTRATION 15

ARTICLE VI: COST SHARING 16

ARTICLE VII: OBLIGATION AND PAYMENT 20

ARTICLE VIII: DISPUTES 23

ARTICLE IX: PATENT RIGHTS 24

ARTICLE X: DATA RIGHTS 30

ARTICLE XI: FOREIGN ACCESS TO TECHNOLOGY 31

ARTICLE XII: TITLE TO AND DISPOSITION OF PROPERTY 32

ARTICLE XIII: SUB-RECIPIENT 33

ARTICLE XIV: CIVIL RIGHTS ACT 33

ARTICLE XV: EXECUTION 34

ARTICLE XVI: SPECIAL CLAUSES 34

ARTICLE XVII: TRANSFERS & ASSIGNMENTS 43

ARTICLE XVIII: CONFIDENTIALITY 43

ATTACHMENT 1: STATEMENT OF WORK (SOW) 45

ATTACHMENT 2: REPORT REQUIREMENTS 73

ATTACHMENT 3: (b) (4) DIAGRAMS 79

ATTACHMENT 4: J&J GLOBAL TRAVEL, MEETINGS AND EXPENSE POLICY 81

ATTACHMENT 5: J&J TRAVEL, MEETINGS & EXPENSE POLICY – UNITED STATES (b) (4) ... 121

ATTACHMENT 6: (b) (4) 127

ARTICLE I: SCOPE OF THE AGREEMENT

A. Background

Chemical, Biological Radiological and Nuclear (CBRN) threats remain important public health concerns. BARDA's mission is to develop and procure needed medical countermeasures against a broad array of public health threats, whether natural or intentional in origin. The CBRN program within BARDA spans a number of threats and focus areas such as Anthrax, Smallpox, Botulinum Toxin, Ebola, Broad Spectrum Antimicrobials, Chemical Medical Countermeasures, Thermal Burn Medical Countermeasures and Radiological and Nuclear Countermeasures. Within the CBRN division, the Radiation and Nuclear group focus' on developing medical countermeasures to address nuclear detonation that result in radiation-induced illness, thermal and radiation burns, and trauma. (b) (4)

(b) (4)

The current portfolio envisioned Under this Agreement includes those assets described in Attachment 1: Statement of Work ("SOW"). The potential programs/platforms that may be developed under this OTA (b) (4) that have the potential to address areas of high unmet medical need for biodefense. (b) (4)

(b) (4)

Collaboration between BARDA and the Consortium Members Under this Agreement will provide the parties the flexibility to implement innovative solutions and execute a portfolio approach to funding promising assets in the complex and uncertain environment of drug and medical device development. To maximize the potential to achieve the objectives of this Agreement, other medical countermeasure candidates

that Consortium Members develop or in-license during the term of the Agreement may be considered by the Joint Oversight Committee (JOC) for inclusion in the portfolio.

For the (b) (4) assets listed in Attachment 1: Statement of Work, no definitive commitment has yet been made by either party to fund their development. The Consortium Members and BARDA will explore the inclusion of potential assets and projects beyond (b) (4)

B. Definitions

Affiliate: Any entity that controls, is controlled by, or is under common control with, a party to this Agreement. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise.

Agreement: The body of this Agreement and all attachments and modifications thereto, including Attachments 1 – 6 are expressly incorporated in and made a part of the Agreement.

Asset: Project or projects related to a drug, device or other technology or solution-based program, which if successfully developed or implemented, has the potential to be utilized as a medical countermeasure against CBRN threats or increase access to medical countermeasure technologies.

Biobanking: A biobank is a type of repository that stores biological samples for use in research.

Business Day: A day that is not: a Saturday or Sunday; a Federal holiday in the United States; a
bank holiday or national public holiday in the Netherlands or in any country where a Consortium Member is located.

Confidential Information: Non-public information, including but not limited to business, strategic, or management information, or data of a personal nature about an individual, or proprietary technical information, manufacturing information, trade secrets financial, administrative, cost, or pricing information, submitted to the Government by or on behalf of Recipient or by the Government to the Recipient in connection with, or during performance of the Agreement, whether or not either Party required or requested that such information be submitted. "Confidential Information" does not include "Data" as defined below.

Consortium: That group of Consortium Members that are: (i) Affiliates of one another; and (ii) have agreed with one another to collaborate to perform the objectives and obligations set forth in this Agreement.

Consortium Member: (b) (4)
(b) (4)

Data: Recorded information first created in performance of the Program, regardless of form or method of recording, which includes but is not limited to, technical data and software, but does not include Subject Inventions, trade secrets, data of a personal nature about an individual, or financial, administrative, cost, pricing, or management information.

Effective Date: The date of execution of this Agreement by the Parties. If this Agreement is executed in counterparts, the Effective Date shall be the date of the last signature.

Field: Means the development and use as medical countermeasure to address CBRN threats as well as emerging infectious diseases and bacterial infections.

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

Government: The United States of America, as represented by HHS/BARDA. For purposes of this Agreement, the Government and HHS and BARDA may be used interchangeably.

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

Know-How: Information, practical knowledge, techniques, and skill development.

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for its research purposes in the Field.

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

Other Transaction Agreement Specialist (OTAS): Is a supporting official that executes agreement modifications on behalf of the Other Transaction Agreement Officer

Other Transaction Agreement Technical Representative (OTTR): Is the primary government official for all technical matters on the Agreement

Party: Either Recipient or Government, and "Parties" means both Recipient and Government.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of product or a medical device; to use in manufacturing, in the case of an invention useful in manufacturing; 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 so as to establish that the Subject Invention is capable of being utilized.

PMO Steering Committee: The Project Management Organization Steering Committee consists of individuals appointed by the Recipient for the dual responsibilities of day-to-day management and execution of the overall Program and providing technical and administrative infrastructure to ensure all executory functions in the accomplishment of the current Statement of Work.

Project: Work activities within the overall Program, focused on specific assets or support of those assets and/or the overall Program.

Program: Research, development and other activities related to the promotion and support of medical countermeasure innovation conducted by or on behalf of the Consortium Under this Agreement, as set forth in Article I., Section C (Scope).

Program Plan: A written document to be delivered to the Government by the Recipient on behalf of the Recipient and all members of the Consortium that outlines the impacts of risks in relation to the cost, schedule and performance objectives of the Agreement with respect to the specific Assets under development at time of plan submission. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance. For purposes of this plan, a risk will be defined as a significant deviation from the anticipated schedule and associated costs outlined in the first Program Plan submitted to the Government with respect to Assets under development obtaining regulatory licensure within the United States.

Property: Any tangible personal property, other than property consumed or generated during the execution of work in performance of the Program.

Recipient: JRD acting on its own behalf and on behalf of the Consortium and each Consortium Member.

Sub-recipient: All entities (supplier, distributor, vendor, consultant or firm) from which goods or services are procured by Recipient or its Affiliates, acting on its behalf or the Consortium, or a Consortium Member, to execute technical or operational requirements of this Agreement. These terms do not include agreements with the Recipient or Consortium Members of a type that are not customarily treated as subcontracts under a Government agreement. The Recipient, its Affiliates and Consortium Members are not considered to be Sub-recipients.

Subject Invention: Any Invention that (i) has utility in the Field; and (ii) where the conception of such Invention and either (a) the first actual reduction to practice or (b) constructive reduction to practice of such Invention occurs in performance of the Program.

Subject Invention (SI) Intellectual Property Rights: Patent rights controlled by Recipient covering a Subject Invention and necessary for such use in the Field.

Technology: Discoveries, innovations and Know-How, 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 first created in the Program and that have not been disclosed to the public, but does not include any Subject Invention.

Total Aggregate Resource Contribution: The amount of cash plus non-cash/in-kind contributions by both Recipient and Government during the course of the period of performance of this Agreement.

Under this Agreement: Means activities conducted pursuant to this Agreement that are BARDA funded or Binding Cost Share by Recipient.

USD: Abbreviation for the United States Dollar, the official currency of the United States of America and its overseas territories.

C. Scope

1. The Consortium Members shall perform an advanced research and development program related to the development of medical countermeasures to address CBRN threats as well as emerging infectious diseases and bacterial infections. Specifically, this Agreement includes those assets described in Attachment 1: Statement of Work ("SOW"). The research related to those assets shall be carried out in accordance with the SOW,

which is incorporated in this Agreement as Attachment 1 and may be modified with the approved recommendation of the JOC and an executed modification by the OTAO.
Consortium Members shall submit or otherwise provide all documentation required by Attachment 2, Report Requirements. The portfolio may also be augmented by the addition of (b) (4) [redacted]

2. Unless otherwise provided for under this Agreement or any amendment hereto, Recipient shall be paid for work performed Under this Agreement upon submission of invoices on a quarterly basis. The agreement payments will be based upon accumulation of expenses incurred by the Consortium Members, or other manner as may be specified from-time-to-time to reflect funding of different Assets.

3. The Government and Recipient anticipate that, unless otherwise stipulated, the work described in the SOW of this Agreement can only be accomplished with an estimated Consortium aggregate resource contribution of (b) (4) [redacted] which represents a (b [redacted]% cost share of the total estimated project costs (CLINs 0001 – 0026) from the effective date of this Agreement through seventy-five (75) months thereafter. By entering into this Agreement, Recipient intends and shall undertake to cause these funds to be provided to the Consortium Members for the purpose of performing the obligations described in this Agreement. At all times during this agreement, the Recipient aggregate resource contribution shall be no less than (b [redacted]% of the total estimated project costs. This amount may be increased by mutual agreement between The Government and Recipient depending on the outcome of accomplishments and milestones resulting from the operation of this agreement by decision of the JOC and modification to the agreement executed by the OTAO. The
Parties also agree that certain CLINS may be exempted from the cost-share requirement, and such decision would be reflected in the budget of such CLIN and/or any statement of work related thereto. If either HHS or The Recipient 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 certain rights to Data and Subject Inventions as stated in this Agreement. The Government acknowledges that Recipient engages in other research and development activities, alone or with third parties, that are directed to products and materials that have similar or the same product characteristics, may perform essentially the same function

and/or could be utilized in combination with one or more Subject Inventions and that such activities and any intellectual property rights resulting therefrom that were not funded pursuant to the terms of this Agreement are not subject to the terms and conditions of this Agreement.

5. This Agreement is an "other transaction" pursuant to Section 319L(c)(5) of the Public Health Service Act, 42 USC 247d-7e(c)(5). The Parties agree that the principal purpose of this Agreement is to support commercially reasonable efforts in achieving the goals of the Program, and not solely 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 Agreement commences on the date of the last signature hereto and continues for a 21 month period (the "Base Period", also referred to as CLIN 0001) with options to extend the term of the Agreement (each an "Option") for a further four years and six months until 31 December 2024. The Government will provide the Recipient a preliminary written notice of its desire to exercise each Option at least ninety (90) days before the expiration of (i) one year following the commencement of the Agreement (for the first Option) and (ii) each Option term thereafter, as applicable. The preliminary notice does not commit the Government to an extension; however, if the Government issues a preliminary notice to Recipient and subsequently elects not to proceed to exercise the Option, the Government shall notify Recipient of this decision not less than thirty (30) days prior to expiration of the term. The Recipient may decline any Option but allow the preexisting Base Period activities or previously executed Options for other Assets to continue. The Parties may agree mutually to extend the term of this Agreement and its Options by modifying the agreement on or before the expiration of the base period or exercised Options.

B. Termination Provisions

Either Party may terminate this Agreement by providing ninety (90) days written notice to the other Party, provided that such written notice is preceded by consultation between the Parties at the level of the JOC. 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 X, Data Rights. The Government and the Recipient will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties resulting from termination, including disposition of animals acquired for research use. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VIII, Disputes. The Government has no obligation to pay the Recipient for activities performed after the date of agreement termination with the exception of any non-cancellable obligations which may have been entered into in the course of performing the approved scope of work. For purposes of this clause, termination expenses shall be those expenses identified in Federal Acquisition Regulation 31.205-42 but do not include re-procurement costs.

C. Extending the Term

The Parties may extend by mutual written agreement the term of this Agreement if activities performed during the extension do not exceed funding obligated to the Agreement and research opportunities reasonably warrant an extension. Any extension shall be formalized through modification of the Agreement by the OTAO and the Consortium Project Management Lead (PML). If the Recipient desires an extension to the period of performance of this Agreement, the Recipient shall submit a request to extend the period of performance in writing to the OTAO. Any request for an extension should include the justification for an extension, a revised milestone/project schedule (if applicable), and an updated budget that illustrates how the remaining funds will cover the extended period of performance.

ARTICLE III: AMENDMENTS

A. Recommendations for Modifications

As a result of quarterly meetings, annual in-performance reviews, JOC meetings or at any time during the term of the Agreement, research progress or results may indicate that a change in the SOW would be beneficial to Program objectives. Any modification to the Agreement, excluding minor modifications discussed below, shall be by mutual written agreement of the Parties. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by the PML to the OTTR with a copy to the OTAO and OTAS. This letter will detail the technical, chronological, and financial impact (if any) of the proposed modification to the Program.

B. Minor Modifications

Notwithstanding the foregoing, minor non-material Agreement modifications that do not affect the obligations of Recipient or Consortium Members, the Government or the terms and conditions of this Agreement (e.g. changes in the paying office or appropriation data, Government or the Recipient's changes to personnel identified in the Agreement, etc.), may be made by either Party with one (1) working-day written notice to the other Party. Failure of the other Party to respond within ten (10) Business Days from submission of the request to either Party will be deemed concurrence that subject modification is minor non-material. If Parties do not reach agreement as to whether a modification is minor non-material, then the process identified Article III, Section C will apply.

C. Modifying the Agreement

The OTAO shall be responsible for agreeing to any modifications to this Agreement on behalf of the Government. The Principal Investigator (PI) and PML shall be responsible for agreeing to any modifications to this Agreement on behalf of the Consortium. No modification, however, is effective unless in writing and signed by the Parties. The OTAO and/or the OTAS are the only signatories that can execute modifications on behalf of the Government. All modifications to this agreement shall take precedence over all prior versions and will be dated.

ARTICLE IV: MANAGEMENT OF THE PROGRAM

A. Project Organization and Management Structure

1. Joint Oversight Committee: The joint oversight committee ("Joint Oversight Committee" or "JOC") is the higher-level decision-making body that provides guidance, direction and control to the Program Management Organization (PMO) Steering Committee (defined below) to ensure execution of the Program according to the SOW. The JOC shall have equal voting representation from both BARDA and the Recipient and shall discuss and jointly approve changes to the SOW. The responsibility of the JOC is to mutually interrogate risks and progress of assets covered under this Agreement, endorse potential new assets and agree on allocation of funding across activities covered Under the Agreement. Any addition or removal of assets or Consortium Members, agreed upon by the JOC for inclusion or removal Under this Agreement shall be added by modification to the Agreement by the OTAO.

The JOC will recommend the strategy to be covered Under this Agreement during the subsequent funding period, as well as how Government funding will be allocated across these activities. The recommendations will be submitted, as appropriate, to the relevant Consortium governance board(s) within the Consortium Members for endorsement and decision. Similar procedures will be implemented by the Government. If endorsed by the relevant Consortium governance boards and by OTTR, the recommendations will be incorporated into the SOW and this Agreement through modifications as described in ARTICLE Ill.

From time-to-time, the JOC may also formulate joint subcommittees to oversee specific Projects Under this Agreement. The establishment, organization, mission, oversight and make-up of any such joint subcommittee shall be included in any corresponding statement of work added to this Agreement in support of such Project and shall be approved by the JOC.

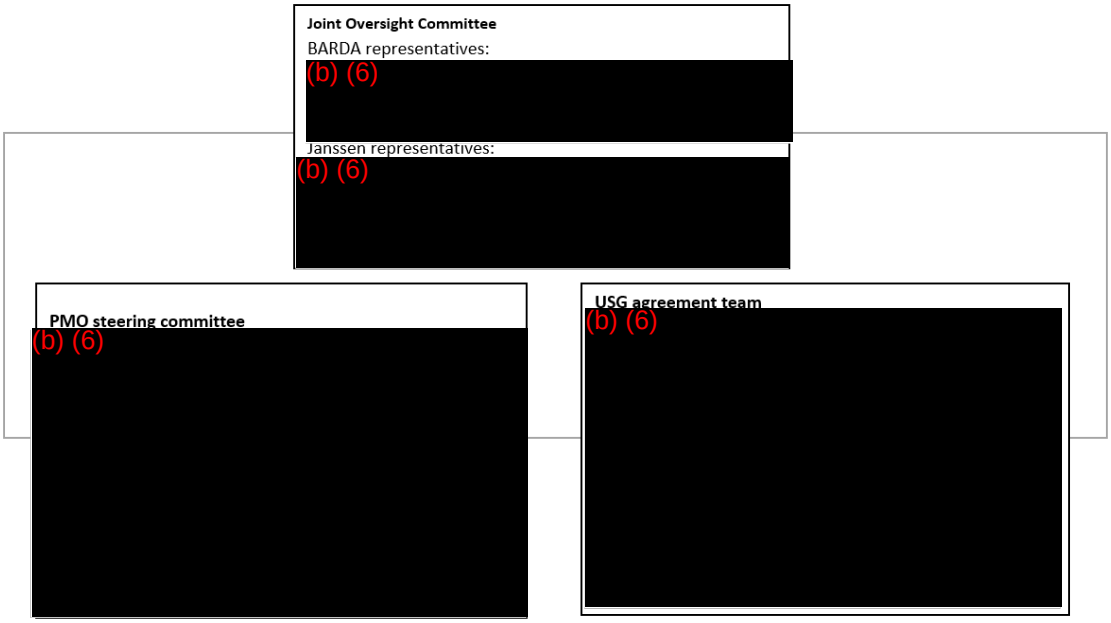
2. PMO Steering Committee: The project management organization steering committee (the "PMO Steering Committee" or "Project Management Organization Steering Committee") has dual responsibilities. First, it is responsible for communication and coordination with BARDA regarding day to day management and execution of the Program; *e.g*.

organizing meetings on a regular, agreed-upon basis. Second, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks, including the establishment of the Asset Project Management Teams (APMT). These SOW activities will be coordinated by the Project Manager Leader (PML). The PMO Steering Committee will assess progress and, where needed, will propose strategic technical changes to be decided upon by the JOC. The PMO Steering Committee consists of a group of dedicated and specialized project management experts, key personnel (shown below) and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area. The PMO Steering Committee will prepare for and participate in quarterly review meetings in conjunction with the BARDA Technical Team including the OTTR, as further described in Article IV, Section B of this Agreement.

3. Asset Project Management Leader. Each Asset will have an Asset Project Management Leader ("Asset PML") who will oversee their specific Project Management requirements. This includes conducting frequent and regular Asset Project Management Team (APMT) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The APMT of each Asset will also include a technical lead, finance representative and, depending on the Asset, also a preclinical leader, clinical leader, CMC leader, and regulatory project management leader. Additional expertise required for executing Asset-specific work possibly including sub-recipient may be added as part of the APMT.

[remainder of page intentionally left blank]

Organizational Chart



B. Project Committees and Meetings

1. Joint Oversight Committee (JOC). The JOC will meet at critical decision points in the program, but no less than two (2) times per year, preferably face to face or alternatively by Video and/or telephone conference. Ad hoc meetings will be organized when urgent matters arise or prior to the exercising of an Option. The JOC will consist of two (2) voting members each from the Consortium and BARDA and non-voting members from the Consortium and BARDA, or other additional Consortium or U.S. Government Members (non-voting) as may be required. Additional, non-voting members may be assigned or invited by Recipient on an adhoc basis. Decisions to reprioritize specific projects and resources within the scope of this Agreement will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Consortium senior management member identified at the start of the Project or identified through written notification to the other Party.

2. Kick-off and Quarterly PMO Steering Committee. A kick-off meeting of PMO Steering Committee will be held within forty-five (45) days of the Effective Date; the

Consortium will provide an updated Program Plan for the Base Period within sixty
(60) days of kick-off meeting. The Consortium, the OTAO and/or OTAS and BARDA
shall participate in meetings to coordinate the performance of the Agreement. These meetings may include face-to-face meetings in Washington, D.C. or at work sites of the Consortium Members. Such meetings may include, but are not limited to, meetings with the Consortium Members to discuss study designs, site visits to Consortium Member facilities, and meetings with the Consortium and HHS officials to discuss the technical, financial, regulatory and ethical aspects of the program. These meetings will also formulate and endorse the activities for the subsequent three (3) months. In order to facilitate review of Program activities, it is expected that the Consortium will provide Data, reports, and presentations to groups of outside experts (subject to appropriate agreements to protect confidential or proprietary data) and Government personnel as requested by the OTTR. The PML shall provide an itinerary and agenda at least five (5) Business Days in advance of a face-to-face meeting.

3. Integrated Program Review (IPR) Meetings. On an annual basis or by an eventdriven need, and with a minimum of sixty (60) days advanced notice, prior to the exercise of additional effort to the Agreement, the Government may invite the Consortium to give a presentation at an Integrated Program Review Meeting attended by BARDA and invited interagency representatives. The Consortium will present Data generated Under the Agreement over the past year as needed to assess progress against portfolio milestones. Successes and challenges of the program will be discussed and plans for the coming year will be presented.

4. Bi-Weekly Teleconferences. A conference call between the OTTR, OTAS and/or OTAO and the Consortium PI/PML shall occur every two (2) weeks or as required, if an urgent matter should arise. During this call, the PI/PML will discuss the activities during the reporting period, any problems that have arisen, and the key activities planned for the ensuing reporting period. The PI/PML may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the OTTR. On an as needed basis, the OTTR or PI/PML may assign this responsibility to a delegate.

5. **Cost Share Determination (CSD) Meeting:** Either by conference call or inperson, between the OTAO, and/or the OTAS, OTTR and the PI/PML will discuss and review cost share contributions of the Agreement. During this meeting, the PI/PML will discuss assets progression to date and provide an update on the commercial viability of portfolio assets. These meetings will be held on annual basis and may be scheduled on an ad-hoc basis after the receipt of study data, FDA feedback and/or future public health scenarios that will guide in the activation of future elements of the Agreement. The recipient will submit to the Government meeting minutes and a revised budget (if applicable) as result of discussions.

C. Document Review: Subject to other provisions specified in this Agreement (see for example Attachment 2), the PML/PI shall notify the OTTR and OTAO of formal and
informal correspondence with the Food and Drug Administration (FDA) or other regulatory agencies as specified in Attachment 2. The PI/PML shall provide the Government sufficient opportunity to review study protocols, reports, and FDA correspondence. The Government's comments on these documents will be viewed as advisory in nature. Specific timelines for document review and responses are outlined in Attachment 2 - Reporting Requirements.

ARTICLE V: AGREEMENT ADMINISTRATION

Administrative and contractual matters Under this Agreement shall be referred to the following representatives of the Parties:

Government Points of Contact:

Other Transaction Agreement Officer (OTAO):
(b) (6)
CBRN Advanced Research and Development
(b) (6)

Other Transaction Agreement Specialist (OTAS):
(b) (6)
OTAS, CBRN Advanced Research and Development
(b) (6)

Other Transaction Agreement Technical Representative (OTTR):

(b) (6)

Health Scientist, CBRN Division, BARDA

(b) (6)

Alternate OTTR:

(b) (6)

Chief, Radiological and Nuclear Countermeasures, CBRN Division, BARDA

(b) (6)

Recipient Points of Contact:

(b) (4), (b) (6)

ARTICLE VI: COST SHARING

A. Acknowledgement: The terms of this Article VI apply to the cost sharing principles as described below. The Parties acknowledge that the activities included Under this Agreement may change at any time due to alterations in development strategy, risk mitigation approaches, technical challenges, or any other circumstance. Any modification will be subject to these cost sharing principles unless otherwise agreed by the JOC. As such, any projection of shared costs or resources will be estimates and will be non-binding, with the exception of the Base Period costs discussed in Article VI, Section B and Article VI, Section C below.

B. Allowable Costs: The Recipient's binding cost share will consist of reimbursable expenses including direct labor dollars charged in the performance of activities covered under the SOW, the indirect dollars (fringe, overhead and G&A) applicable to the direct labor and material costs, and sub-recipient, consultant, and other costs. No fee or profit is allowable. These costs will reasonably relate to the activities conducted under the SOW. For those Consortium Members' with government-approved rates, budgets will be updated at least once a year to reflect changes to those indirect rates, which are updated annually and shall be set at government-approved provisional rates for the forthcoming year. Any rate changes that increase the total budget ceiling for a Project under the Agreement, or beyond what was previously agreed by the JOC and approved by the OTAO, shall require agreement by JOC and approval by the OTAO of the budget and project scope. Direct labor will be charged based on effort reports from Consortium personnel who will track their time in the Consortium Member's standard timekeeping system. These personnel allocate their effort to specific projects and activities, but the time can be recorded per standard practices of Consortium Members, and does not require manager review or approval. Once Government approved provisional billing rates are established for any given year, revised retrospective indirect rate reconciliation will not be required for that year.

Pricing for other sectors (Medical Device or Consumer) or Consortium Members without government-approved rates, shall be proposed and negotiated as these companies or Assets are added to the Agreement, after agreement by the OTAO. Certain Assets may be added to the Agreement using non-rate-based budget structures. Recipient agrees total cost of activities performed under this agreement will not exceed total obligated amount.

Charges made Under this Agreement may include:

1. Direct materials and supplies that are used in the performing of the work provided for under this Agreement, including those purchased for sub-recipients and purchase orders.

a. Travel Costs – Recipient will not seek reimbursement of travel costs for the Recipient and Johnson & Johnson (J&J) Consortium Members. The Recipient may seek reimbursement of travel costs for Subrecipients or Non-J&J Consortium Members in accordance with the applicable J&J Travel Policy. The current J&J Travel Policy will be provided to the OTAO on

an annual basis; any changes to the spending limits in the J&J travel policy will be provided to the OTAO for information purposes. Following OTAO review of the changes in spending limits, OTAO may reopen negotiations regarding the allowable reimbursement of travel costs under this Agreement.

2. Labor, including supervisory, that is properly chargeable directly to the Agreement, and inclusive of fringe benefits

3. Indirect Costs

Other items as agreed upon by the Parties may be included by modification to this Agreement.

C. Global Cost Share: The Global Cost represents the estimated total cost for activities under the SOW that support the development of the assets described in Attachment 1 during the term of the base and option periods of the Agreement. The Recipient Global Cost Share of (b % represents the Recipient's estimated contribution as a percentage of the Global Cost during the Base Period of the Agreement. Unless otherwise approved by the OTAO, at no time on an annual basis during this Agreement will the Recipient's Global Cost Share be below (b % of the total estimated cost of the Agreement. Upon mutual decision between The Government and the Recipient, the Recipient's Global Cost Share may increase due to accomplishments and/or milestones being performed Under this Agreement. The table as shown below represents the Recipient's total estimated cost share under the SOW for the Base Period and the proposed option periods of this Agreement. The cost share estimates would need to be re-established under any of these scenarios through a CSD meeting. A schedule outlining the cost share allocation of each CLIN exercised under this Agreement will be submitted to the OTAO/OTAS before exercise of those respective CLINs. This schedule and allocation will be reviewed by the OTAO/OTAS and accepted in writing in advance of any CLIN being exercised.

(b) (4)

D. Financial Reporting: In lieu of earned value management reporting, Consortium will provide quarterly Business Status report found in Attachment 2, A.2. Additionally, at least once a year, in alignment with the timing of a JOC meeting and the timing for exercise of Options, Recipient will provide financial information to the OTAO identifying the total charges made during the performance of this Agreement with a budget update for future periods. This report is for informational purposes only. Consortium Members' accounting for Government-reimbursed and Recipient costs shall be in accordance with Consortium Members' accounting practices but must comply with Generally Accepted Accounting Principles or other international standards. The Cost Accounting Standards and the cost principles at Federal Acquisition Regulation Subpart 31 are not applicable to costs incurred Under this Agreement.

ARTICLE VII: OBLIGATION AND PAYMENT

A. Obligation

1. The Government's obligation to make payments to Recipient is limited to only those funds described in the Agreement or by modification to the Agreement. The Government is obligated to fund the amount of (b) (4) (b) (4) for CLIN 0027 for a total Government obligation of (b) (4). The Government and Recipient are not obligated to fund work that is to be performed during the Option periods until an Option is exercised and not declined by Recipient. Recipient is not obligated to perform work beyond that which has been funded by the Government.

2. If modification of the payment terms or schedule becomes necessary in performance of this Agreement, pursuant to Article III, Section C, the ASPR OTAO and PML/PI Administrator shall make revisions to this Agreement and any attachments hereto consistent with the then current Program Plan.

B. Payments

Recipient has an established and agrees to maintain an accounting system which complies with Generally Accepted Accounting Principles and international standards as required, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for the funds dispersed Under this Agreement. An acceptable accounting system is one in which all cash receipts and disbursements are controlled and documented properly.

Properly prepared invoice(s) shall be submitted by Recipient for payment not more than once per quarter in Adobe Acrobat (.pdf) format. The invoice shall be uploaded to a shared electronic file server, with an email copy to the OTAO, OTAS and OTTR cited below. The invoice shall be accompanied by adequate documentation as may be required to support the payment. After verification of the accomplishment of the work, the OTAS and OTTR will forward the invoice(s) to the payment office. Each invoice must contain the following information in order to be deemed properly prepared:

a. Name and address of Recipient

b. Invoice Date and Invoice Number

c. Agreement Number

d. Description, quantity, unit of measure, unit price, and extended price

e. Recipient Cost Share

f. Name and address of OTAR official to whom voucher is to be sent

g. Name, title, phone number, and mailing address of person to notify in the event of a defective invoice.

h. Taxpayer Identification Number (TIN)

i. Electronic Funds transfer (EFT) banking information

Documents should be delivered electronically to the OTAO, OTAS and OTTR. Unless otherwise specified by the OTAO all deliverables and reports furnished to the Government under the resultant Agreement (including invoices) shall be addressed to the OTAO, OTAS and OTTR.

Quarterly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

The Recipient will convert foreign currency costs to US Dollars each quarter using the spot exchange rate published by Reuters at 4 PM ET on the last working day of each quarter as specified in the invoice submitted for reimbursement.

The Recipient will email the invoice to PSC_Invoices@psc.hhs.gov promptly after receiving email approval from the OTAO or OTAS that the invoices has been reviewed and approved for further processing.

The Recipient agrees to promptly notify the OTAO and OTAS in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base segment or any option segment(s) and the reasons for the variance.

The Government will pay all proper invoices in US dollars within 30 days of receipt or pay interest on any amounts due in accordance with the Prompt Payment Act.

C. Limitation of Payments

It is herein understood and agreed that Government funds and funds identified as Recipient contributions are to be used solely for Agreement-related expenditures that are reasonable in nature and amount, and allocable to this Agreement.

D. Financial Records and Reports:

The Recipient shall maintain adequate records to account for its expenditure of all funding Under this Agreement. Upon completion or termination of this Agreement, whichever occurs earlier, the Recipient Administrator shall furnish to the OTAO a copy of the Final Report required by Attachment 2, Part E. Recipient's relevant financial records are subject to examination or audit 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 be provided direct access to sufficient records and information of Recipi ent, to ensure accountability for 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.

E. Comptroller General Access to Records

To the extent that the total Government payment Under this Agreement exceeds $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Consortium Member participating 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 Consortium Member 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 access by a Government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that was created or maintained in the ordinary course of business or pursuant to a provision of law in the performance of the Agreement. Recipient and Consortia Members shall ensure that their sub-recipients' agreements are consistent with this Article.

ARTICLE VIII: DISPUTES

A. General

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

B. Dispute Resolution Procedures

1. Any 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, shall only be raised under this Article.

2. Whenever legal disputes or claims arise, the Parties shall attempt to resolve the issue(s) by discussion and come to mutual agreement on a resolution as soon as practicable. In no event shall a dispute, disagreement or misunderstanding that arose more than three (3) months prior to the notification made under Article VIII, sub-section B.3 of this article constitute the basis for relief under this article unless one level above the OTAO, 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 OTAO or Consortium's Administrator, as the case may be) in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the Assistant Secretary for Preparedness and Response (ASPR) Head of Contracting Activity, and senior executive appointed by Consortium. The other Party shall submit a written response on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ASPR Head of Contracting Activity (HCA) and the recipient senior executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, upon written request to the Senior Procurement Executive (SPE) made within thirty (30) calendar days of the expiration of the time for a decision under Article VIII, sub-section B.3 above, the dispute shall be further reviewed. The SPE may elect to

conduct this review personally or through a designee or jointly with a senior executive appointed by Consortium. Following the review, the Chief Acquisition Officer or designee will resolve the issue(s) and notify the Parties in writing. Such resolution shall be final and binding.

5. The Parties agree that the Agreement satisfies the elements of a "contract" for jurisdiction under the Tucker Act. After appropriate exhaustion of the administrative and other remedies identified in this Agreement, recipient shall have the right to appeal or pursue any Agreement dispute arising Under this Agreement at the Court of Federal Claims or, if applicable, the Court of Appeals for the Federal Circuit or the Supreme Court.

C. Escalation Procedure for Technical Matters

In the event of a technical disagreement the procedures for resolution are depicted in Attachment 3, Technical Escalation Procedure

D. 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 either Party be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, or other indirect damages.

ARTICLE IX: PATENT RIGHTS

A. Allocation of Principal Rights

Unless Recipient notifies the Government that Recipient does not intend to retain title, Recipient or its designee shall retain the entire right, title, and interest throughout the world to each Subject Invention and patent rights thereon consistent with the provisions of this Article and 35 U.S. § 202.

Recipient or its designee shall retain title of all other Inventions and patent rights thereon made in the performance of this Agreement.

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

1. Recipient shall identify Subject Inventions in the annual report and the final report as specified in Attachment 2, which shall be in sufficiently complete technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention.

2. If Recipient determines that neither it nor its designee intends to file any patent applications on a Subject Invention, Recipient shall notify HHS, in writing, within two (2) years of disclosure of such Subject Invention to HHS. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by HHS to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

3. Recipient shall file its initial patent application on a Subject Invention to which it retains title prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. Recipient may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) at its discretion.

C. Conditions When the Government May Obtain Title

Upon HHS's written request, Recipient shall convey title to HHS:

1. Of any patent or patent applications solely claiming Subject Inventions, if Recipient fails to disclose the Subject Invention within the times specified in Article IX, Section B; provided, that HHS may only request title if HHS gives written notice to Recipient of Recipient's failure to report within sixty (60) calendar days after learning of the failure of Recipient to disclose within the specified times, and Recipient fails to report such Subject Invention within sixty
(60) calendar days of such written notice (the "Cure Period"). HHS shall have sixty (60) days from the end of the Cure Period in which to claim title. For the avoidance of doubt, disclosure under this paragraph shall be deemed to have occurred at the time of Recipient's written notification to the Government of a Subject Invention regardless of whether such

disclosure meets the standards set forth in Article IX, sub-section B.1 above.

2. Of a patent application or patent that solely claims Subject Inventions, as the case may be, in any country in which Recipient decides not to continue the prosecution of such patent application, or to pay the maintenance fees on or defend in reexamination or opposition proceedings of such a patent.

D. Minimum Rights to Consortium and Protection of Consortium's Right to File

1. Recipient shall retain a nonexclusive, royalty-free license throughout the world in each Subject Invention and patents and patent applications claiming a Subject Invention to which the Government obtains title under Article IX, Section C. The Recipient license extends to the Recipient's Affiliates, and includes the right to grant licenses of the same scope to the extent that Recipient was legally obligated to do so at the time the Agreement was awarded or at the time of the Subject Invention was invented. 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 Subject Invention pertains. HHS approval for license transfer shall not be unreasonably withheld.

2. The Recipient license may be modified by HHS to the extent necessary to achieve diligent Practical Application of the Subject Invention pursuant to an application for an exclusive or non-exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404 if Practical Application of such Subject Invention has not already been achieved or is not likely to be achieved by Recipient, its Affiliates or licensees.

3. Before modification of the license, HHS shall furnish Recipient a written notice of its intention to modify the license, and Recipient shall be allowed sixty (60) 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 modified.

E. Action to Protect the Government's Interest

1. Recipient agrees to execute or to have executed and promptly deliver to
HHS all instruments necessary to (i) establish or confirm the rights the

Government has throughout the world in those patents claiming Subject Inventions to which Recipient elects to retain title, and (ii) convey title to HHS when requested under section D of this Article and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

2. Recipient agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format suggested by Recipient, each Subject Invention in order that Recipient can comply with the disclosure provisions of Article IX, Section C. Recipient shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting Subject Inventions in sufficient time to permit the filing of patent applications prior to US statutory bars.

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

4. Recipient shall include, within the specification of any United States patent application and any patent issuing thereon claiming a Subject Invention, the following statement: "This invention was made with Government support under Agreement HHSO100201800012C, awarded by HHS. The Government has certain rights in the invention."

F. Lower Tier Agreements

Recipient shall include the substance of Article IX, suitably modified, in its agreements with sub-recipients for experimental, developmental, or research work Under this Agreement.

G. Reporting on Utilization of Subject Inventions

1. Recipient shall submit, during the term of the Agreement, in the annual report as specified in Attachment 2, information on the utilization of Subject Inventions or on efforts at obtaining such utilization that are being made by or on behalf Recipient or its licensees or assignees. Such reports will include information regarding the status of development, date of first commercial sale or use, and such other data and information as HHS may reasonably specify. Recipient shall provide additional reports as may be requested by HHS in connection with any march-in proceedings undertaken by HHS in accordance with section H 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 Recipient. No such reporting shall be required for Subject Inventions if all patents or patent applications claiming such Subject Inventions have been abandoned, or if both Recipient and Government elect not to file a patent application on such Subject Invention.

2. All required reporting shall be submitted to the OTAS, OTAO, and OTTR.

3. Where the Subject Invention is a drug or a vaccine, or a method of manufacturing, administering or using a drug or vaccine, Practical Application is achieved with respect to:

a. such drug or vaccine, (b) (4) [redacted] or

b. such method of use, if the method of use is employed in manufacture, administration or use of such drug or vaccine in connection (b) (4) [redacted].

4. Where the Subject Invention is a biologic or medical device as regulated by the Food and Drug Administration that requires a clinical study for approval, or a method of manufacturing, administering or using such a biologic or medical device, Practical Application is per se achieved with respect to:

a. such biologic, (b) (4) [redacted]; or

b. such method of use, if the method of use is employed in manufacture, administration or use of such biologic in connection (b) (4) .

c. such medical device, if (b) (4) ; or

d. such method of use, if the method of use is employed in manufacture, administration or use of such medical device (b) (4)

5. Failure to complete (b) (4) does not per se constitute a failure to achieve Practical Application.

H. March-in Rights

Recipient agrees that, with respect to any Subject Invention in which it has retained title, HHS may request Recipient, an assignee, or exclusive licensee of a
Subject Invention to grant a non-exclusive license within the Field to a responsible third party, upon terms that are reasonable under the circumstances. If Recipient, assignee, or exclusive licensee refuses such a request, HHS has the right to require Recipient to grant such a license if HHS determines that:

1. Such action is necessary because Recipient, assignee their licensees or their Affiliates have not taken steps, consistent with the intent of this Agreement, to achieve Practical Application of the Subject Invention; or

2. Such action is necessary to alleviate the following urgent health or safety needs that effect the United States and that are not reasonably satisfied by Recipient, assignee, or their licensees or their Affiliates:

a. declaration for Public Health Emergency by the Secretary of HHS;

b. determination that there is a significant potential for a public Health emergency that has a significant potential to effect a national or health security of U.S. citizens as determined by the Secretary of HHS; or

c. declaration by WHO Director General of a public health emergency of international concern.

3. Where the circumstances described in subsection H.2 are met, Recipient will act promptly to negotiate in good faith with the responsible third party a nonexclusive license on terms that are reasonable under the circumstances under the SI Intellectual Property Rights it controls at the time to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States.

ARTICLE X: DATA RIGHTS

A. Allocation of Principal Rights

1. The Government will receive Limited Rights in Data delivered in the performance of the SOW that is marked with the "Limited Rights" legend required by Article X, Section C below. Any delivered Data which is part of a patent application claiming a Subject Invention will be subject to the disclosure and release restrictions set forth in Article IX, Section B of this Agreement.

2. The Government may not, without the prior written permission of Recipient, release or disclose Data outside the Government, use Data for competitive procurement or manufacture, release or disclose Data for any purpose, or authorize Data to be used by another party. The Government will be able to share Data within the Government provided that the Government recipient is obligated to keep the information confidential. The Government shall inform all Government recipients of Data of the relevant restrictions of this Agreement. Data in any document which is a part of a patent application that would disclose a Subject Invention will be subject to Limited Rights until publication of patent application in accordance with Article IX of this Agreement.

3. Recipient agrees to retain and maintain in good condition all Data necessary to achieve Practical Application of any Subject Invention in accordance with the Recipient's established record retention practices. In the event of exercise of the Government's March-in Rights as set forth under Article IX, Section H, Recipient agrees, upon written request and with adequate additional support from the Government, as mutually agreed between the Parties, to deliver Data necessary to achieve Practical Application with respect to use of the Subject Invention in the Field within

one-hundred and twenty (120) calendar days from the date of the written request.

4. Recipient's right to use Data is not restricted and includes the right under Recipient's established business policies to make public research data (especially human research data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis.

B. IDENTIFICATION AND DISPOSITION OF DATA

Recipient shall keep copies of all Data required by the Food and Drug Administration (FDA) relevant to this Agreement for the time specified by the FDA and provide such Data to OTAO. HHS reserves the right to review any other Data determined by HHS to be relevant to this Agreement. Recipient shall provide regulatory data to the OTTR and OTAS in accordance with Attachment 2: Reporting Requirements.

C. Marking of Data

Pursuant to Article X, Section A above, any Data delivered Under this Agreement shall be marked with the following legend or similar:

> "*LIMITED RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by Agreement HHSO100201800012C between the Government and Recipient, and those restrictions do not permit disclosure to any party outside the Government without prior agreement of Recipient. Any reproduction of this Data or portions thereof must be marked with this legend.*"

D. Lower Tier Agreements

Recipient shall include the substance of this Article in all agreements with subrecipients for experimental, developmental, or research work performed Under this Agreement.

ARTICLE XI: FOREIGN ACCESS TO TECHNOLOGY

a. Except as authorized by the Office of Foreign Assets Control (OFAC) in the Department of the Treasury, the Recipient shall not acquire, for use in the performance of this Agreement, any supplies or services if any proclamation,

Executive order, or statute administered by OFAC, or if OFAC's implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.

b. Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea, into the United States or its outlying areas. Lists of entities and individuals subject to economic sanctions are included in OFAC's List of Specially Designated Nationals and Blocked Persons at http://www.treas.gov/offices/enforcement/ofac/sdn/. More information about these restrictions, as well as updates, is available in the OFAC's regulations at 31 CFR chapter V and/or on OFAC's website at http://www.treas.gov/offices/enforcement/ofac.

c. The Recipient shall insert this clause, including this paragraph (c), in all sub-agreements.

ARTICLE XII: TITLE TO AND DISPOSITION OF PROPERTY

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 Recipient 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, Recipient shall obtain prior written approval of the OTAO. Title to this Property shall also vest in Recipient and HHS upon acquisition in accordance with the cost share of the acquisition. Recipient shall be responsible for the maintenance, repair, protection, and preservation of all Property at its own expense. For all property generated during the execution of work in performance of the Program, title will vest with the Government, unless in the case of clinical samples the site performing the clinical trials has Biobanking requirements. In the event the Recipient requests a transfer of title from the Government to the Recipient during the course of the Agreement, a written request will be sent to the OTAO for consideration and transfer will only take place after agreement in writing by the OTAO. Disposition at the end of the Agreement of property generated during the course of the Agreement will be handled in the same manner described in Article XII, Section B.

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 in full by Recipient at a price that the parties agree represents fair market value of the property at the time of purchase with an agreed upon markdown due to the Recipients care of the property, with the proceeds of the sale being returned to HHS; 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 XIII: SUB-RECIPIENT

For any Sub-recipient in excess of $250,000 that will be reimbursed Under this Agreement, Recipient will provide BARDA the opportunity to review the subject Sub-recipient agreement ten (10) Business Days before execution. The Sub-recipient agreement shall include the nature of the work that the sub-recipient is going to perform, an estimated period of performance and the proposed costs for the work. Recipient will provide OTTR, OTAO, OTAS and OTTS with an electronic copy of the Sub-recipient agreement. For avoidance of doubt, once the ten (10) Business Days review period has expired the Recipient is not required to wait any further for the Government comments before executing an Agreement with a Sub-recipient. If the Government does provide comments within 10 Business Days, the Recipient will not proceed with the Sub-recipient Agreement until an agreement between Recipient and Government is reached.

ARTICLE XIV: CIVIL RIGHTS ACT

Performance of this Agreement in the US is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to

nondiscrimination in Federally assisted programs. Recipient has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

ARTICLE XV: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of Recipient and the OTAO. 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 XVI: SPECIAL CLAUSES

A. Inspection and Acceptance

1. The OTAO or the duly authorized representative will perform inspection and acceptance of deliverables to be provided Under this Agreement

2. For the purpose of this Section, the designated OTTR is the authorized representative of OTAO. The OTTR will assist in resolving technical issues that arise during performance. The OTTR; however, is not authorized to change any Agreement terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

3. Inspection and acceptance will be performed at the Recipient's facilities or at:

Biomedical Advanced Research and Development Authority (BARDA)
and/or
Contract Management and Acquisition (CMA) under the Office of the Assistant
Secretary for Preparedness and Response U.S. Department of Health and Human Services

B. PROTECTION OF HUMAN SUBJECTS

1. The Recipient agrees that the rights and welfare of human subjects involved in research Under this Agreement shall be protected in accordance with 45 CFR Part 46 and with the Recipient's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Recipient further agrees to provide certification 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 Recipient shall bear full responsibility for the performance of all work and services involving the use of human subjects Under this Agreement and shall ensure that work is conducted in a proper manner and as safely as is feasible. The Parties hereto agree that the Recipient retains the right to control and direct the performance of all work Under this Agreement. Nothing in this Agreement shall be deemed to constitute the Recipient or any sub Recipient, agent or employee of the Recipient, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Recipient agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent consortium while holding the Government harmless for the acts of the Recipient, any subrecipients, or their employees.

3. If at any time during the performance of this Agreement, the ASPR OTAO determines that the Consortium is not in compliance with any of the
requirements and/or standards stated in Article XVI, Section B, subsections 1 and 2 above, the ASPR OTAO may immediately suspend, in whole or in part, work and further payments Under this Agreement until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Consortium fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the ASPR OTAO may terminate this Agreement in whole or in part, and the Recipient's name may be removed from the list of those consortiums with approved Health and Human Services Human Subject Assurances.

C. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

1. The acquisition and supply of all human specimen material (including fetal material) used Under this Agreement shall be obtained by the Recipient 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 Recipient shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted Under this Agreement, by collaborating sites, or by sub-recipients identified
Under this Agreement, were obtained with prior approval by the 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 OHRPapproved Assurances, whether domestic or foreign, and compliance must be ensured by the Recipient.

3. Provision by the Recipient to the ASPR 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).

D. 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/noticefiles/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice. The Recipient shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC

289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Recipient.

E. NEEDLE EXCHANGE

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

F. CARE OF LIVE VERTEBRATE ANIMALS

1. Before undertaking performance of any Agreement involving animal related activities, the Recipient shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.30 through 2.38. Recipient shall furnish evidence of the registration to the OTAO.

2. The Recipient agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this Agreement will conform with the U.S. Public Health Service (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.

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

Note: The Recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. 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)

G. 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

H. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All 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 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 Recipient for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Recipient under this award unless a satisfactory assurance of compliance with 7 U.S.C. 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 2.30-2.38 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 Recipient 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 Recipient and any affected sub Recipients are granted a

certificate of registration or are authorized to work with the applicable select agents.

For prime or sub-recipient awards to domestic institutions who possess, use, and/or transfer Select Agents under this sub-recipient, 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 sub-recipient awards to foreign institutions who possess, use, and/or transfer Select Agents Under this Agreement, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Recipient must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the OTAO, the 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 Agreement.

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

L. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of any products to be administered to human subjects Under this Agreement.
If at any time during the life of this Agreement, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of the products and such failure results in a material adverse effect on the safety, purity or potency of the products (a material failure) as identified by CBER and CDER, the Recipient shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Recipient fails to take such an action within the thirty (30) calendar day period, then the Agreement may be terminated.

M. PRODUCT APPROVAL

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

The Recipient agrees to advise the ASPR OTAO and OTTR promptly of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility during the term or this Agreement. The Recipient also agrees to advise the ASPR OTAO's and OTTR immediately if at any time during the term of this Agreement, the items Under this Agreement fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

N. ANTI-BRIBERY AND ANTI-CORRUPTION

Each Party agrees to perform its obligations Under this Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Agreement, to terminate this Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article XVI, Section M.

O. GOVERNMENT OBSERVER IN RECIPIENT FACILITY

With seven (7) days advance notice to the Recipient in writing from the OTAO/OTAS, the
Government may place an observer in a Recipient facility, who shall be subject to Recipient's policies and procedures regarding security and facility access at all times while in the Recipient's facility. As determined by federal law, no Government representative shall publish, divulge, disclose or make known in any manner, or to any extent not authorized by law, any information disclosed to that person in the course of employment or official duties performed while stationed in a Recipient facility.

P. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and
abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector
General
Department of
Health and Human
Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Q. PROHIBITION ON SUB-RECIPIENT INVOLVEMENT WITH TERRORIST ACTIVITIES

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.0.13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with

these Executive Orders and Laws. This clause must be included in all sub-agreements issued Under this Agreement.

ARTICLE XVII: TRANSFERS & ASSIGNMENTS

Any transfer or assignment will be conducted in a manner consistent with the Assignment of Claims Act (31 U.S. Code § 3727) and the Prohibition on transfer of Agreement and certain allowable assignments (41 U.S.C.A. § 6305, the "Anti-Assignment Act"). In the event there is a transfer to an independent 3rd Party who is not a consortium member, then the provisions of FAR 42.1204 would apply.

ARTICLE XVIII: CONFIDENTIALITY

It is recognized by the parties that success of the Agreement is enhanced by sharing of Confidential Information to inform the Government and Recipient of developments outside of, but potentially relevant to, the scope of work being performed under the Agreement. The Parties may use Confidential Information submitted hereunder for purposes of the Agreement, but for no other purpose. It is expressly agreed that the Government is not granted Limited Rights hereunder to Confidential Information.

Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202 and shall not be disclosed by the Government or its representatives or Recipient without the prior written consent of the providing Party except to the extent such disclosure is required by law. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government or Recipient, shall be shared strictly on a need to know basis for the purposes of the Agreement, and is subject to the restrictions of this provision.

In addition to the above, Confidential Information is subject to the protections of the Trade Secrets Act as well as any other remedies available Under this Agreement or the law.

In order to be subject to the provisions of this Article XVIII, the providing Party shall identify Confidential Information as confidential or proprietary at the time of disclosure, either by separate written communication or by use of an appropriate stamp or legend; or shall provide written notice to the receiving Party within thirty (30) days of disclosure

of the information's confidential or proprietary nature. Any disclosure of Confidential Information by either Party or its representatives prior to receipt of such notice of its confidential or proprietary nature shall not constitute a breach of this Article XVIII. It is the Recipient's responsibility to identify that information which is deemed confidential. Notwithstanding the foregoing, information of a personal nature about an individual shall be treated as Confidential Information even if not so marked.

Recipient shall mark Confidential Information with the following legend or similar:

" Business *Confidential and Proprietary. This information is confidential and proprietary. The receiving party may not use, modify, reproduce, perform, display or disclose this information except within the receiving party's organization on* a *need to know basis for the purposes of Agreement HHS0100201800012C, and may not disclose to any party outside the receiving party's organization without prior agreement of the providing party. Any reproduction of this information or portions thereof must be marked with this legend."*

The obligations of this ARTICLE XVIII shall survive expiration or termination of the Agreement.

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

ATTACHMENT 2: REPORT REQUIREMENTS

Item Description	Delivery Date	Deliver To
1. Monthly Technical Progress Report describing project progress over the previous month. **Business status update** will be provided on a quarterly basis consistent with the invoice cycle.	The 15th of each month, except on the Agreement anniversary month when an Annual Report is to be submitted in lieu of a monthly report.	OTAO/OTAS and OTTR via e-mail. Additionally, email invoices to PSC_Invoices@psc.hhs.gov
2. Quarterly Invoices	Within sixty (60) calendar days of the end of each quarter	
3. Bi-Weekly Conference Call Minutes	Proposed agenda two (2) Business Days prior to call. Minutes within seven (7) Business Days following each conference call	
4. Quarterly PMO Steering Committee / Site Visit Minutes	Within ten (10) Business Days following each PMO Steering Committee /site visit	
5. Bi-annually JOC minutes	Within ten (10) Business Days following each JOC	
6. Bi-annual Cost Share Determination revised budget and meeting minutes	Within ten (10) Business Days following each Cost Share Determination meeting	
7. Portfolio Progress Milestone Presentation. Annual or event driven review of program	No later than ten (10) business days before Milestone Review at JOC	
8. Study Protocols for each non-clinical or clinical trial	No later than ten (10) Business Days before submission to the FDA	OTAO/OTAS and OTTR via e-mail and, if requested, CD-ROM

9. Study Reports for each non-clinical or clinical trial	No later than fifteen (15) Business Days before submission to the FDA	
10. Manufacturing Campaign Reports for Agreement funded clinical trial material and registration lots	No later than fifteen (15) Business Days before submission to the FDA	
11. Technical Documents from Agreement funded activities such as Process Development Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs,	Within ten (10) Business Days upon request by CO/COR or fifteen (15) Business Days prior to submission to FDA*	
12. QA Audit Reports including findings, results and next steps. BARDA reserves the right to participate in the audits.	Within five (5) Business Days of report completion	
13. Formal FDA Submissions for activities to be performed Under the Agreement	No later than ten (10) Business Days before submission to the FDA. BARDA will coordinate with Recipient for reviewing NDA sections	
14. Memo with Date and Time of Scheduled Meetings with FDA. Pertaining to activities to be performed Under the Agreement.	As soon as possible after scheduling, but no later than 2 Business Days	
15. Communications from FDA pertaining to activities Under the Agreement	Within two (2) Business Days of receipt from FDA	
16. Minutes for Formal Meetings with FDA pertaining to activities Under the Agreement	Within two (2) Business Days of receipt from FDA	

17. Draft Final Report	No later than forty-five (45) Business Days prior to Agreement expiration	OTAO/OTAS and OTTR via e-mail.
18. Final Report	No later than Agreement expiration	

19. Incident Report for any critical programmatic concerns, risks or potential risks	Within ninety-six (96) hours of incident	OTAO/OTAS and OTTR via e-mail or telephone
20. Raw Data and Analysis Pertaining generated in the performance of the Program	Within a reasonable time after request within industry standards	OTAO/OTAS via e-mail
21. Weekly Clinical Report during Active Enrollment Periods	The Monday following the week being reported	OTTR via email
22. Clinical Site Enrollment Reporting and Updates to support the BARDA Clinical Trial Database	Submitted monthly as part of technical report	
23. Quality Agreements with Sub-Recipients	Within ten (10) Business Days upon request by OTAO/OTTR	OTAO/OTAS and OTTR via e-mail
24. Publications/Presentations	No later than thirty (30) calendar days before submission for publications and fifteen (15) calendar days	OTAO/OTAS and OTTR via email
25. Subject Invention Report / Annual Utilization Report	Due on or before the 30th of the month following each 12month period of performance	OTAO/OTAS and OTTR via e-mail.
26. Kick-Off Meeting	Due on or before forty-five (45) days after award of Agreement. Documents to be presented at the meeting due seven (7) Business Days before occurrence of meeting	OTAO/OTAS and OTTR via e-mail.

27.Program Plan	Due sixty (60) days after Agreement award. Updated version of the plan due thirty (30) calendar days following an IPR. The program plan shall be delivered at least once during a 12-month period.	OTAO/OTAS and OTTR via e-mail.
28. Regulatory Strategy Plan	Due ninety (90) days after Agreement award. Updated version of the plan to be on annual basis within 15 Business days after the award date of the Agreement.	OTAO/OTAS and OTTR via e-mail.

A. Monthly/Quarterly Reports

On or before ninety (90) calendar days after the Effective Date and monthly thereafter throughout the term of the Agreement, Recipient shall submit or otherwise provide a monthly 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 ASPR 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 will be provided on a quarterly basis consistent with the invoice cycle. The business status report shall provide summarized details of the resource status of this Agreement, including the status of Recipient 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. Recipient 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, Recipient 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

Recipient shall submit or otherwise provide to the OTTR and OTAO one (1) copy each of a report which describes the Annual Program Plan. This document shall be submitted not later than thirty (30) calendar days following the Integrated Program Review as described in Article IV, Section B. Submission of the Annual Program Plan Document may be waived by OTAO or OTAS after a written request by the Recipient to the OTAO and OTAS.

C. SPECIAL TECHNICAL REPORTS

As agreed to by Recipient and the OTTR , Recipient 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 Recipient, significant tests, experiments, or symposia.

D. FINAL REPORT

1. Recipient shall submit or otherwise provide a Final Report making full disclosure of all major developments by Recipient and Subject Inventions upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement. With the approval of the OTAO, 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. Evidence of submission to the National Technical Information Center will be submitted to the OTAO/OTAS.

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 the ASPR OTAO/OTAS and OTTR."

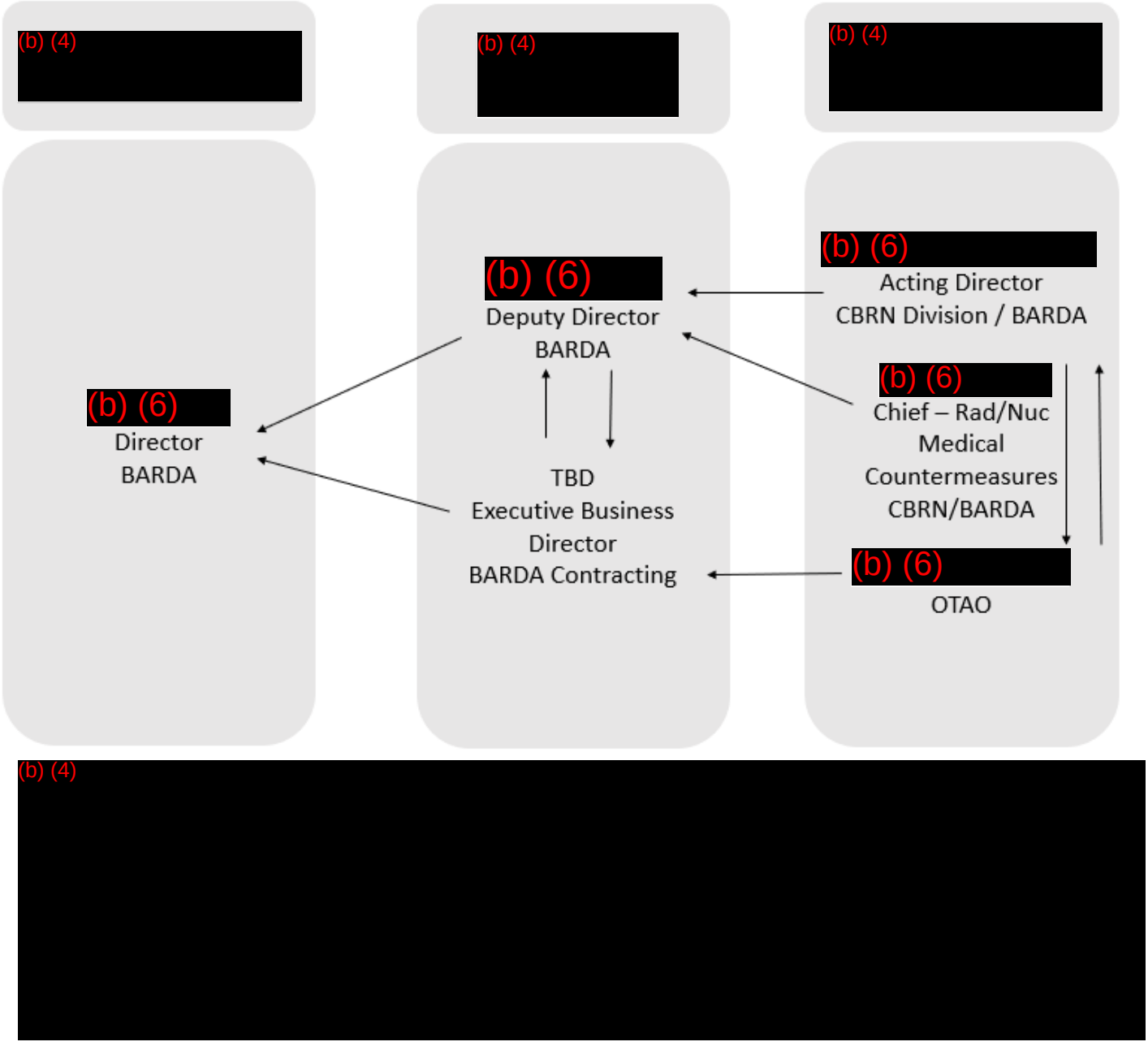
E. EXECUTIVE SUMMARY

Recipient shall submit an executive-level summary, not to exceed two (2) pages, of the major accomplishments of the Agreement and the benefits of using the "other transactions" authority

pursuant to Section 319L(c)(5) of the Public Health Service Act, 42 USC 247d-7e(c)(5). 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 ASPR OTAO.

(b) (4), (b) (6)

BARDA (b) (4) Diagram:



ATTACHMENT 4: J&J GLOBAL TRAVEL, MEETINGS AND EXPENSE POLICY

(b) (4)

[redacted]

[Remainder of this page intentionally left blank]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

ATTACHMENT 5: J&J TRAVEL, MEETINGS & EXPENSE POLICY – UNITED STATES (b) (4) [redacted]

[Remainder of this page intentionally left blank]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)