

**OTHER TRANSACTION AUTHORITY
FOR PROTOTYPE
AGREEMENT**

BETWEEN

**The Henry M. Jackson Foundation for the Advancement of Military Medicine,
Inc. (Awardee)
6720A Rockledge Drive, Suite 100
Bethesda, MD 20817**

And

**NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr.
Frederick, MD 21702**

Effective Date: 27 March 2020

Agreement No.: W911QY-20-9-0004

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

**Awardee
Signature**

(b) (6)



Government

(b) (6)

Printed Name

(b) (6)

Printed Name

Agreements Officer

Title

Title

3/27/2020

27 Mar 2020

Date

Date

This Other Transaction Authority for Prototype Agreement is entered into between the United States of America, hereinafter called the Government, pursuant to and under U.S. Federal law and The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc, a not-for-profit organization established in the state of Maryland, hereinafter called the Awardee. The United States of America and Awardee are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

WHEREAS, the Awardee is eligible for an Other Transaction Authority for Prototype Agreement in accordance with 10 USC § 2371b(d)(1)(A) as amended by the National Defense Authorization Act for Fiscal Year 2018 as they are a nonprofit research institution participating to a significant extent in the prototype project;

WHEREAS, the DoD currently has authority under 10 U.S.C. § 2371b to award “other transactions” (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the DoD, or to improve platforms, systems, components, or materials in use by the Armed Forces;

WHEREAS, a prototype can generally be described as a physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system;

WHEREAS, this Agreement meets the criteria for a prototype project;

NOW THEREFORE, the Parties have agreed as follows:

ARTICLE 1. Scope.

A. This Other Transaction Authority for Prototypes Agreement (the “Agreement”) is entered into between the Government and the Awardee on the Effective Date set forth above. For the avoidance of doubt, this Agreement is entered into pursuant to 10 U.S.C. § 2371b and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, or cooperative agreement. The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200-212.

B. The Parties agree that the ultimate purpose of this Agreement is to perform research and development for the completion of clinical studies and trials in outbreak settings to prepare for evaluation of medical countermeasures (MCMs) in support of FDA

approval reporting, technical documentation and regulatory filings (hereinafter referred to as the “Prototype Project(s)” or “Prototype(s)”). Prototype development will include clinical studies and trials necessary for medical countermeasure development based on the requirements of the Government. The Awardee shall develop the Prototype as described in the Awardee’s Statement of Work, which is incorporated herein and attached hereto as Appendix A.

C. The prototype will be deemed successful where the Awardee’s efforts meet the key technical goals of the project or accomplish a favorable or unexpected result that justifies the development of data necessary for the completion of an observational study or clinical trial.

ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends through final payment. This Agreement is anticipated to end 60 months after the Effective Date. A transaction for a prototype project is complete upon the written determination of the appropriate official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project, or (2) accomplished a particularly favorable or unexpected result that justifies the completion of the prototype.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least ninety (90) calendar days’ prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, consistent with the terms of this Agreement.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Other Transaction Agreement Officer (OTAO), after issuance of a cure notice and failure of the Awardee to cure the defect within ten (10) calendar days or the time allowed by the OTAO after Awardee’s receipt of the cure notice, whichever is longer, may take one or more of the following actions as appropriate:

- (i) temporarily withhold payments pending correction of the deficiency,
- (ii) disallow all or part of the cost of the activity or action not in compliance,
- (iii) wholly or partly suspend or terminate this Agreement,

- (iv) withhold further funding, or
- (v) take any other legally available remedies.

If this Agreement is terminated for Cause, Awardee will grant the Government a non-exclusive, paid up, perpetual license to the Awardee and subawardee patents and documentation necessary for the purpose of developing the Prototype. The Awardee shall provide the Government or its designee with a non-exclusive, paid up, license to any patent, copyright, technical data or regulatory information held by the Awardee that relates to the technology to permit the Government to pursue commercialization of the technology with a third party, on terms to be agreed between the Parties and subject to rights granted or held by third parties. The terms of this section and the obligations herein will be included in any exclusive license given by the Awardee to a third party for any intellectual property covered by this Agreement, on terms to be agreed between Awardee and such third party. This clause will survive the acquisition or merger of the Awardee by or with a third party.

Notwithstanding this Article 2.C, the Government's rights and Awardee's obligations under this paragraph will cease to exist if the Government terminates this Agreement for any reason other than for Awardee's failure to materially comply with the terms of this Agreement.

D. Survival: In the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and Proprietary Information), and product support obligations shall survive the expiration or termination of this Agreement.

ARTICLE 3. Project Management.

A. Program Governance: The Awardee is responsible for the overall management of the project development program and related program decisions. The Government will have continuous involvement with the Awardee. The Awardee shall provide access to project results in accordance with the Awardee's Project Timeline located in Appendix A.

B. Project Managers: The Awardee and the Government will each designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. Each Party will also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable. See Project Manager/Alternate Project Manager point of contact information for each respective party below:

Awardee Project Managers

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

Government Project Managers (GPM)

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

C. Key Personnel: The Awardee's organization shall be established with authority to effectively develop the Prototype. This organization shall become effective upon execution of this Agreement and its integrity shall be maintained until completion or acceptance of the effort by the Government. The key personnel listed in Appendix C are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall provide written notification to the OTAO. The Awardee shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

D. Subaward Approval: Modifications to subawards and/or new subcontracts under this Agreement that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the OTAO prior to being executed.

E. The OTAO has assigned an Agreements Officer's Representative (AOR) for this agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR's authority to act on behalf of the OTAO. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

ARTICLE 4. Agreement Administration.

In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this Agreement between the Awardee and a person other than the OTAO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the OTAO.

Government Representatives:

Other Transaction Agreements Officer (OTAO)

(b) (6)

ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702

(b) (6)

Other Transaction Agreement Specialist (OTAS)

(b) (6)

ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702

(b) (6)

Agreements Officer's Representative (AOR)

(b) (6)

110 Thomas Johnson Dr.
Frederick, MD 21702

(b) (6)

Awardee Representatives:

Director of Contracts:

(b) (6)

The Henry M. Jackson Foundation for the Advancement of Military
Medicine, Inc.
6720A Rockledge Drive, Suite 100
Bethesda, MD 20817

(b) (6)

ARTICLE 5. Performance Objectives and Changes.

A. Statement of Work (SOW): The SOW, Appendix A, describes the scope of activities that will be undertaken by the Awardee to achieve the objective.

B. Recommendations for Modifications: At any time during the term of this Agreement, progress or results may indicate that a change in the SOW would be beneficial to the project objectives. Recommendations for modifications, including

justifications to support any changes to the SOW, will be documented in a letter and submitted by Awardee to the GPM with a copy to the OTAO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised costs unless and until this Agreement is formally revised by the OTAO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Payable Milestones will be considered a supplemental agreement.

C. Review of Recommendations: The OTAO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, the milestone payments, or other proposed changes to the terms and conditions of this Agreement.

D. Minor Modifications: The Government may make minor or administrative Agreement modifications unilaterally (e.g., changes in the paying office or appropriation data, changes to Awardee personnel proposed by Awardee, etc.).

E. Amending the Agreement: The Government will be responsible for effecting all modifications to this Agreement, with the concurrence of the Awardee for modifications that are not minor or administrative. Administrative and material matters under this Agreement will be referred to OTAO.

F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.

G. Government Property: If applicable, terms and conditions applicable to Government Property shall be incorporated through Appendix D.

H. Disputes: For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the OTAO. The OTAO will review the matter and render a decision in writing within sixty (60) calendar days. Thereafter, either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree by mutual consent to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute. The Awardee shall proceed diligently with performance under this agreement pending resolution of the dispute.

ARTICLE 6. Inspection/Acceptance

A. Inspection: The Government has the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the premises of the Awardee or any subawardee engaged in performance. The Government shall perform inspections and tests in a manner that will not unduly delay the work. If the Government performs any inspection or test on the premises of the Awardee or a subawardee, the Awardee shall furnish and shall require subawardees to furnish, at no increase in price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's or subawardee's premises.

B. The Government shall inspect/accept or reject the work as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the work shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. Inspection/Acceptance of the Prototype performed should not exceed 90 days after completion.

ARTICLE 7. Financial Matters

This Agreement is an expenditure type Other Transaction Authority agreement. The payments provided under this Agreement are intended to compensate the Awardee on a cost basis for performance under this Agreement. The Awardee shall provide its best efforts to complete a prototype project based on the estimated cost. Payments are based on amounts generated from the Awardee's financial or cost records.

A. Payment. Payments are based on amounts generated from the Awardee's financial or cost records. The Awardee shall be reimbursed for each element identified in the awarded cost proposal, executed and accomplished in accordance with the performance schedule set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each year, and ends on September 30 of the subsequent calendar year.

B. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated by this Agreement and available for

payment is set forth on page 1, Line of Accounting and Appropriation. The Government may incrementally fund this agreement.

C. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

D. The Government shall pay the Awardee, upon submission of proper invoices, the costs stipulated in this Agreement for work delivered or rendered and accepted, less any deductions provided in this Agreement. Unless otherwise specified, payment shall be made upon acceptance of any portion of the work delivered or rendered for which a price is separately stated in the Agreement. Payments will be made within thirty (30) calendar days of receipt of a request for payment.

E. Prior written approval by the OTA/O, or the AOR, is required for all travel directly and identifiably funded by the Government under this agreement. The Awardee shall present to the OTA/O or AOR, an itinerary for each planned trip, showing the name of the traveler, purpose of the trip, origin/destination, dates of travel, and estimated cost broken down by line item as far in advanced of the proposed travel as possible, but no less than two weeks before travel is planned to commence. In the event that emergency travel is required (e.g. in the event of an outbreak) that would make two weeks' notice impractical, travel requests may be submitted to the Government for an expedited review. Emergency travel requests shall be labelled as such and shall include a brief summary of the emergency situation and rationale for expedited review.

F. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

(a) Definitions. As used in this clause--

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Awardee shall (i) have a designated electronic business point of contact in the System for Award Management at <https://www.acquisition.gov>; and (ii) be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this website.

(d) WAWF training. The Awardee should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at <https://wawf.eb.mil/>.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this Agreement:

(1) Document type. The Awardee shall use the following document type:
Voucher

(2) Inspection/acceptance location. The Awardee shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

(3) Document routing. The Awardee shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC	W911QY
Inspect By DoDAAC	W56XNH

(4) Payment request and supporting documentation. The Awardee shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, costs, fee (if

applicable), and all relevant back-up documentation in support of each payment request.

(5) WAWF email notifications. The Awardee shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

(b) (6)

(g) WAWF point of contact.

(1) The Awardee may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of Clause)

G. Comptroller General Access to Records: To the extent that the total Government payments under this Agreement exceed \$5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

ARTICLE 8. Report and Data Requirements

1. Weekly Teleconferences and Communication

Awardee shall conduct weekly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. The Government anticipates reducing the teleconferences once enrollment executes and again after completion of the trial. Awardee shall provide agendas and read-ahead material as required two days prior to the meetings and shall provide minutes of each meeting to the Government. Awardee shall include key subcontractors as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with MCS/JPEO.

2. Quarterly Progress Reports

The Awardee shall submit a Quarterly Progress report (b) (4) after the end of each quarter of performance. The Quarterly Progress report shall contain the technical progress made during the previous quarter and the updated resource loaded Integrated Master Schedule (IMS) in Microsoft Project format. The schedule update shall include the explanation for any changes in the schedule, and drivers for the changes, as applicable. The report should also address any concerns that would impact the performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix format to include risk mitigation strategies. Note: Any identified changes require formal notification to the OTA in accordance with the Agreement provisions.

In addition, the Quarterly Progress Report shall contain regular status updates of all Intellectual Property (IP) license(s) related to the effort to ensure that all license(s) are in good standing as the project progresses. In the event of any change in IP license(s) status or potentially imminent change in status, the Awardee shall immediately contact the OTA and GPM in writing.

The Government will (b) (4) respond to the report with any comments and the Awardee will (b) (4) revise the deliverable or respond to those comments.

3. Quarterly Financial Status Report

The Awardee shall submit a Quarterly Financial Status Report (b) (4) after the end of each quarter of performance. The Government will (b) (4)

(b) (4) respond to the report with any comments and the Awardee will
(b) (4) revise the deliverable or respond to those
comments. Reports will cover work performed every three (3) months for the duration
of the Period of Performance (PoP).

In addition, the Quarterly Financial Status Report shall include quarterly expenditure forecasts with both the quarterly planned accrual and the cumulative total. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

4. Expenditure Forecasts

The Awardee shall submit the first expenditure forecast (b) (4)
after receiving the project award. An updated forecast shall be submitted (b) (4)
of any project modifications that modify the PoP or the cost of the
prototype. Expenditure forecast submissions shall include analysis of the cost drivers
for Estimate to Complete changes, if any, from the previous projection. The Awardee
shall provide all submissions in Excel format, including all formulas.

5. Final report

A Final Report shall be prepared at the end of the effort by the Awardee. The Final Report shall narrate a complete summary of the project execution and associated results obtained. The narration will include outstanding problems and their potential solutions, problems solved during the course of the agreement, and the solutions to the solved problems. The Final Report shall demonstrate how the prototype was developed and advanced.

The Awardee shall submit a Draft Final Report (b) (4)
following the end of the project. The Government shall provide comments to the
Awardee (b) (4) following receipt of the Awardee's Draft
Final Report. The Awardee shall submit the Final Report (b) (4)
after receipt.

6. Ad Hoc Meetings

In addition to the monthly meetings and written quarterly program updates, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held.

7. Patents - Reporting of Subject Inventions

For purposes of this paragraph, “Subject Invention” is defined as any invention, discovery, or improvement of the Awardee, whether or not patentable, that are conceived of or first actually reduced to practice in the performance of work under this Agreement. The Awardee shall report any OTA Inventions in accordance with the terms and conditions of this Other Transaction Agreement (OTA).

8. Regulatory Documentation and Technical Data Packages

The Awardee shall work in consultation with the Government Regulatory and Quality Affairs staff for the development of all regulatory submission packages to the FDA and include Government Regulatory and Quality Affairs staff in all formal discussions with the FDA. The Awardee shall provide the Government copies of all technical data generated by the Awardee prior to and during performance of the project, necessary to pursue FDA approval and notify the Government of FDA decisions as these take place.

If applicable, the Awardee shall prepare an IND/BLA in the Electronic Common Technical Document (eCTD) format for submission to the FDA and the Government. The awardee shall submit all pre-IND, IND, pre-EUA, and/or BLA report submissions to the AOR. The Awardee shall provide all written communications to and/or from the FDA to the Government as it takes place. The Awardee shall courtesy copy the AOR on all email traffic to the FDA and will forward all emails received from the FDA to the AOR. Meeting minutes will be forwarded to the AOR within seven (7) calendar days of the meeting or teleconference.

9. Miscellaneous Data Submissions

If applicable, the Awardee must submit to the Government all Point Papers, Briefings, Technical Performance Plans (TPP), Program Development Plans (PDP), Regulatory Strategy, Technology Transfer Report and Gap Analysis, Formulation Development, Feasibility and Optimization Reports, United States Army Medical Research and Material Command Animal Care and Use Review Office (USAMRMC ACURO) Approvals, Human Resources Operations Branch (HROB) Approvals, Technical Presentations and Publications, and any formal technical reports that have been prepared for eventual submission to FDA or other regulatory agencies. Examples include the following reports related to: pharmaceutical development, manufacturing development, manufacturing validation, completed batch records, certificates of analysis, analytical development and validation, drug substance and product stability, nonclinical testing, and clinical testing.

10. Work Breakdown Structure

Three-level WBS with costs and schedule (top level is program, level two (2) is phase, level three (3) are major tasks). For WBS level two (2), show breakdown for labor, material, and other indirect costs.

WBS shall be updated annually or thirty (30) calendar days after a Statement of Work modification. Government review/approval is fifteen (15) calendar days after receipt of first submittal. Provide changes to draft within ten (10) calendar days of such request. Provide final document within ten (10) calendar days after approval of changes is received.

11. Integrated Master Schedule

The Awardee shall provide within thirty (30) calendar days after project award an IMS in Microsoft Project format. Any updates to the IMS shall be included in the monthly progress reports.

Submission shall be thirty (30) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the performer will have an additional five (5) calendar days to revise the deliverable or respond to those comments.

12. Incident Report.

The Awardee shall report any incident to the Government that could result in more than a one month delay in schedule from the most recent IMS critical path delivered to the Government. Telephonically contact the GPM within one day of incident. A written summary report shall be submitted within three (3) business days of an incident, to include, what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place.

A.

ARTICLE 10. Confidential Information

A. Definitions

- (1) "Disclosing Party" means the Government or the Awardee who discloses Confidential Information as contemplated by the subsequent Paragraphs.
- (2) "Receiving Party" means Government or the Awardee who receives Confidential Information disclosed by a Disclosing Party.
- (3) "Confidential Information" means information and materials of a Disclosing Party

which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret (as defined below) if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. "Confidential Information" includes any information and materials considered a Trade Secret by the Awardee. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

- (a) The Disclosing Party thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

B. Exchange of Information: The Government shall not be obligated to transfer Confidential Information independently developed by or on behalf of the Government absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

C. Authorized Disclosure: The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article 11, Intellectual Property Rights, and Article 12, Data Rights, provided that the duty to protect such “Confidential Information” and “Trade Secrets” shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article 12 entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

D. Return of Proprietary Information: Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

E. Term: The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

F. The Government shall flow down the requirements of this Article 10 to their respective personnel, member entities, agents, and Awardees (including employees) at all levels, receiving such Confidential Information under this Agreement.

ARTICLE 11. Intellectual Property Rights

A. Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement (“Background IP”). Additionally, no party to the Agreement will enter into an agreement with any contract manufacturer or other third party whereby the third party will obtain rights in OTA Inventions or Study Data, as those terms are defined in this Agreement, absent the mutual consent of the parties to the awarded contract.

B. Awardee’s Background IP. Awardee warrants that it has filed patent application(s) or is the assignee of issued patent(s) listed below which contain claims that are related to research contemplated under this Agreement. No license(s) to any patent applications or issued patents shall be granted under this Agreement, and the application(s) and any continuing applications (except for continuing applications pursuant to this agreement) are specifically excluded from the definitions of "OTA Invention" contained in this Agreement: None.

C. Patent Indemnity. The Awardee indemnifies the Government and its officers, employees and agents against liability, including costs, for infringement of any United States or foreign patent, trademark or copyright, arising out of deliverables or services

provided under this Agreement, provided the Awardee is reasonably notified of such claims and proceedings and given such opportunity as is afforded by applicable laws, rules, or regulations to participate in its defense. Notwithstanding the foregoing, Awardee is not required to indemnify the Government for infringement when such infringement resulted from a unilateral Government directed change to this Agreement or a claimed infringement that is unreasonably settled without the consent of the Awardee unless required by final decree of a court of competent jurisdiction. This clause is not applicable to the Government's practice of any nonexclusive paid-up license in Awardee Subject Inventions granted to the Government pursuant to Section 11.H. of the Agreement.

D. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to the work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual report on the status of Awardee Background IP. Prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering an OTA Invention, which is defined below, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision. Nothing in this ARTICLE shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an OTA Invention.

E. Patent Enforcement. Awardee will have the first option to enforce any patent rights covering an OTA Invention owned jointly by the Parties or solely by Awardee, at Awardee's expense. If Awardee chooses not to exercise this option, the Government may enforce patent rights covering a joint OTA Invention only with Awardee's prior written approval.

F. Ownership. Ownership of any invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement ("OTA Invention") will follow inventorship in accordance with U.S. patent law. The Bayh-Dole Act, 35 U.S.C. §§ 200-212 does not apply to this Agreement and, as such, title to inventions will accrue to the inventor or inventor-organization. The Parties represent and warrant that each inventor will assign his or her rights in any such inventions to his or her employing organization. If either an Awardee employee or a Government employee makes a sole OTA Invention, the entire rights to that OTA Invention will be respectively assigned to the Awardee or the Government. If an Awardee employee and a Government employee jointly make an OTA invention, it will be owned jointly by the Awardee and the Government. Ownership of inventions made in whole or in part with subawardee or collaborator employees, including employees of

other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable subawardee or collaborator.

G. Patent Applications. The Parties will respectively have the option to file a patent application claiming any OTA Invention made solely by their respective employees. The Parties will consult with each other regarding the options for filing a patent application claiming a joint OTA Invention. Within thirty (30) calendar days of being notified of the discovery of an OTA invention or filing a patent application covering an OTA Invention, each Party will provide notice of such discovery or filing to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming an OTA Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties.

H. Licenses. Upon the Awardee's request, the Government agrees to enter into good faith negotiations with the Awardee regarding the Awardee's receipt of a nonexclusive commercialization license covering the Government's interest in any OTA Invention made in whole by a Government employee. Any OTA Invention made solely by an Awardee employee is subject to a nonexclusive, nontransferable, irrevocable, paid-up license for the Government to practice and have practiced the OTA Invention with "Unlimited rights," as this term is defined in DFARS 252.227-7013a(16), as if this regulation were applicable to inventions, rather than technical data.

I. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

ARTICLE 12. Data Rights

A. All data generated in connection with the performance of this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this Agreement, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Study Data"), shall be owned by the Awardee. The Government shall have the right to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this Agreement within the Government and otherwise for "Unlimited rights," as this term is defined in DFARS 252.227-7013(a)(16). The Government may, under a separate agreement or by modification to this agreement, obtain any rights to use or disclose the Awardee's material or data to the extent that such material or data was produced outside the scope of this Agreement.

Notwithstanding the above, as a result of this Agreement, the Government shall obtain "Unlimited rights," as this term is defined in DFARS 252.227-7013(a)(16) specific to any data generated under this agreement.

B. The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this Agreement, all data generated under this Agreement. In the event of exercise of the Government's rights as potentially granted under paragraph 2.C, the Awardee agrees to deliver at no additional cost to the Government, all data, in Awardee's possession and developed under this Agreement, necessary to develop the Prototype within sixty (60) calendar days from the date of the written request.

C. Marking of Data: The Awardee will mark any data delivered under this Agreement with the following legend:

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W911QY-20-9-0006 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

D. All Technical Data and Software (each term as defined under DFARS 252.227-7013) which shall be delivered under this Agreement with less than unlimited rights shall be identified in reasonable specificity and particular rights granted (Government Purpose, Limited or Restricted (all as defined in DFARS 252.227-7013)) prior to entering into the Agreement. All other Technical Data and Software developed under funding of this agreement shall be delivered with unlimited rights as provided for within this Article.

ARTICLE 13. Regulatory Rights

This Agreement may include research with investigational drugs, biologics or medical devices that are regulated by the U.S. Food and Drug Administration (FDA) and require FDA pre-market approval or clearance before commercial marketing may begin (the "Technology"). The Awardee may serve as the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this agreement. The

Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20) has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the Government in the event of certain regulatory product development failures related to the Technology.

Regarding any Technology developed under this agreement for which Awardee serves as regulatory Sponsor, the Awardee agrees to the following:

a. Communications. The Awardee shall provide the Government with all material communications and summaries thereof, both formal and informal, that it sends to or receives from FDA regarding the Technology. Awardee shall (1) ensure that the Government representatives are consulted and are invited to participate in any formal or informal Sponsor meetings with FDA related to the Technology; and (2) notify the FDA that the Government has the right to discuss with FDA any development efforts regarding the Technology.

b. Non-compliance with section (a) may result in termination of the Agreement.

c. Product Development Failure. Certain product development failures may trigger certain remedies in Section “d.” below for the Government advanced developer funding the development of this Technology. This remedy is not available to the Government for any cause outside of the following:

1. if this agreement is terminated for nonperformance; or
2. the Awardee gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate a product development effort, or to file for Federal bankruptcy protection.

d. If any of the product development failures listed in section “c” occur, the Awardee, upon the request of the Government:

1. Shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to the Government or its designee;

2. Shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (c)(i) above; and

3. Shall negotiate in good faith and upon fair and reasonable terms a non-exclusive license to any patent, copyright, Technical Data or other intellectual property owned or controlled by the Awardee, developed prior to or outside the scope of this Agreement

that is necessary for the Government to pursue commercialization of the Technology, with a third party for sale to the Government or otherwise.

e. This clause will survive the acquisition or merger of the Awardee by or with a third party. This clause will also be included in any subcontracts/subagreements relating to the development of the Technology. This clause will survive the expiration of this Agreement.

f. In accordance with Public Law 115-92, the Government may request the sponsor to submit a fully executed sponsor authorization letter enabling FDA to disclose information to JPEO CBRND EB and its government support contractors related to the IND product. JPEO CBRND EB shall submit the executed letter to the FDA only if the IND product becomes a DoD medical product priority under Public Law 115-92, or otherwise mutually agreed upon, and subject to modification of the Agreement.

ARTICLE 14. Foreign Access to Data.

A. Export Compliance: The Parties will comply with any applicable U.S. export control statutes or regulations in performing this Agreement.

ARTICLE 15. Scientific Publications and Press Releases.

A. The Parties shall jointly agree on a publication plan for the Study Data derived from studies executed under this Agreement. This publication plan will identify key new Data to be disclosed or presented and the target date for finalizing any related scientific abstract or manuscript. As part of its Quarterly Program Reviews, the Awardee will share the publication plan with the Government.

B. The Parties will jointly develop each abstract or manuscript and agree on the authorship and the content of the final draft to be submitted; provided that authorship for each abstract and manuscript will be determined based on whether a particular individual made a significant contribution to the conceptualization, design, execution, or interpretation of a research study, as authorship is defined in the fifth edition of the Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH, available at: https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research.pdf.

C. Prior to submission for publication, the Parties shall provide drafts of proposed publications to the authors of such publications for review and comment, and shall provide copies to non-authors for viewing purposes. Review periods are ten (10)

business days for abstracts, or less than ten (10) business days if agreed by Project Managers and in order to meet publication submission deadlines. Review periods are twenty (20) calendar days for manuscripts. Contributing parties shall be appropriately accredited in any publication.

D. The Parties will jointly agree on whether to issue one or more press releases related to the resulting Data. If all Parties agree that one or both Parties will issue a press release, each Party will also have the right to review and agree on the content in advance of its publication. Other parties, if any, contributing to the studies, will have review rights and will be appropriately accredited in the press release. For data generated in studies executed by Awardee outside the scope of this Agreement, the Awardee, at its sole discretion, may issue a press release related to such data.

ARTICLE 16. Human Subjects.

(a) Definitions. As used in this clause -

(1) Assurance of compliance means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) Human Research Protection Official (HRPO) means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) Institution means any public or private entity or agency (32 CFR 219.102(b)).

(5) Institutional Review Board (IRB) means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) Research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

(b) The Awardee shall oversee the execution of the research to ensure compliance with this clause. The Awardee shall comply fully with 32 CFR Part 219 and DoD Instruction 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

(c) The Awardee shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Awardee furnishes to the HRPO, with a copy to the Agreements Officer, an assurance of compliance and IRB approval and receives notification from the OTAO that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Awardee may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Awardee shall notify the OTAO immediately of any suspensions or terminations of the assurance.

(2) The Awardee furnishes to the HRPO, with a copy to the OTAO, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the OTAO that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Awardee's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the agreement.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Awardee's research and research procedures involving human subjects and, based on

such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Awardee to comply with the requirements of this clause will result in the issuance of a stop-work order to immediately suspend, in whole or in part, work and further payment under this Agreement, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the OTAO.

(f) The Awardee shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Instruction 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

ARTICLE 17. Miscellaneous Clauses.

A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.

B. Patent Infringement. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

C. Limitation of Liability. In no event will either Party be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages.

D. Disclosure of Information. Subject to Article 10, the Awardee shall not release to anyone outside the Awardee's organization any unclassified information, regardless of medium (e.g., film, tape, document), pertaining to any part of this Agreement or any program related to this Agreement, unless (i) the OTAO has given prior written approval or (ii) the information is otherwise in the public domain before the date of release. For purposes of this clause, Awardee's Organization includes entities identified as Collaborators in Appendix A Table 1.

E. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Force Majeure as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events.

F. Severability. If any provision of this Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

G. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation either directly or indirectly or by operation of law. When a specific FAR requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

H. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving precedence in descending order as follows: (i) the Articles of this Agreement, and (ii) the Appendices to the Agreement.

Appendix A Statement of Work

I. INTRODUCTION/BACKGROUND

The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF) is a not-for-profit global organization dedicated to advancing military medicine. HJF serves military, medical, academic and government clients by administering, managing and supporting preeminent scientific programs that benefit members of the armed forces and civilians alike. Since its founding in 1983, HJF has served as a vital link between the military medical community and its federal and private partners. Today, HJF manages more than 700 research grants, contracts and cooperative agreements and its projects range from small bench-top experiments to complex multisite programs.

The Austere Environments Consortium for Enhanced Sepsis Outcomes (ACESO), implemented through HJF, is a consortium consisting of United States (U.S.) Government, non-profit, academic and industry partners. Under ACESO, HJF has established a robust research platform with the ability to conduct high quality clinical research protocols across multiple countries from Southeast Asia to Africa to the U.S. The mission of ACESO is to improve survival for patients with sepsis through development of host-based diagnostic/prognostic assays and evidence-based clinical management. To accomplish this mission, (b) (4)

(b) (4)

(b) (4)

JPEO-CBRND Enabling Biotechnologies (JPEO-CBRND-EB) will build on this capacity and direct the efforts outlined in this scope of work. HJF will provide mobile support and clinical trial capability and response to sites identified by JPEO-CBRND-EB, COCOMs and international partners to support Force Health Protection (FHP) globally. To this effect, HJF will:

1. (b) (4)

JPEO-CBRND-EB and HJF agree that the ultimate purpose of this Agreement is to perform research and development for the completion of clinical studies and trials in outbreak settings to prepare for evaluation of medical countermeasures (MCMs) in support of FDA approval reporting, technical documentation and regulatory filings, to include operational readiness of the Biological Threat Clinical Trials (BTCT), reporting, technical documentation and regulatory filings (hereinafter referred to as the “Prototype Project(s)” or “Prototype(s)”). Prototype development will include observational studies and clinical trials based on emerging threats and requirements of JPEO-CBRND-EB.

II. GENERAL CAPABILITIES

General capabilities under this Agreement are as follows:

A. Archiving Data

HJF shall provide archiving of relevant study data including; the Clinical Trial Master File, data management documentation, statistical documentation, and clinical study report for the duration of the period of performance (PoP). Clinical trial records are maintained in accordance with 21 CFR 312.62 and 812.140 for disposition of study drug, case histories and record retention. Supporting documents referred to as 'source documents' will be retained per ICH E6. JPEO-CBRND-EB retains the option of transferring records if a site is unable to comply, or the PoP is up.

B. Project Management for the Clinical Trial

HJF shall provide an updated project Integrated Master Schedule (IMS) in accordance with the deliverable schedule for all activities to include but not limited to Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI) Trial, Observational Studies, and other clinical studies as required by JPEO-CBRND-EB. Detailing each task, timeline and milestone for the entire project. The IMS shall identify the industry partner responsible for performing each task.

C. Technical and Financial Progress Reporting

HJF shall provide all technical and financial progress reporting to JPEO-CBRND-EB in accordance with the deliverable schedule. The Quarterly Progress Reports shall include status updates on all the tasks to include subcontractor status as applicable. The Final Technical Report shall provide detailed data and results from the Clinical Studies captured in a Clinical Study Report.

D. Audits

JPEO-CBRND-EB has the option of visiting the clinical site or executing a routine or for-cause audit. Audits may be conducted remotely through document review and teleconference.

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IV. TECHNICAL REQUIREMENTS

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Requirement 5: Novel Coronavirus – CONUS/US

Objective 1: READINESS - Establish the regulatory framework, IRB approved protocols, stakeholder engagement, and a trained staff required to safely conduct regulated clinical studies at multiple CONUS locations during an outbreak of a novel coronavirus.

Task 5.1 – Stakeholder Engagement

A. Activities

Activity 5.1.1

Maintain stakeholder engagement thru coordination, meetings, workgroups related activities with relevant response organizations, partners and sponsors.

B. Deliverables

- a. Status report on activities will be provided during the weekly calls and updates, as well as the quarterly progress report. Updates shall describe the stakeholder engagement activities held, objective of meeting/activity as well as outcome.
- b. Share meeting minutes from various stakeholder engagement activity meetings when available.

Task 5.2 – Plan for Clinical Study Management

A. Activities

Activity 5.2.1

At the direction of JPEO-CBRND-EB, design an observational study in compliance with Good Clinical Practices, FDA 21 CFR Part 50, FDA Guidance Documents, and ICH E6.

Activity 5.2.2

Develop a clinical study management plan identifying:

- Necessary components of preparation, implementation, and closeout; and spells out the logistics and operations necessary to achieve clinical objectives in accordance with 21 CFR and ICH E6.
- Activities based on the planning stage, execution through to study close out, and final reports.

- Requirements for clinical documents as defined in the glossary.

B. Deliverables

- a. Clinical study design
- b. Clinical study management plan defining components such as:
 - Quality monitoring, quality assurance, formal communications procedures, reporting processes, roles, responsibilities, essential documents for the conduct of a clinical study (e.g., Investigator Brochure; IRB Submission Tracking Log, Approvals, Correspondence; Insurance Statement), record keeping, data management plan, statistical plan, pharmaceutical control, as well as defining the necessary services such as labs, shipping and DSMB members, tied to schedule. Clinical study documents and operations shall be compliant with regulatory requirements to include, 21 CFR Part 50 Protection of Human Subjects, 45 CFR Part 46 Protection of Human Subjects and DoDI 3216.02.
 - Necessary clinical activities tied to schedule for awareness and input. As appropriate HJF will identify critical pathways and decision points. The plan shall identify the partner responsible for performing each task.
 - Provisions for HRPO clinical document review in accordance with DoDI 3216.02 via usarmy.detrick.dod-jpeo-cbrnd.mbx.regulatoryaffairs@mail.mil (Note: JPEO-CBRND-EB review times are 10 business days from submission, reviews of drafts may take longer. Meeting may occur for discussion of comment resolution)
 - The management and reporting of SAEs in accordance with Human Research Protection Officer (HRPO) procedures along with the incorporation of a Research Monitor.
 - Archiving of relevant study data including:
 - Clinical Study Master File, data management documentation, statistical documentation, and clinical study report for seven years.
 - Provide copies of all relevant study data to JPEO-CBRND-EB upon request.
 - Repository provisions for investigational product stating:
 - Shall be stored for up to 1 year
 - HJF shall return any unused investigational products to JPEO-CBRND-EB, at their request.
 - Return shipment of material shall be coordinated with the contract AOR.
 - Repository provisions for clinical specimens stating:
 - Shall be stored for the duration of the PoP.
 - HJF upon agreement with JPEO-CBRND-EB shall return any remaining clinical specimens or dispose of appropriately.
 - Return shipment of material shall be coordinated with the contract AOR.

Task 5.3 – Clinical, IPC, and Laboratory Training

A. Activities

Activity 5.3.1

When directed by JPEO-CBRND-EB, provide training to research staff in compliance with the appropriate IPC procedures as well as performing standard clinical and laboratory procedures in PPE under different scenarios simulating an outbreak setting.

B. Deliverables

- a. Status report describing planned and conducted training activities will be provided during the weekly calls and updates, as well as the quarterly progress report.

Task 5.4 – Pre-Study Activities

Ensure that the rights, safety and welfare of study participants are protected and study results from clinical and laboratory data meet requirements for product development prior to subject participation.

A. Activities

Activity 5.4.1

Identify and provide for the oversight agencies with responsibility towards independent assessment of the study ethics in ensuring the protection of the rights, safety and well-being of the human subjects.

Activity 5.4.2

Position pre-approved protocols by U.S. and other applicable regulatory bodies.

Activity 5.4.3

Coordinate with oversight bodies and relevant agencies to execute regulatory tasks according to schedule.

Activity 5.4.4

Provide site training and site initiation, study randomization, study monitoring and hold the study trial master file (if needed).

Activity 5.4.5

Provide for the Quality Assurance of the clinical study to ensure that the study is performed, data generated, documents and reports are compliant with Good Clinical Practices and the applicable regulatory requirements.

B. Deliverables

- a.
 - a. Status report on activities will be provided during the weekly calls and updates, as well as the quarterly progress report.
 - b. As risks are identified they are communicated to JPEO-CBRND-EB.
 - c. A mitigation plan, if directed by JPEO-CBRND-EB.

Task 5.5 - Project management for clinical study planning, execution, monitoring and final reporting.

A. Activities

Activity 5.5.1

Ensure routine reporting on project management for protocol ethic/regulatory coordination, clinical study status, coordination of third-party vendor activities, and technical along with schedule and financial progress.

Activity 5.5.2

Integrate all qualified and trained personnel, facilities, equipment, supplies, materials, services, quality oversight, and related administrative and information technology necessary to accomplish all the objectives and requirements.

Activity 5.5.3

HJF shall coordinate among service providers, clinical sites, laboratories and oversight agencies, so that logistics are managed and maintained within quality and schedule parameters according to the clinical plans developed. HJF shall coordinate with the site to ensure that it remains in good standing with the regulatory bodies throughout the clinical study.

Activity 5.5.4

HJF shall manage communication with JPEO-CBRND-EB and its key stakeholders and subcontractors. Ensure routine reporting to JPEO-CBRND-EB project management for the clinical study status, coordination of third-party vendor activities, and technical along with schedule and financial progress.

Activity 5.5.5

Coordinating JPEO-CBRND-EB requirements such as IRB documents through regulatory pathways as well as identified review boards.

B. Deliverables

- a. Project management for regulatory, protocol ethic/regulatory coordination, clinical study status, coordination of third-party vendor activities, technical, schedule, and financial progress reports.
- b. Initiation of Office of Research Protection ethical review submission to usarmy.detrick.dod-jpeo-cbrnd.mbx.regulatoryaffairs@mail.mil

Objective 2: CONDUCT - Conduct clinical studies, to include, investigational new product(s) in an outbreak setting at multiple locations.

Task 5.1 –Outbreak Response Engagement

A. Activities

Activity 5.1.1

Maintain a direct link to the Military Treatment Facilities (MTFs) to be included in identified response alert system(s) requirements for suspect novel coronavirus cases within US military

populations and maintain continuous integrated into outbreak response at multiple locations.

B. Deliverables

- a. Status report on activities will be provided during the weekly calls and updates, as well as the quarterly progress report. Update to include a description of the stakeholder engagement activities held, objective of meeting/activity as well as outcome.
- b. Share meeting minutes from various stakeholder engagement activity meetings when available.

Task 5.2 – Stakeholder Engagement

A. Activities

Activity 5.2.1

Maintain public health community engagement activities, as relevant to study implementation.

Activity 5.2.2

Maintain public health community engagement activities sensitizing the MTFs, and national authorities, stakeholders, and JPEO-CBRND-EB about research and clinical studies to support response during a novel coronavirus outbreak.

B. Deliverables

- a. Status report on activities will be provided during the weekly calls and updates, as well as the quarterly progress report. Updates to include a description of the public health community engagement activities, plan and objectives, as necessary.

Task 5.3 – Project management for the execution, monitoring and final reporting for the clinical study.

A. Activities

Activity 5.3.1

Ensure routine reporting to JPEO-CBRND-EB on project management for regulatory, protocol ethic/regulatory coordination, clinical study status, coordination of third-party vendor activities, and technical along with schedule and financial progress.

Activity 5.3.2

HJF shall coordinate and manage service providers, the clinics, laboratories and oversight agencies so that logistics are maintained within quality and schedule parameters according to the Clinical Study Management plans developed. HJF shall coordinate with the sites to ensure that they remain in good standing with the regulatory bodies throughout the clinical study.

Activity 5.3.3

MHJF shall manage communication with JPEO-CBRND-EB and HJF subcontractors.

B. Deliverables

- a. Archiving provisions for relevant study data including the:
 - Clinical Study Master File, data management documentation, statistical documentation, and clinical study report for seven years. Provide copies of all relevant study data to JPEO-CBRND-EB upon request.
- b. Documentation that investigational product shall be stored for up to 1 year.
- c. Documentation that HJF shall return any unused investigational products to JPEO-CBRND-EB.
 - Return shipment of material shall be coordinated with the contract AOR.
- d. Documentation that clinical specimens shall be stored for the duration of the PoP.
- e. Documentation that HJF upon agreement with JPEO-CBRND-EB shall return any remaining clinical specimens or dispose of appropriately.
 - Return shipment of material shall be coordinated with the contract AOR.

Task 5.4 – Activate protocol(s) and engage research team for clinical study patient enrollment and data collection.

A. Activities

Activity 5.4.1

If not yet approved, seek rapid approval of protocols by the relevant IRBs in the US.

Activity 5.4.2

Activate conduct at multiple site locations for clinical study patient enrollment, pharmacy and drug administration, sample and patient management, data collection and safety monitoring and assessment.

B. Deliverables

- a. Regulatory approval documentation
- b. Site activation documentation

Task 5.5 - Execute, maintain and closeout the clinical study.

A. Activities

Activity 5.5.1

Perform activities such as clinical protocol coordination between oversight agencies and clinical sites. Ensure service providers, pharmaceutical control, site/data quality compliance, investigator protocol training, clinical monitoring activities and clinical study reporting.

Activity 5.5.2

The clinical management plan will be executed according to schedule. HJF shall notify JPEO-CBRND-EB as schedule changes are identified.

Activity 5.5.3

Coordinate ethical review documents through the oversight agencies per agreements and according to schedule.

Activity 5.5.4

Coordinate all ethical review documents with JPEO-CBRND-EB in agreement with the HRPO DoDI13132.02 requirements to the usarmy.detrick.dod-jpeo-cbrnd.mbx.regulatoryaffairs@mail.mil mailbox

Activity 5.5.4

Conduct study closeout and document lessons learned.

B. Deliverables

- a. All deliverables under Task 5.2 Readiness (if applicable during conduct) are provided to JPEO-CBRND-EB as requested, in draft form with a 10-business day turnaround time. Final forms are provided to JPEO-CBRND-EB once complete and updated accordingly.
- b. All site assessments, clinical compliance reviews, inspections, quality monitoring and safety monitoring reports are provided to JPEO-CBRND-EB for the clinical study.
- c. The clinical schedule as defined in the clinical study management plan is updated routinely and provided to JPEO-CBRND-EB.
 - o Points where schedule is pushing out or critical pathways and decision points are at risk are identified to JPEO-CBRND-EB.
- d. All Quality Monitoring reports/agreements are provided to JPEO-CBRND-EB.
- e. Summary of lessons learned.

Requirement 6: Novel Coronavirus - Southeast Asia

Objective 1: READINESS - Establish the regulatory framework, pre-approved protocols, stakeholder engagement, and a trained staff required to safely conduct regulated clinical studies at multiple locations during an outbreak of a novel coronavirus.

Task 6.1 – Stakeholder Engagement

A. Activities

Activity 6.1.1

Maintain stakeholder engagement activities with relevant response organizations, partners and sponsors.

B. Deliverables

- a. Quarterly update describing stakeholder engagement activities held, objective of meeting/activity as well as outcome. Share meeting minutes from various stakeholder engagement activity meetings when available.

Task 6.2 – Plan for Clinical Study Management

A. Activities

Activity 6.2.1

Design an Observational study in compliance with applicable regulations

Activity 6.2.2

Develop a clinical study management plan identifying:

- Necessary components of preparation, implementation, and closeout; and spells out the logistics and operations necessary to achieve clinical objectives in accordance with 21 CFR and ICH E6.
- Activities based on the planning stage, execution through to study close out, and final reports.
- Requirements for clinical documents as defined in the glossary.

B. Deliverables

a. Clinical study design

b. Clinical study management plan defining components such as:

- Quality monitoring, quality assurance, formal communications procedures, reporting processes, roles, responsibilities, essential documents for the conduct of a clinical study (e.g., Investigator Brochure; IRB Submission Tracking Log, Approvals, Correspondence; Insurance Statement), record keeping, data management plan, statistical plan, pharmaceutical control, as well as defining the necessary services such as labs, shipping and DSMB members, tied to schedule. Clinical study documents and operations shall be compliant with regulatory requirements to include, 21 CFR Part 50 Protection of Human Subjects, 45 CFR Part 46 Protection of Human Subjects and DoDI 3216.02.
- Necessary clinical activities tied to schedule for awareness and input. As appropriate critical pathways and decision points are identified. The plan shall identify the partner responsible for performing each task.
- Provisions for HRPO clinical document review in accordance with DoDI 3216.02 via usarmy.detrick.dod-jpeo-cbrnd.mbx.regulatoryaffairs@mail.mil (Note: JPEO-CBRND-EB review times are 10 business days from submission, reviews of drafts may take longer. Meeting may occur for discussion of comment resolution)
- The management and reporting of SAEs in accordance with Human Research Protection Officer (HRPO) procedures along with the incorporation of a Research Monitor.
- Archiving of relevant study data including:
 - Clinical Study Master File, data management documentation, statistical documentation, and clinical study report for seven years.
 - Provide copies of all relevant study data to JPEO-CBRND-EB upon request.
- Repository provisions for investigational product stating:
 - Shall be stored for up to 1 year
 - HJF shall return any unused investigational products to JPEO-CBRND-EB, at the JPEO-CBRND-EB's request.
 - Return shipment of material shall be coordinated with the contract AOR.

- Repository provisions for clinical specimens stating:
 - Shall be stored for the duration of the PoP.
 - HJF upon agreement with JPEO-CBRND-EB shall return any remaining clinical specimens or dispose of appropriately.
 - Return shipment of material shall be coordinated with the contract AOR.

Task 6.3 – Clinical, IPC, and Laboratory Training

A. Activities

Activity 6.3.1

Provide training to research staff under the appropriate IPC procedures as well as performing standard clinical and laboratory procedures in PPE under different scenarios simulating an outbreak setting.

B. Deliverables

- a. (b) (4) update describing planned and conducted trainings. Share training reports when available.

Task 6.4 – Pre-Study Activities

Ensure that the rights, safety and welfare of study participants are protected and study results from clinical and laboratory data meet requirements for product development prior to subject participation.

A. Activities

Activity 6.4.1

Identify and provide for the oversight agencies with responsibility towards independent assessment of the study ethics in ensuring the protection of the rights, safety and well-being of the human subjects.

Activity 6.4.2

Position pre-approved protocols by U.S. and other applicable regulatory bodies.

Activity 6.4.3

Coordinate with oversight bodies and relevant agencies to execute regulatory tasks according to schedule.

Activity 6.4.4

Provide site training and site initiation, study randomization, study monitoring and hold the study trial master file (if needed).

Activity 6.4.5

Provide for the Quality Assurance of the clinical study to ensure that the study is performed, data generated, documents and reports are compliant with Good Clinical Practices and the applicable regulatory requirements.

B. Deliverables

- a.
 - a. Status report on activities will be provided during the weekly calls and updates, as well as the quarterly progress report.
 - b. As risks are identified they are communicated to JPEO-CBRND-EB.

- c. A mitigation plan, as requested by JPEO-CBRND-EB.

Task 6.5 - Project management for clinical study planning, execution, monitoring and final reporting.

A. Activities

Activity 6.5.1

Ensure routine reporting on project management for protocol ethic/regulatory coordination, clinical study status, coordination of procurement and management of goods and services, and technical along with schedule and financial progress.

Activity 6.5.2

Integrate all qualified and trained personnel, facilities, equipment, supplies, materials, services, quality oversight, and related administrative and information technology necessary to accomplish all the objectives and requirements.

Activity 6.5.3

Coordination among service providers, clinical sites, laboratories and oversight agencies is managed so that logistics is maintained within quality and schedule parameters according to the clinical plans developed. HJF coordinates with the site to ensure that it remains in good standing with the regulatory bodies throughout the clinical study.

Activity 6.5.4

HJF shall manage communication with JPEO-CBRND-EB and its key stakeholders and subcontractors. Ensure routine reporting to JPEO-CBRND-EB on project management for the clinical study status, coordination of third-party vendor activities, and technical along with schedule and financial progress.

Activity 6.5.5

Coordinating JPEO-CBRND-EB requirements such as IRB documents through regulatory pathways as well as identified review boards.

B. Deliverables

- a. Project management for regulatory, protocol ethic/regulatory coordination, clinical study status, coordination of third-party vendor activities, technical, schedule, and financial progress reports.
- b. Initiation of Office of Research Protection ethical review submission to usarmy.detrick.dod-jpeo-cbrnd.mbx.regulatoryaffairs@mail.mil , as well as, other related regulatory submissions.

Objective 2: CONDUCT - Conduct Coronavirus clinical studies in an outbreak setting at multiple locations in Southeast Asia

Task 6.1 –Outbreak Response Engagement

A. Activities

Activity 6.1.1

Maintain a direct link to the civilian hospital sites to be included in identified response alert system(s) requirements for suspect novel coronavirus cases within host country populations and maintain continuous integration into outbreak response at multiple locations.

B. Deliverables

- a. Status report on activities will be provided during the weekly calls and updates, as well as the quarterly progress report. Updates shall include a description of stakeholder engagement activities held, objective of meeting/activity as well as outcome.
- b. Share meeting minutes from various stakeholder engagement activity meetings when available.

Task 6.2 – Stakeholder Engagement

A. Activities

Activity 6.2.1

Maintain public health community engagement activities, as relevant to study implementation.

Activity 6.2.2

Maintain public health community engagement activities sensitizing the hospitals, and national authorities, stakeholders, and funders about research and clinical studies to support response during a novel coronavirus outbreak.

B. Deliverables

- a. Status report on activities will be provided during the weekly calls and updates, as well as the quarterly progress report. Updates to include a description of public health community engagement activities.
- b. Monthly community engagement activities plan and objectives, as necessary.

Task 6.3 – Project management for the execution, monitoring and final reporting for the clinical study.

A. Activities

Activity 6.3.1

Ensure routine reporting to JPEO-CBRND on project management for regulatory, protocol ethic/regulatory coordination, clinical study status, coordination of third-party vendor activities, and technical along with schedule and financial progress.

Activity 6.3.2

Coordination among service providers, the clinic, laboratories and oversight agencies are managed so that logistics is maintained within quality and schedule parameters according to the Clinical Study Management plans developed. HJF shall coordinate with the sites to ensure they

remain in good standing with the regulatory bodies throughout the clinical study.

Activity 6.3.3

HJF shall manage communication with JPEO-CBRND-EB and its key subcontractors. Ensure routine reporting to JPEO-CBRND-EB on project management for regulatory, the clinical study status, coordination of third-party vendor activities, and technical along with schedule and financial progress.

B. Deliverables

- a. Archiving provisions for relevant study data including the:
 - Clinical Study Master File, data management documentation, statistical documentation, and clinical study report for seven years. Provide copies of all relevant study data to JPEO-CBRND-EB request.
- b. Documentation that investigational product shall be stored for up to 1 year.
- c. Documentation that HJF shall return any unused investigational products to JPEO-CBRND-EB.
 - Return shipment of material shall be coordinated with the contract AOR.
- a. Documentation that clinical specimens shall be stored for the duration of the PoP.
- b. Documentation that HJF upon agreement with JPEO-CBRND-EB return any remaining clinical specimens or dispose of appropriately.
 - Return shipment of material shall be coordinated with the contract AOR.

Task 6.4 – Activate protocol(s) and engage research team for clinical study patient enrollment and data collection.

A. Activities

Activity 6.4.1

If not yet approved, seek rapid approval of protocols by the relevant regulatory bodies.

Activity 6.4.2

Activate conduct at multiple site locations for clinical study patient enrollment, pharmacy and drug administration, sample and patient management, data collection and safety monitoring and assessment.

B. Deliverables

- a. Regulatory approval documentation
- b. Site activation documentation

Task 6.5 - Execute, maintain and closeout the clinical study.

A. Activities

Activity 6.5.1

Perform activities such as clinical protocol coordination between oversight agencies and clinical sites. Ensure service providers, pharmaceutical control, site/data quality compliance,

investigator protocol training, clinical monitoring activities and clinical study reporting.

Activity 6.5.2

The clinical management plan will be executed according to IMS.HJF shall notify JPEO-CBRND-EB as schedule changes are identified.

Activity 6.5.3

Coordinate ethical review documents through the oversight agencies per agreements and according to IMS.

Coordinate all ethical review documents with JPEO-CBRND-EB in agreement with the HRPO DoDI13132.02 requirements to the usarmy.detrick.dod-jpeo-cbrnd.mbx.regulatoryaffairs@mail.mil mailbox

Activity 6.5.4

Conduct study closeout and document lessons learned.

B. Deliverables

- a. All deliverables under Task 6.2 Readiness (if applicable during conduct) are provided to JPEO-CBRND-EB as requested, in draft form with a 10-business day turnaround time. Final forms are provided to JPEO-CBRND-EB once complete and updated accordingly.
- b. All site assessments, clinical compliance reviews, inspections, quality monitoring and safety monitoring reports are provided to JPEO-CBRND-EB for the clinical study.
- c. The clinical schedule as defined in the clinical study management plan is updated routinely and provided to JPEO-CBRND-EB.
 - o Points where schedule is pushing out or critical pathways and decision points are at risk are identified to JPEO-CBRND-EB.
- d. All Quality Monitoring reports/agreements are provided to JPEO-CBRND-EB.
- e. Summary of lessons learned.

JPEO-CBRND-EB

Option A: Earned Value Management

Required if funded amount exceeds \$20M. Defense Federal Acquisitions Regulations Supplement (DFARS 252.234-7001, 7002) Earned Value Management System (EVMS) clauses require the implementation of an ANSI/EIA-748 (EIA-748) compliant system.

Glossary (Supplemental Material)

Good Clinical Practice: Providing a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of trial subjects are protected.

Protocol(s): A protocol is a document that describes the objectives, rationale, design, methodology statistical consideration and organization of a trial. A Clinical trial protocol will be developed using all pertinent supportive documents including, but not limited to, the scientific literature, and cross referencing of information. The statistical section of the protocol shall be prepared at the start of the project agreement; this includes defining the set-up and pre-results needed for the Drug Safety Monitoring Board. Protocols shall be established that place emphasis on the definition of safety, effectiveness or efficacy parameters that will be used for review by the DSMB and the FDA.

Informed Consent Forms (ICF): The ICFs for use in the trial will identify and use language that is understandable to the lay person in the appropriate language. Where languages other than English are used a certified translator may be needed to confirm the content of the ICF to the ethics review board. The ICF identifies all relevant aspects of the trial that are relevant to the subject's decision to participate and confirms that decision. ICF format shall be compliant with 21 CFR 50.20 General requirements for informed consent, 45 CFR 46 Protection of Human Subjects and incorporate Common Rule. Provisions in the ICF need to include general terms regarding the use of laboratory specimens for research purposes at a future date.

Investigator Brochure (IB): Defines the pharmaceutical identity and highlights the significant clinical information available that is relevant to the stage of clinical development along with the rationale for performing research with the investigational product. The IB is drafted in compliance with 21 CFR 312 and utilizing related FDA/ ICH guidance documents.

Recruitment Plan: Provides metrics for periodic assessment, risks to enrollment with mitigation, and frequency for re-assessment. The recruitment plan should address strategies which utilize media, transportation, location and hours of access. Advertising is conducted in agreement with FDA stipulations under 21 CFR part 56, 21 CFR 312.7, 21 CFR 812.7, and utilizing FDA guidance's, ICH and sound business practice to remain within ethical requirements.

Safety Monitoring Plan: Provides for adequate safety surveillance, skills and infrastructure to identify and deal with genuine adverse events. In accordance with the protocol medical safety monitoring is conducted and procedures developed for the identification, classification, trending and reporting of adverse events. Adverse event is defined under 21 CFR 312.32(a), requirements for reporting individual and aggregate safety data. A plan for the identification and reconciliation of SAEs that will be followed

throughout the course of the clinical trial needs to be defined prior to the start of the clinical trial. Expedited adverse events require parallel notification to JPEO-CBRND-EB's reporting system: usarmy.detrick.mcs.mbx.regulatoryaffairs@mail.mil and HRPO.

Independent Research Monitor: Performs oversight functions and reviews all unanticipated problems involving risk to subjects or others with the responsibility to provide an unbiased evaluation. Events may require reporting his/her observations and findings to the IRB or other designated official and the HRPO. Compliance requirements for DoDI 3216.02 can be found at: http://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

Case Report Forms (CRF): Case Report Forms are designed to collect study data in a practical manner, with easily understood practices to limit errors, clear identification of the individual roles and quality check points. The format and media of the CFR is identified with electronic source data utilizing the FDA's requirement(s) for electronic data capture. Attention should be paid to the FDA's Guidance for Industry, Electronic Source Data in Clinical Investigations, September 2014. Processes for reporting will meet the requirements of FDA requirements 21 CFR Part 314 and based on the FDA/ICH guidelines.

Clinical Study Report: Integrated clinical and statistical description, presentation and analysis of the clinical trial into a single report. The format is based on the ICH E3: Structure and Content of Clinical Study Reports, November 1995. The draft CSR is provided to JPEO-CBRND-EB for review 9 months after completion of the trial, including biostatistics input to the report.

Clinical Site Documents: Site protocol and operational documents drafted in compliance with the FDA regulatory and quality requirements. Site execution documents will remain in agreement with the protocol objectives and parameters. All documents will utilize version control and be executed per the clinical trial plan to ensure that only approved versions are in use. JPEO-CBRND-EB will be provided with draft review prior to coordination with external oversight agencies.

Source Documents: Source documents consist of checklists and other documents applicable to each study visit. Source documents are developed and retained in accordance with ICH E6. ICH E6 refers to original documents, data and records necessary for the reconstruction and evaluation of the trial. Procedures in the clinical trial plan should identify when electronic capture of data serves as a source document.

Data Management Plan: Where a Drug Safety Monitoring Board is utilized the NIH policies and procedures are recommended, see https://humansubjects.nih.gov/data_safety. Develop the data management and validation plans prior to performing the clinical trial. The clinical data management plan summarizes the study's approach to handling data entry, validation and query resolution towards maintaining data integrity. It includes a description of the system utilized to capture and handle data, identifies what data to capture, methods for confirming data is correct (validation), how data will be reviewed and integrated along with provisions for analysis. Reporting formats are

designed to address compliance requirements and oversight agencies such as the IRB, DSMB and the FDA. Reports are provided initially, interim and final to clarify study progress and safety metrics such as the identification of adverse events, adverse event profiles and safety/adverse event assessments. Data management is planned in accordance with FDA requirements and guidance documents.

Randomization Plan/schedule (if applicable): Minimizes variability and provides an unbiased evaluation of the treatment by reducing or avoiding confounding factors. The methodology provides the basis for the statistical methods used in analyzing data; and provides subject numbering and methodology of blinding subgroups within each group before recruiting the first patient.

Pharmaceutical Management Plan: Procedures for tracking, storage, accountability, handling, and administering drug based on information provided in the IB, or with special instructions provided by the sponsor or JPEO-CBRND-EB as applicable. Procedures will account for final accountability and disposition of remaining pharmaceutical product.

Training Plan: Identifies the minimum training needed and process to provide. This should include a baseline understanding of the protocol, enrollment criteria, laboratory assays, safety information, procedures to maintain protocol integrity, and data management. Provision for training in Good laboratory Practices, and Good Clinical Practices should be identified. JPEO-CBRND-EB retains the option of material review and attending. Where an Investigator meeting is coordinated the meeting agenda and date shall be coordinated with the contract AOR and is anticipated to last for one day, with JPEO-CBRND-EB attendance an option

Quality Monitoring Plan: A plan which functions to facilitate compliance with good clinical practices, FDA guidelines and regulations. Quality Assurance ensures that the trial is performed and that the data generated, documents and records are compliant with Good Clinical Practices. Qualified personnel are designated to monitor the clinical activities. The plan provides for monitor responsibilities, schedule, line of communication and reporting processes to demonstrate that the trial is performed under quality conditions. Provisions are typically defined for monitor knowledge, training and position appointment. The monitor plan provides for the site qualification, through the site initiation and activation, monitoring and close out. The authority of the monitor is defined in relation to clinical site monitoring practices, review of study procedures, identification and reporting of findings and remediation. Certificates, or the method for notification of compliance is provided within an established timeline. Quality monitoring plan to include an identified quality metric towards data verification.

Drug Safety Monitoring Board: Serves as an independent team of experts to periodically review and evaluate the study data for participant safety, study conduct and make recommendations. The DSMB charter typically identifies minimum participates, specialized expertise, methods for review, communication, documentation, issue resolution and tied to schedule. Provisions should be made to ensure that the DSMB is satisfied with the completeness and accuracy of the data provided. DSMB/PRNTs membership, roles and responsibilities, relationships and provisions are provided for with a Charter or similar enabling document. DSMB procedures are based off of Guidance for Clinical

Trial Sponsors, Establishment and Operations of Clinical Trial Data Monitoring Committees, March 2006 and through the NIH Data and Safety Monitoring Board Guidelines (<https://www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/DSMBGuidelines.htm>).

Site Selection Rationale: In relation to the protocol and recruitment plan along with Federal Wide Assurance (FWA) documentation.

Ethical Review Submissions Plan: IRB/ HRPO identification and provide for ethical review under an IRB agreement and manage documents in accordance. Ethic review submission are provided to JPEO-CBRND-EB with review responses.

Analytical Methodology Plan: Clinical assays are identified, and service provider agreements initiated.

Specimen Repository: Clinical specimens will be maintained until JPEO-CBRND-EB provides for disposal or transfer.

Appendix B
Project Schedule/Milestone Payment Schedule

The Government shall pay the Awardee, upon the submission of proper invoices or vouchers, the prices stipulated in this Agreement for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this Agreement. Expenditures shall be submitted based on the awarded budget. Federal funds are to be used only for costs that a reasonable and prudent person would incur in carrying out the prototype project. The Awardee must maintain a financial system capable of identifying costs applicable to this Agreement, compliant with Cost Principles (48 CFR Part 31) and/or the Cost Accounting Standards (CAS) (48 CFR Part 99). An invoice will be submitted through Wide Area Work Flow (WAWF) in accordance with agreement requirements. Final payment of the Agreement shall be determined upon mutual agreement and settlement of any outstanding costs.

The Awardee shall proceed with the performance in accordance with the terms and conditions of this Agreement and its Appendices. However, the Government may require the Awardee to cease performance at any time prior to the commencement of any milestone or task. Such notice to cease performance must be from the OTAO and be in writing, of which email is an acceptable form.

The Parties acknowledge that the nature of this Prototype Project requires flexibility and the ability to react to changing circumstances. Although the Statement of Work sets the scope for activities the Government may require under this Agreement, it is not intended to, and does not, prescribe with specificity each task that HJF will perform. Instead, the Government shall direct HJF to perform specific tasks under the framework established in Articles 3 and 8 of the Agreement, with Government-approved tasks, funding, and deadlines contained in the Integrated Master Schedule. HJF shall not perform any tasks that have not been explicitly authorized by the Government.

HJF will be responsible for submission of SOW's, quotes, and proposals for cost, performance, and schedule for those efforts identified as TBD or proposed for budget purposes only. Government approval will be required prior to incurring costs.

(b) (4)				

Appendix C Key Personnel

1. Awardee’s Organization and Key Personnel.

a. The Awardee’s organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the Agreement and its integrity shall be maintained for the duration of the effort.

b. The key personnel listed below are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall obtain the written consent of the OTAO. In order to obtain such consent, the Awardee shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

c. Prior to permanently removing any of the specified individuals to other contracts, the Awardee shall provide the OTAO not less than thirty (30) calendar days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No reassignment shall be made by the Awardee without written consent of the OTAO. The “Key Personnel” list presented in Table 2 below may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

**Table 2: Key Personnel
Summary**

Name	Organization	Proposed Role
(b) (6)		

Appendix D Government Property

Government Property: “Government Property” means any property (i) furnished by the Government and facilitating performance of this Agreement, (ii) acquired by the Awardee under cost reimbursement terms of this Agreement, or (iii) acquired by the Awardee under fixed price terms of this Agreement (FP-GP) if specifically identified in this Government Property Appendix. Except for commercial off the shelf software and licenses thereto, Government Property does not include intellectual property and software. The Government owns and holds title to all Government Property.

The Government shall deliver to the Awardee any Government Property required to be furnished as described in this Agreement together with related data and information needed for its intended use. The delivery and/or performance dates specified in this Agreement are based upon the expectation that the Government-furnished property will be suitable for performance and will be delivered to the Awardee by the dates stated in the Agreement. If not so suitable, the Awardee shall give timely written request to the OTAO who will advise the Awardee on a course of action to remedy the problem.

FPGP includes: [Mark N/A if none]:

Reference Government provided spreadsheet maintained by the Awardee and incorporated into the agreement upon approval by the OTAO.

The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subcontracts under which Government Property comes into the possession of any subawardee. Unless otherwise provided for in this Agreement or approved by the OTAO, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.

The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the OTAO.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the OTAO, for disposition/disposal instructions and shall store Government Property not to exceed 120 days pending receipt of such instructions. Storage shall be at no additional cost to the Government unless otherwise noted in the Agreement. The Government, upon written notice to

the Awardee, may abandon any Government Property in place, at which time all obligations of the Government regarding such Government Property shall cease.

Awardee Liability for Government Property. “Loss of Government Property” means the loss, damage or destruction to Government Property reducing the Government’s expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, reasonable wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE’S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES: (I) OTAO GRANTS RELIEF OF RESPONSIBILITY AND LIABILITY FOR LOSS OF THE PARTICULAR GOVERNMENT PROPERTY; (II) GOVERNMENT PROPERTY IS DELIVERED OR SHIPPED UNDER THE GOVERNMENT’S INSTRUCTIONS AND SHIPPERS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT’S DIRECTIONS.