Request for Prototype Proposals (RPP)

Under

Medical CBRN Defense Consortium (MCDC) OTA

Number: W15QKN-16-9-1002

Solicitation Number: MCDC-RPP-18-01

Issued by:

Advanced Technology International (ATI)
MCDC Management Firm
315 Sigma Drive
Summerville, SC 29486
For the
Joint Science and Technology Office (JSTO), Defense Threat Reduction Agency (DTRA)
Through
The Joint Program Manager - Medical Countermeasure Systems (JPM-MCS)
and the
Army Contracting Command – New Jersey
Picatinny, NJ 07806-5000

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Table of Contents

Part 1 - Executive Summary

The U.S. Army Contracting Command (ACC) – New Jersey, on behalf of the Joint Project Manager for Medical Countermeasure Systems (JPM-MCS) and the Joint Science and Technology Office of the Defense Threat Reduction Agency through the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) entered into a Section 815 Prototype Other Transaction Agreement (OTA) with the MCDC through its Consortium Management Firm (CMF), Advanced Technology International, Inc. (ATI). The OTA was entered into under the authority of 10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act (NDAA), Public Law (P.L.) 114-92. This instrument is not subject to the Federal Acquisition Regulations (FAR). The total estimated amount of the effort is $10,000,000,000.00 for a period of twenty (20) years.

OTA W15QKN-16-9-1002 was signed between the Government and the MCDC on 8 April 2016. The terms and conditions agreed to under this OTA will serve as the terms and conditions for future Project Agreements and Modifications to the OTA. The USG anticipates that the type of Project Agreement awards under this OTA will be Firm Fixed Price, Cost Plus Fixed Fee, Cost Reimbursement or Cost Reimbursement Cost Share Agreements as appropriate.

The principle purpose of the OTA is to conduct Research and Development into prophylactic, therapeutic, and diagnostic technologies to enhance mission effectiveness of military personnel, collaborating with industry partners for the advanced development of medical countermeasures for chemical and biological defense. JPM-MCS will also utilize this vehicle to partner with other agencies in the Department of Defense (DoD) chemical and biological defense enterprise to collaborate with industry on applied research on candidate medical countermeasures and supporting technologies. The MCDC shall perform coordinated planning and research and development prototype efforts in support of the JPM-MCS mission through development of products in major MCS objective areas, including Detection, Prevention, and Treatment. Through the MCDC, the Government expects to increase advances in medical countermeasure systems.

In March 2013 after a competitive source selection process, the DoD awarded contract W911QY-13-C-0010 to Nanotherapeutics, Inc. (now Ology Bioservices, Inc.) of Alachua, Florida, to design, establish, and maintain the DoD Medical Countermeasures (MCM) Advanced Development and Manufacturing (ADM) capability. The facility is a flexible, multiproduct, multipurpose, 180,000-square-foot facility for biologics development and manufacturing. Based on single-use technology and disposable equipment, this facility permits development and manufacturing of MCMs faster and more effectively than most current production processes. The Government intends on utilizing the DoD ADM to facilitate lessons learned, to ensure DoD Medical Countermeasure (MCM) product development schedules are not impacted, and to reduce MCM development costs. Select projects, specifically those that include biologics manufacturing activities, will be evaluated on the proposed use of the DoD ADM.

Only those members of the MCDC who have executed (signed) the MCDC Articles of Collaboration (AoC) and are members in good standing will be eligible to submit proposals for evaluation under the OTA. An Offeror that submits a White Paper or Full Proposal prior to their signature of said AoC does so solely at their own risk and the Government accepts no responsibility for any costs associated with such a proposal submission.

As described in Article I of the basic OTA, the Government will issue Requests for Prototype Proposals (RPPs) to the Consortium Management Firm (CMF) as an agent of the MCDC. The CMF will in turn, issue a similar request to the MCDC members who have met the terms outlined, including the evaluation factors upon which the Government will evaluate each request and select a proposal(s) for performance. The individual MCDC member will then decide whether to submit proposals in response to such calls and prepare their individual proposal(s). The technical proposal must identify the specific prototype deliverable and, if applicable, the quantity of that deliverable. These MCDC member proposals will be submitted to the CMF for review for completeness and format compliance under the RPP. The CMF will transmit the MCDC member proposals to the Government. As part of this submission, the CMF will provide a summary of the project proposals submitted, inclusive of detailing significant participation of Nontraditional Defense Contractors (NDCs) and/or Cost Share and verify in the summary that all submitted project proposals are compliant. The Government shall be solely responsible for evaluation and selection of proposals for project funding from among the proposals submitted. Projects will be selected for funding by the Government to the MCDC based on the merits of the proposals received in response to the Government announcement and the requirements for each project, as a best value assessment of all proposals. **For additional guidance, review ACC-NJ Memorandum "Policy Guidance – Prototype Project" located in the Document Library of the MCDC Members Only site.**

The Government-selected projects will be funded under the Other Transaction Agreement W15QKN-16-9-1002 with the MCDC, which is administered by the CMF. The CMF will negotiate and execute a Base Agreement with MCDC member(s) that flows down applicable terms and conditions from the Other Transactions Agreement W15QKN-16-9-1002 between the Government and MCDC. The Base Agreement will serve as the baseline agreement for all Project Agreement awards to the MCDC member. Subsequently, any proposal that is selected for award will be funded through a Project Agreement issued under that MCDC member's Base Agreement. A sample of the Base Agreement may be found on the Members Only portion of the MCDC website at www.medcbrn.org. Offerors must certify on the cover page of their proposals that, if selected for award, they will abide by the terms and conditions of the latest version of the Base Agreement. Offerors are advised to contact the CMF if they have any questions regarding this requirement. Offerors are also advised to check the MCDC website periodically during the proposal preparation period for any new changes to the Base Agreement terms and conditions. As practicable, changes will be electronically forwarded to the MCDC member organizations prior to posting.

Due to limited funding, the Government reserves the right to limit Project Agreements funded under any objective area and only proposals considered to be of superior quality will be funded. The Government reserves the right to select for funding any, all, part, or none of the proposals received. Selection will be dependent upon the amount of Government funds received. The Government can refuse to fund project agreements or renegotiate proposals if there is not sufficient Nontraditional Defense Contractor participation or (in the alternative) cost sharing from a traditional contractor.

If funding is not available for one or more technically sound evaluated proposals for a project, the Government will place said proposals in the electronic "basket" file, otherwise referred to as "Basket," until funding becomes available. The available proposal ratings and definitions to be assigned to proposals as a result of the technical evaluation as well as which specific ratings will qualify a proposal

for inclusion in the Basket are located in Part 5 of this RPP. The Government reserves the right to determine which, if any, proposals are to be selected according to the published criteria. A selected proposal will reside in the "Basket" for a period of thirty six (36) months from the date the corresponding RPP is closed unless funded or the submitting MCDC member requests in writing beforehand to have it removed.

Funding availability is assigned a Confidence Level (CL) by the responsible Agreements Officer Representative (AOR) for each individual project. A project designated as a CL-1 means the AOR is highly confident funds will be available. For CL-2, funds are considered moderately confident of being available. For CL-3, funding availability is unknown.

Part 2 – Project by Objective Area

2.1 OBJECTIVE AREA: DETECTION

2.1.1 SUB-OBJECTIVE AREA: (DET 18-01): Rapid Single-molecule-based Diagnostic Platform Assessment of Pathogen Susceptibility to Anti-microbial Agent

White Paper Required: Yes

2.1.2 BACKGROUND/DESCRIPTION:

Faced with the challenges of constantly evolving and emerging biological threats, the need to identify and characterize etiological agents is being pushed closer to the time of exposure / infection. The Assays and Biomarkers Team, a component of the Joint Science and Technology Office, is developing Point of Need (PoN) diagnostic platforms that, when utilized, would lead to rapid clinical decision making such that antibiotic use and/or outcomes of patients infected with resistant pathogens are fundamentally improved compared to current standard of care Innovative approaches will provide infectious bio- and emerging agent diagnostic information, to include identification and Antibiotic Susceptibility Testing (AST).

Antibiotic sensitivity will examine the response of gram negative and gram positive bacterial pathogens to a range of antibiotics- each at a series of dilutions/concentrations sufficient to establish categorical agreement (susceptible, resistant, intermediate) relative to the gold standard method, as recommended by the Clinical and Laboratory Standards Institute.

Proposed work shall support submission for FDA clearance in support of the Joint Program Executive Office (JPEO) Joint Program Management Office for Medical Systems (JPM MCS) Diagnostic program.

2.1.3 STATEMENT OF OBJECTIVES (SOO):

The government seeks a platform capable of directly isolating bacteria from a minimum of two (2) matrices (*e.g.* whole blood and wound swabs) and evaluating directly for bacterial pathogen response to antibiotics to establish categorical agreement (susceptible, resistant, intermediate) relative to the gold standard method, as recommended by the Clinical and Laboratory Standards Institute.

The Awardee shall address the below items in order to meet the requirement for this Statement of Objectives.

a. Description of the platform technology.

b. Current TRL 3 device and path to achieving TRL 5 at end of Period of Performance shall be described.

c. Extent to which platform has been used for existing product development efforts.

d. Platform benefits.

e. Intellectual Property associated with the platform.

f. Biosafety containment/specialized or unique equipment required to support the platform.

g. Intent to deliver a Pre-Submission application to the Food and Drug Administration (FDA).

h. Ability to obtain, store and meet Centers for Disease Control and Prevention (CDC) criteria for the handling of Biological Safety Level (BSL) 1, 2, and/or 3 agents. If capability to work with BSL-2, 3 agents is absent, state willingness to collaborate with laboratories supported by BSL-2, 3 facilities.

i. Assay reproducibility, specificity and sensitivity will be demonstrated for each pathogen with regard to species identification.

j. Antibiotic sensitivity will examine the response of gram negative and gram positive bacterial pathogens to a range of antibiotics- each at a series of dilutions/concentrations sufficient to establish categorical agreement (susceptible, resistant, intermediate) relative to the gold standard method, as recommended by the Clinical and Laboratory Standards Institute (https://www.fda.gov/downloads/medicaldevices/newsevents/workshopsconferences/ucm575636.pdf; https://www.clsi.org/standards/products/microbiology/).

k. An FDA Pre-Submission Package for 510(k) approval will be developed based upon data resulting from the subject project.

l. The PoN diagnostic device is intended for use at multiple echelons of care, to include the patient bedside, physician offices, neighborhood clinics and diagnostic laboratories. Relevant characteristics for the prototype include:
    - No External Hardware or Laboratory Infrastructure Required
    - Fully Integrated from Sample to Result
    - Battery Powered or AC adapter
    - Inexpensive (*i.e.* incorporation of CMOS optics and/ or a docking station)
    - Easy to Use
        - Minimum User Steps
        - Minimal Training
        - Docking station reader or visual detection
    - Sensitivity and Specificity Comparable to Laboratory-based Molecular/PCR Methods

m. Rapid: ≤ 2 hours, Sample-to-Result

2.1.4 DATA DELIVERABLE(S):

The Awardee shall submit all deliverable report submissions to the Agreement Officer's Representative (AOR) in the applicable format.

2.1.4.1 Meeting/Teleconference Agendas and Minutes.

Provide an agenda and all supporting documentation at least three days prior to the scheduled meeting. The agenda shall include action items from the previous meetings as well as new topics to discuss. Provide meeting minutes within 3 calendar days after all meetings / teleconferences conducted. Frequency is anticipated to be bi-monthly. However, this may vary depending on critical issues.

2.1.4.2 Monthly Financial Status and Progress Report

The Awardee shall include an expenditure forecast for each reporting period and include both the monthly planned accrual, as well as, the cumulative total. The schedule update shall include the explanation for any changes on the schedule, drivers for the change, as applicable.

The progress report should also address any concerns the Awardee might have that would impact performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix format to include risk mitigation strategies.

Submission shall be 15 calendar days after the end of each month of performance. The Government will have 5 business days to respond to the report with any comments and the awardee will have an additional 5 calendar days to revise the deliverable or respond to those comments.

2.1.4.3 Final Report

A Final Report shall be submitted at the end of the contract, regardless of whether any or all of the contract options are exercised. This report takes the place of the last annual report due. (A Financial Report is still required.) The report shall narrate a complete summary of the contract performance and associated results obtained. The report shall document any outstanding problems and their potential solution, as well as any problems solved during the course of the contract, along with the solution to the solved problems. The report shall address whether the Technology Readiness Level (TRL) has been advanced, and if so, provide details as to its advancement.

2.1.4.4 Patents-Reporting of Subject Inventions

The Awardee shall furnish the Agreements Officer Representative the following for those prototype project efforts under this agreement fully funded by the Government:

a. Interim reports every twelve (12) months from the date of the award, listing subject inventions during that period and stating that all subject inventions have been disclosed or that there are no such inventions.

b. Upon request, the Awardee shall furnish the Government the filing date, serial number and title, a copy of the patent application and patent number, and issue data for any subject invention for which the Awardee has retained title.

2.1.5 PROTOTYPE DELIVERABLE(S):

- The prototype resulting from the Government project will be a Single-Molecule-based Point-of-Need antibiotic susceptibility platform that would identify the pathogen and test the response (*i.e.* changes in gene expression) of two (2) Select Agents (https://www.selectagents.gov/SelectAgentsandToxinsList.html) and two (2) ESKAPE (see below) pathogens to antibiotics in a pathogen-specific manner (as per CLSI Standards).
- Select Agents pathogens analyzed will include one (1) representative strain of *Bacillus anthracis*, and one (1) representative strain from one (1) species from the following *Burkholderia mallei, Burkholderia pseudomallei, Francisella tularensis* and *Yersinia pestis*. In addition, one (1) representative strain from each of two (2) ESKAPE pathogens shall be analyzed. ESKAPE pathogens include *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa,* and *Enterobacter spp*.

2.1.6 FUNDING CONFIDENCE LEVEL:

CL-2: Moderately confident funds will be available.

2.1.7 AGREEMENTS OFFICER REPRESENTATIVE (AOR):

Name: Dr. Diane L. Dutt
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2.1.8 ALTERNATE AOR:

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E-mail: charles.l.fromer2.civ@mail.mil

2.2 OBJECTIVE AREA: DETECTION

2.2.1 SUB-OBJECTIVE AREA (DET 18-02): Development of Multiplex Molecular Diagnostics Based on CRISPR-Cas and other Synthetic Biology Approaches

White Paper Required: Yes

2.2.2 BACKGROUND/DESCRIPTION:

Over the last several years, the mechanism by which resistance to foreign invasive and functional nucleic acid elements (e.g., from viruses) have been conferred to adaptive "immune systems" of prokaryotes. These foreign nucleic acids are integrated into clustered regularly interspaced short palindromic repeat (CRISPR) loci via genome editing controlled by specific RNA processing by a CRISPR endonuclease. Thus, the use of CRISPR in viral detection has been suggested for years; likewise, the targeting of the CRISPR locus has been proposed for bacterial strain genotyping identification. However, both sensitivity and off-target effects (i.e., specificity), limited utility even with Cas9 enzyme used in the construct. Recently, an enhanced CRISPR-Cas13/Recombinase Polymerase Assay (RPA) isothermal method, known as SHERLOCK (Specific High Sensitivity Enzymatic Reporter UnLOCKing) methodology was published (http://science.sciencemag.org/content/early/2017/04/17/science.aam9321.full) and accomplished attomolar sensitivity and single base mismatch specificity.

This capability will provide on-site near or real-time identification, confirmation and/or quantification of a biological warfare agent or disease. This will enable commanders in timely decision-making regarding health risk assessments, medical countermeasure administration, and protective equipment requirements.

2.2.3 STATEMENT OF OBJECTIVES (SOO):

DTRA-JSTO seeks to develop an ultra-sensitive and specific molecular diagnostics platform (assays and/or devices) based on genome editing methods (e.g., CRISPR, SHERLOCK or other genome editing synthetic biochemistry) for identification and diagnosis of biological warfare agents and emerging biological threat agents (including, but not limited to NIAD Category A, B, C Priority Pathogen list or CDC Bioterrorism Agent/Disease list) within 36 months.

Helpful Links:
https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens
https://emergency.cdc.gov/agent/agentlist-category.asp
https://www.selectagents.gov/SelectAgentsandToxinsList.html

The platform should take into account:

a. Identification and diagnosis at clinically relevant concentrations.
    a. Analytical and clinical sensitivity equal/superior to qPCR/RTqPCR: validated LOD ≥95% sensitive; clinical detection ≥90% sensitive at days 1-7 days post-symptoms/≥95% 1-14 days post symptom presentation.

    b. Specificity (detection of Inclusivity and ≥90% Detection of target at 10XLOD ≥80% Detection of target at 1000XLOD

b. Functional use on multiple relevant clinical sample matrices, preferably from non- or minimally invasive sampling (e.g., whole blood, saliva, urine, nasal swabs, etc.).

c. Capability for analyte/pathogen markers of multiple classes of agents (i.e., DNA viruses, RNA viruses, Gram-negative bacteria, and Gram-positive bacteria) to be combined into a notional syndromic panel.

d. Development of functional beta prototypes for use at multiple echelon of diagnostics to verify performance.

Prototype testing will involve the evaluation of the assays resilience to signature erosion, analytical performance, applicability for use at the point-of-need/care (i.e., design and considerations for use in austere environments), and readiness for pre-clinical validation in small and large animals (non- human primates).

2.2.4 DATA DELIVERABLE(S):

The Awardee shall submit all deliverable report submissions to the Agreement Officer's Representative (AOR) in the applicable format, preferably using Microsoft Office products.

2.2.4.1 Meeting/Teleconference Agendas and Minutes.

Provide an agenda and all supporting documentation at least three days prior to the scheduled meeting. The agenda shall include action items from the previous meetings as well as new topics to discuss. Provide meeting minutes within 3 calendar days after all meetings / teleconferences conducted. Frequency is anticipated to be bi-monthly. However, this may vary depending on critical issues.

2.2.4.2 Monthly Financial Status and Progress Report

The Awardee shall include an expenditure forecast for each reporting period and include both the monthly planned accrual, as well as, the cumulative total. The schedule update shall include the explanation for any changes on the schedule, drivers for the change, as applicable.

The progress report should also address any concerns the Awardee might have that would impact performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix format to include risk mitigation strategies.

Submission shall be 15 calendar days after the end of each month of performance. The Government will have 5 business days to respond to the report with any comments and the awardee will have an additional 5 calendar days to revise the deliverable or respond to those comments.

2.2.4.3 Patents-Reporting of Subject Inventions

The Awardee shall furnish the Agreements Officer Representative the following for those prototype project efforts under this agreement fully funded by the Government:

a. Interim reports every twelve (12) months from the date of the award, listing subject inventions during that period and stating that all subject inventions have been disclosed or that there are no such inventions.

b. Upon request, the Awardee shall furnish the Government the filing date, serial number and title, a copy of the patent application and patent number, and issue data for any subject invention for which the Awardee has retained title.

2.2.5 PROTOTYPE DELIVERABLE(S):

The prototype resulting from the Government project will be a diagnostic assay and/or device using specified genome editing methods for identification and diagnosis of BWA agents.

This prototype is directly relevant to worldwide force protection capability that requires prevention, diagnosis, treatment, and surveillance to protect U.S. Forces against potential infectious disease threats.

2.2.6 FUNDING CONFIDENCE LEVEL:

CL-2: Moderately confident funds will be available.

2.2.7 AGREEMENTS OFFICER REPRESENTATIVE (AOR):

Name: Charles M. Hong
Telephone: 703-767-3299
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2.2.8 ALTERNATE AOR:

Name: Charles L. Fromer
Telephone: 703-767-3299
E-mail: charles.l.fromer2.civ@mail.mil

2.3 OBJECTIVE AREA: TREATMENT

2.3.1 SUB-OBJECTIVE AREA (TRE 18-03): Late Discovery and Development of Therapeutics to Treat Symptoms of Exposure to Organophosphorus Chemical Warfare Nerve Agents

White Paper Required: Yes

2.3.2 BACKGROUND/DESCRIPTION:

OP agents act by inhibition of acetylcholinesterase (AChE) resulting in reduced hydrolysis of the neurotransmitter, acetylcholine. Accumulation of acetylcholine causes overstimulation of the acetylcholine receptor. Physiological responses comprise hypotension, rhinorrhea, wheezing, and diarrhea among other symptoms, with severe exposures leading to death. OP intoxication poses a significant threat to military forces. Current medical countermeasures constitute pralidoxime (2-PAM), a charged oxime reactivator of OP-inhibited AChE, atropine, an antimuscarinic agent that blocks the acetylcholine receptor, and diazepam to treat seizures resulting from excess acetylcholine in the central nervous system by enhancing the inhibitory effects of gamma-aminobutyric acid in the brain.

A majority of research within this arena target reactivation of OP-inhibited AChE using oxime-based compounds. Few groups have explored AChE reactivators containing different functional moieties or pursued targets other than AChE and the acetylcholine receptor to treat OP intoxication. New approaches to treat OP agent intoxication are desired with focus on a wider spectrum of targets involved in the biological cascade resulting from exposure. The current standard of care for nerve agent treatment is not effective against all of the OP chemical warfare (CW) nerve agent threats nor can it cross the blood brain barrier (BBB) to reactivate inhibited acetylcholinesterase in the brain.

2.3.3 STATEMENT OF OBJECTIVES (SOO):

The Government seeks methodologies that effectively treat against a broad range of Chemical Warfare (CW) nerve agents in addition to being blood brain barrier (BBB) permeable and therefore Central Nervous System (CNS) active. Principal Investigators (PIs) should present projects with established assays, lead compounds with defined mechanisms of action, compelling *in vitro* data and proof of concept *in vivo* data to demonstrate efficacy.

White Papers should outline plans for further preclinical testing to support transition of lead candidates into Advanced Development. Such plans may comprise secondary *in vitro* assays, Absorption/Distribution/Metabolism/Excretion (ADME) studies (*in vitro* and *in vivo*), and definitive *in vivo* studies in relevant animal models that are powered to yield statistically significant results. PI must set forth options for route of administration and scenarios for use. The Government prefers to test lead reactivator compounds against live CW nerve agent such as sarin, soman, and/or VX rather than against surrogates or OP pesticides. If the performer is not able to work with live agent, the PI

must subcontract that work to a facility with that capability. The goal is to advance lead compounds into the clinic for Phase 1 clinical trial.

Lead candidates may be drugs approved by the FDA or other health agencies. Thus, compounds must be past the structure-activity relationship phase of drug discovery. Lead optimization is permitted to improve ADME, PK/PD, and toxicology profiles. Candidates may be non-oxime reactivators of nerve agent inhibited acetylcholinesterase. Novel small molecules, peptides, peptidomimetics, or proteins will be considered as potential therapeutics to treat nerve agent exposure.

Oxime reactivators of AChE inhibited by CW nerve agent will be considered with the proviso that they are not positively charged, pyridinium-based structures. Neutral or zwitterionic oximes that cross the blood brain barrier will be considered.

Note - This topic is not interested in pursuit of protein or enzymatic bioscavengers to remove nerve agent from circulation, acetylcholine receptor inhibitors, AChE inhibitors, new anticonvulsants, gamma-aminobutyric acid or glutamate receptor modulators.

Performance Objectives:

a. Identify a safe and efficacious lead candidate for proposed indication that performs better than the current standard of care, 2-PAM .

b. Complete lead candidate development through preclinical studies to support transition to Advanced Development.

c. Set forth a compound that is stable in proposed formulation that matches Warfighter needs.

2.3.4 DATA DELIVERABLE(S):

The Awardee shall submit all deliverable report submissions to the Agreement Officer's Representative (AOR) in the applicable format.

2.3.4.1 Meeting/Teleconference Agendas and Minutes.

Provide an agenda and all supporting documentation at least three days prior to the scheduled meeting. The agenda shall include action items from the previous meetings as well as new topics to discuss. Provide meeting minutes within 3 calendar days after all meetings / teleconferences conducted. Frequency is anticipated to be bi-monthly. However, this may vary depending on critical issues.

2.3.4.2 Monthly Financial Status and Progress Report

The Awardee shall include an expenditure forecast for each reporting period and include both the monthly planned accrual, as well as, the cumulative total. The schedule update shall include the explanation for any changes on the schedule, drivers for the change, as applicable.

The progress report should also address any concerns the Awardee might have that would impact performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix format to include risk mitigation strategies.
Submission shall be 15 calendar days after the end of each month of performance. The Government will have 5 business days to respond to the report with any comments and the awardee will have an additional 5 calendar days to revise the deliverable or respond to those comments.

2.3.4.3 Patents-Reporting of Subject Inventions

The Awardee shall furnish the Agreements Officer Representative the following for those prototype project efforts under this agreement fully funded by the Government:

a. Interim reports every twelve (12) months from the date of the award, listing subject inventions during that period and stating that all subject inventions have been disclosed or that there are no such inventions.

b. Upon request, the Awardee shall furnish the Government the filing date, serial number and title, a copy of the patent application and patent number, and issue data for any subject invention for which the Awardee has retained title.

2.3.4.4 Final Report

A Final Report shall be submitted at the end of the contract, regardless of whether any or all of the contract options are exercised. This report takes the place of the last annual report due. (A Financial Report is still required.) The report shall narrate a complete summary of the contract performance and associated results obtained. The report shall document any outstanding problems and their potential solution, as well as any problems solved during the course of the contract, along with the solution to the solved problems. The report shall address whether the Technology Readiness Level (TRL) has been advanced, and if so, provide details as to its advancement.

2.3.4.5. Miscellaneous Data Submission

Required submissions may include Point Papers, Briefings, TPP, PDP, ACURO Approvals, ROB Approvals, Technical Presentations and Publications. Unless format provided, contractor format is acceptable. Deliverables shall be Microsoft Office or Adobe PDF compatible format.

2.3.4.6. Target Product Profile (TPP)

A draft TPP shall be provided via email, in Microsoft Office compatible format within 30 days after award. An updated TPP shall be submitted 60 days prior to the end of each performance period. TPP format shall comply with the Guidance for Industry and Review Staff Target Product Profile—A strategic Development Process Tool issued by FDA in March 2007

2.3.4.7. FDA Meeting Minutes

The Contractor shall provide meeting minutes documenting the proceedings of each meeting or teleconference it conducts with the FDA within 7 working days after the occurrence of each meeting or teleconference. The minutes shall be provided via email, in Microsoft Office compatible format, to the AOR for approval.

2.3.5 PROTOTYPE DELIVERABLE(S):

The prototype resulting from the Government project will be a prototype assay for medical countermeasure for treating warfighters exposed to CW nerve agents. The Government is seeking an agile development strategy that may include, but is not limited to:

a. Sequestration and/or hydrolysis of excess acetylcholine

b. Reactivation of AChE inhibited by a broad range of OP agents

This prototype is directly relevant to countering the Organophosphorus (OP) agents threat to the Armed Forces. New candidate countermeasures should be effective against a broad range of chemical warfare nerve agents and effective within the central nervous system (CNS).

2.3.6 FUNDING CONFIDENCE LEVEL:

CL-1: Highly confident funds will be available.

2.3.7 AGREEMENTS OFFICER REPRESENTATIVE (AOR):

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2.3.8 ALTERNATE AOR:

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Part 3 – White Paper and Full Proposal Submission

3.1 White Papers

Each White Paper shall address only **one (1)** sub-objective area in sufficient detail to determine technical feasibility. If an Offeror wishes a submission to be considered under multiple sub-objective areas in any given Objective Area, then a White Paper must be submitted multiple times under each pertinent sub-objective area.

3.1.1 White Paper Deadline and Feedback

The due date for White Papers is no later than as indicated on the front page of the RPP**. Full Proposals will not be considered under this RPP unless a White Paper was received on or before the White Paper due date specified above**. A Full Proposal may be submitted by any Offeror who submitted a White Paper regardless of the feedback provided by the Government.

White Papers submitted in accordance with the RPP by the time and date specified will be distributed to the POC identified in the RPP. Reviewers will evaluate the White Papers in accordance with guidelines provided in the RPP. He or she will provide the Offeror feedback based on the Government needs, technical merit of the proposed effort, and the funding available as follows:

- Technical Merit – Green or Red
- Funding Available – Yes (confidence level provided) or No
- Proposal Submission Recommendation – Yes or No
- Narrative Comments

Green – The proposed solution has significant technical merit and has the potential to address the requirements of the sub-objective area. Certain aspects of the proposed solution may require refinement.
Red – The proposed solution does not have sufficient technical merit and is not likely to address the requirements of the sub-objective area.

A summary of any Government feedback will be provided to the White Paper submitter through its CMF for dissemination. However, a favorable response does not assure a subsequent award. The Government does not intend to award a Project Agreement based on this request for White Papers or otherwise pay for the information requested. Submission of a White Paper is mandatory in order to submit a Full Proposal that may be considered for funding. Offerors are responsible for all expenses associated with responding to this RPP.

Upon receipt of feedback, Offerors will have the opportunity to submit proposals based upon the Government's feedback provided. The decision to submit a proposal based upon the feedback of the Offeror is solely at the discretion of the Offeror and the feedback provided is not a guarantee of future project funding. If all White Paper submissions in a specific sub-objective area receive a "proposal

submission recommendation" of "NO" in the feedback, the Government may inform the Offeror that they will not accept any proposal submissions to that sub-objective.

3.1.2. White Paper Instructions

White Paper submissions are mandatory for all three projects in order to submit a Full Proposal. We recognize that considerable effort is required to prepare a competitive proposal to DTRA/JSTO. Accordingly, White Papers are being used to minimize the burden on the proposing organizations. White Papers are intended to provide intermediate feedback as to whether the Offeror is on track in gathering and articulating some of the key information required for a successful project and whether that project would be appropriate for funding from the JPM-MCS/JSTO. While White Papers are typically requested at the time a RPP is released, in some cycles they may be requested prior to release of a RPP.

The content of the white paper should be generally consistent with the information to be provided in the Full Proposal. White Papers should include the following:

- **Project Title**. This is the title of the proposed effort, not the title of the area objective in the Annual Technology Plan.
- **Background / Problem to be Addressed.** This section provides a summary of what problem the proposed technology addresses.
- **Objective and Sub-Objective**. The RPP Objective and Sub-Objective to which the Offeror intends to propose must be included.
- **Sub-Objective POC:*** Identified in the RPP.
- **Government POC/Stakeholders**. (Armed Service / Program(s) that will be benefited by the proposed project).** This discussion should also include a statement indicating what Government office and individual has been or should be engaged, to champion the proposed solution as applicable. Contact information for the Government POC such as phone number and e-mail should be listed.
- **Participants.** Provide a brief overview of the project team, their roles and responsibilities for the project, and their business status (i.e. nontraditional contractor, small business, veteran own small business, etc.). Also include a brief discussion of what facility or facilities will be utilized. A summary table that identifies each project participant, their role and key contributions to the project would suffice to meet this requirement.
- **Project Milestones**. Provide an overview of key milestones and deliverables. A tabular presentation of this information may also be used to provide this information.
- **Outline of Technical Strategy and Key Innovations.** This section provides a summary of how the project will approach the problem, and the key innovations expected from the project. If the proposed effort is follow-on work to a previously funded effort, include a brief synopsis of what was accomplished, the previous project's results, and how the proposed effort builds upon previous work.
- **Intellectual Property/Data Rights Assertions**. Include a discussion on intellectual property or data rights assertions.
- **Significant Materials and Equipment Required.** This paragraph should include a list of materials and equipment to be procured. Estimate if necessary what new equipment will need to be purchased and or refurbished. Also indicate if the materials will be consumable or not consumable.

- **Technical Maturity.** Provide a summary of the current level of maturity of the technology your project intends to address.
- **Success Metrics -** Indicate the performance improvement metrics (e.g. capability, affordability, weight, etc.) that will be developed for the project and how they will be measured.
- **Implementation and Transition –** Include an overview of how the technological solution proposed will be implemented as an end item and/or brought to market in a commercial application.

* This will be the recipient of your White Paper and proposal for evaluation.

**This is intended to be an organization(s) or individual(s) who will benefit from the technology proposed. If this POC is different than RPP POC, they are strongly encouraged to contact the RPP POC so their feedback can be considered as part of the evaluation.

Each whitepaper is limited to five pages plus a cover page (6 pages total). The following formatting requirements apply:

- Times New Roman 10 (or larger) Single-spaced, single-sided, 21.6 x 27.9 cm (8.5 by 11 inches).
- Smaller type may be used in figures and tables, but must be clearly legible.
- Margins on all sides (top, bottom, left, and right) should be at least 2.5 cm (1 inch).

The page limit is intended to focus the responses on a few essential and important details of a proposal. There is not enough room to address peripheral issues or to provide the complete content required for a Full Proposal. The **White Paper** should constitute a fact sheet for the proposed project. Background information, rationale, detailed elaboration, and other information not specifically requested in the **White Paper** should be held for incorporation into a Full Proposal.

White Papers must include a cover sheet that includes:

- RPP Solicitation number and Sub-Objective Number
- Project title
- Primary point of contact, including name, address, phone and e-mail contact information
- **A proprietary data disclosure statement, when proprietary data is included**

White Papers must be **received by the time and date specified in the RPP.**

No other form of debriefing will be provided for whitepapers. However, any such favorable response does not assure a subsequent award. The JPM-MCS/JSTO does not intend to make an award based on this request for White Papers or otherwise pay for the information requested. Submission of a White Paper is voluntary and does not obligate the JPM-MCS/JSTO or the MCDC CMF to pay or entitle the submitter to payment. Respondents are solely responsible for all expenses associated with responding to this White Paper.

Note: MCDC members may communicate with the Government AOR and/or Government Alternate AOR identified within the RPP during the White Paper solicitation window from release of the RPP through the White Paper due date, however these communications must take place via telephone or e-mail only, not face-to-face. The AOR may or may not contact a company regarding a White Paper submission if clarification is needed in order to provide adequate feedback to the company.

White Papers shall be submitted by the date and time specified above using the form located here:

DET-18-01: Rapid Single-molecule-based Diagnostic Platform Assessment of Pathogen Susceptibility to Anti-microbial Agent

https://secure.ati.org/mcdc/DET-18-01/whitepaper.html

DET-18-02: Development of Multiplex Molecular Diagnostics Based on CRISPR-Cas and other Synthetic Biology Approaches

https://secure.ati.org/mcdc/DET-18-02/whitepaper.html

TRE 18-03: Late Discovery and Development of Therapeutics to Treat Symptoms of Exposure to Organophosphorus Chemical Warfare Nerve Agents

https://secure.ati.org/mcdc/TRE-18-03/whitepaper.html

A receipt confirmation, including a unique reference number will be provided by email.

3.2 Full Proposals

Full Proposals in response to this RPP must be received as indicated on the front page of the RPP.

Note: MCDC members may communicate with the Government AOR and/or Government Alternate AOR identified within the RPP with clarification questions during the Full Proposal solicitation window. These communications must cease following the due date and time for Full Proposal submission identified in the RPP. During the evaluation of the Full Proposal, communication is prohibited. Should the Government customer require additional information, they must contact the JPM-MCS Program Manager and the Agreements Officer.

A Full Proposal submission must consist of three volumes: Volume 1: Technical (with appendices) Volume 2 Management and Resources (with appendices) & Volume 3: Cost. Full Proposal shall be submitted by the date and time specified above using the form located here:

DET-18-01: Rapid Single-molecule-based Diagnostic Platform Assessment of Pathogen Susceptibility to Anti-microbial Agent

https://secure.ati.org/mcdc/DET-18-01/proposal.html

DET-18-02 Development of Multiplex Molecular Diagnostics Based on CRISPR-Cas and other Synthetic Biology Approaches

https://secure.ati.org/mcdc/DET-18-02/proposal.html

TRE 18-03: Late Discovery and Development of Therapeutics to Treat Symptoms of Exposure to Organophosphorus Chemical Warfare Nerve Agents

https://secure.ati.org/mcdc/TRE-18-03/proposal.html

The proposal format provided below is mandatory. Proposals not following this format will not be considered for award. Any general questions received and corresponding answers (without attributable proprietary data) will be posted to the Members Only portion of the MCDC website.

Proposals received after the time and date specified will not be evaluated.

3.2 Submissions of Proposals

Full Proposals must be submitted to the CMF using the above link. Neither the Government nor CMF can make allowances/exceptions for submission problems encountered by the Offeror. If the Offeror receives errors or fails to provide the full submission prior to the submission deadline, the submission will not be accepted.

3.2.1 Submission Format

Files should be submitted in Microsoft Office formats or searchable Adobe Acrobat (PDF – portable document format) as indicated below. Other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .xlsx, .xls .pdf, etc.). Filenames should not contain special characters. Apple/Macintosh users must ensure the entire filename and path are free of spaces and special characters.

- **Volume 1 Technical Proposal:** One MS Word (.docx/.doc or .pdf)
  Volume 1 Appendices: As described below (in separate documents):
  - Appendix A – Statement of Work: One MS Word (.docx/.doc)
  - Appendix B – Proof of Maturity (if required): One MS Word (.docx/.doc or .pdf)
  - Appendix C – Integrated Master Schedule: One MS Project (.mpp) file
  - Appendix D – Work Breakdown Structure: One MS Word (.docx/.doc or .pdf) file

- **Volume 2 Management and Resources**: One MS Word (.docx/.doc or .pdf)
  Volume 2 Appendices: As described below (in separate documents).
  - Appendix A – Corporate Experience. One MS Word (.docx/.doc or .pdf)
  - Appendix B – Resumes of Key Personnel. One MS Word (.docx/.doc or .pdf)
  - Appendix C – Facilities and Equipment. One MS Word (.docx/.doc or .pdf)
  - Appendix D – Proprietary Data/Data Rights Assertions. One MS Word (.docx/.doc or .pdf)
  - Appendix E – Nontraditional Defense Contractor Warranties and Representations. One MS Word (.docx/.doc or .pdf)

Volume 3 Cost: One MS Word (.docx/.doc or .pdf) for Sections I-V AND One Excel (.xlsx/.xls) for

Section VI and VII. *The preference is for the Excel file to contain working formulas.*

Part 4 – Proposal Preparation Instructions

4.1 General Instructions

Technical and cost proposals must be submitted in separate volumes, and shall remain valid for three (3) years unless otherwise specified by the Offeror in the proposal. Proposals shall reference this RPP number and Sub-objective Area (i.e. RPP-18-01, DET 18-01 or DET 18-02 or TRE 18-03))

For this RPP, Offerors may submit multi-year proposals. The total length/duration of the technical effort is expected to vary by project complexity.

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are advised that only the MCDC's CMF, with the approval of the Government's Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected projects as result of this RPP.

4.2 Nontraditional Defense Contractor

A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the RPPs, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.

Each project awarded under the OTA must contain either significant nontraditional defense contractor participation or one-third cost sharing. If the contractor is not proposing one-third cost share, the Offeror shall assert either (1) it is a nontraditional defense contractor or (2) proposes a nontraditional defense contractor as a team member/subcontractor by submitting a signed Warranties and Representations (Enclosure 1) for each nontraditional contractor, specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor. Although the Technical proposal may make reference to the use of Nontraditional Defense Contractor participation, it is important that the detailed information is documented in the Warranties and Representations. Failure to support significant nontraditional participation will make the proposal ineligible for award.

4.3 Cost Share

Cost share is not a mandatory requirement. However, if a proposal does not contain at least one nontraditional defense contractor participating to a significant extent, then it is anticipated the proposal will contain at least one third of the total Project cost as cost share. Beyond that, cost sharing is encouraged if possible as it leads to stronger Government-contractor technology leveraging.

Cost sharing is defined as the resources expended by the award recipients on the proposed Statement of Work and subject to the direction of the project's management. If cost sharing is proposed, then the MCDC Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution as discussed below. If the offer contains multiple team members, this information shall be provided for each individual team member providing cost share.

Cost sharing includes any costs a reasonable person would incur to carry out (necessary to) Statements of Work not directly paid for by the Government. There are two types of cost sharing: (1) Cash: Outlays of funds to perform the SOW. Cash includes labor, materials, new equipment, and relevant subcontractor efforts. Sources include new IR&D funds, profit or fee from another contract, overhead or capital equipment expense pool. New IR&D funds offered to be spent on the Statement of Work and subject to the direction of the project's management may be utilized as cost share. (2) In-Kind: Reasonable value of in-place equipment, materials or other property used in performance of the project. All cash or in-kind cost sharing availability must be clearly and convincingly demonstrated by the MCDC Offeror. The MCDC Offeror will be required to provide financial reporting with appropriate visibility into expenditures of Government funds vs. private funds. Parallel research that might be related to the project, but will not be part of the SOW or subject to the direction of the project's management will not be considered for cost sharing. All costs, fees, profits, G&A, bid and proposal costs, or intellectual property value incurred prior to the project award will not be accepted.

Unacceptable cost share sources include the following:

a) Sunk costs or costs incurred before the start of the proposed project
b) Foregone fees or profits
c) Foregone G&A or cost of money applied to a base of IR&D
d) Bid and proposal costs
e) Value claimed for intellectual property or prior research
f) Parallel research or investment, i.e., research or other investments that might be related to the proposed project but which will not be part of the SOW. Typically these activities will be undertaken regardless of whether the proposed project is awarded.
g) Off-Budget Resources, i.e., resources that will not be risked by the Offeror in performance of the proposed project, will not be considered when evaluating cost share.

4.4 Proposal

The Proposal must include the requested information in the format provided below. Each proposal must address only one Sub-objective Area and factor in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluations factors set forth in the RPP.

This section shall state under which Sub-objective Area the proposal is being submitted for evaluation (e.g. DET-18-01). Volume 1 – Technical is limited to **50 pages** and Volume 2 Management and Resources is limited to **25 pages**. Both volumes are restricted further: font size 10 or larger, appendices do not count against the page limit, single-spaced, single-sided, 21.6 x 27.9 cm (8.5 by 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 2.5 cm (1 inch). The page limitation excludes the cover page, project awardee/contractor information sheet, table of contents, and all appendices. Pages in excess of this limitation may not be considered.

To ensure proposals receive proper consideration, the proposal format shown below is mandatory. The Technical Volume shall include a detailed discussion for each Section I through IV below. If there are any items which are not applicable to a specific proposal, include the section topic in the proposal and annotate the section as not applicable with a short explanation as to why it is not applicable. All major sections (i.e. those listed below that begin with a capital Roman numeral) should start on a new page.

4.4.1 Volume 1: Technical

I. Cover Page – A Cover Page is required and shall include the following information and statements:

- Prototype Proposal Submission by:
- Base Certification Statement (see Part 1):
- RPP #:
- Sub-objective Area:
- Project Title:
- Project Proposed Period of Performance:
- Total Proposed Cost:
- Technical POC:
- Contractual POC:
- Prototype Proposal Submission Date:
- Authorized Signatory Contact Info:

II. Project Awardee/Contractor Information Sheet – A Project Awardee/Contractor Information Sheet is required and shall include the following information. If an item is non-applicable, then that section should be marked "non-applicable."

- Proposal Project Title:
- Project Awardee/Contractor Name and Address:
- DUNS #:
- Cage Code:
- Tax Payer ID Number:
- Business Size / Type:
- Proposal Validity Period (120 days from proposal submission):
- Agreement Type (Cost Plus Fixed Fee, Cost Reimbursement, Cost Reimbursement/Cost Share, or Firm Fixed Price):
- Facility Clearance Level:
- List of Team Members:
- Data Rights (If there is any exception to providing the Government with unlimited rights in technical data than it shall be highlighted here):

III. Table of Contents

IV. Technical Prototype Proposal

a. Project Overview – The project overview segment of the technical proposal must address the SOW in sufficient detail to permit evaluation from a technical perspective. This segment allows MCDC Offerors to present briefly and concisely the important aspects of the proposal to evaluators. The segment should present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core concepts of the proposed project.

b. Technical Approach and Plan – The technical approach and plan section must provide sufficient technical detail and analysis to support the technical solution being proposed in alignment with the outlined objectives, requirements, and proposed milestone timeline of the project for the project. It is not effective to simply address a variety of possible solutions to the technology problems. This segment allows Offerors to present a detailed summary of the progression of efforts to be accomplished which aligns with the SOW, IMS and all deliverables.

4.4.2 Volume 1 Appendices

Appendices to the proposal are required. They provide the Offeror an opportunity to provide additional information that may enhance or supplement the technical proposal. Appendices that contradict each other, the technical proposal, the management and resources proposal or the cost proposal will result in unfavorable government evaluations. If Proof of Maturity is required by a prototype project (See applicable section 2 above) then Appendix B is required.

The Offeror is required to submit the following appendices:

A. Statement of Work – **NO PAGE LIMIT.** The Offeror is required to provide a detailed SOW in accordance with guidance prescribed in the Objective Area requirements (above). Enclosure 2: Statement of Work Template outlines the required format. The SOW developed by the Offeror and included in the proposal is intended to be incorporated into a binding agreement if the proposal is selected for award. If a proposal is submitted without an SOW, then the proposal will be deemed non-responsive and no award will be made. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the agreement inflexible. If the offer contains multiple team members, the SOW shall include a summary section that states the portion of the effort that each team member will be conducting and a schedule indicating when each team member will participate in the SOW effort. **DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT**. Based on the results of the Technical Evaluation, the Government reserves the right to negotiate and revise any or all parts of SOW. Offerors will have the opportunity to concur with revised SOW and revise cost proposals as necessary.

B. Proof of Product Maturity (see applicable section 2) – **LIMITED TO 20 PAGES.** This appendix is to contain the evidence of product maturity as described in the applicable Section 2 above. NOTE: Not all prototype projects may require a proof of product maturity

C. Integrated Master Schedule – NO PAGE LIMIT. Provide a schedule (e.g. Gantt chart) that clearly shows the plans to perform the program tasks in an orderly, timely manner. Provide each major task identified in the SOW as a separate line on the program schedule chart. Each of the tasks should include milestones that relate to specific deliverables during the task. The scheduled work shall align with the associated cost in the cost proposal. The IMS shall include any key technical and/or schedule risks, their potential impacts, and mitigation plans, as applicable.

D. Work Breakdown Structure – NO PAGE LIMIT. The WBS shall align with both the SOW

and the IMS. The WBS precisely defines the work to be accomplished for each activity. The level of detail required shall align with the SOW/IMS and the cost proposal.

4.4.3 Volume 2: Management and Resources

To ensure proposals receive proper consideration, the proposal format shown below is mandatory. The Management and Resources Volume shall include a detailed discussion for each Section I through VII below. If there are any items which are not applicable to a specific proposal, include the section topic in the proposal and annotate the section as not applicable with a short explanation as to why it is not applicable. All major sections (i.e. those listed below that begin with a capital Roman numeral) should start on a new page.

I. Cover Page – A Cover Page is required and shall include the following information and statements:

- Prototype Proposal Submission by:
- Base Certification Statement (see Part 1):
- RPP #:
- Sub-objective Area:
- Project Title:
- Project Proposed Period of Performance:
- Total Proposed Cost:
- Technical POC:
- Contractual POC:
- Prototype Proposal Submission Date:
- Authorized Signatory Contact Info:

II. Project Awardee/Contractor Information Sheet – A Project Awardee/Contractor Information Sheet is required and shall include the following information. If an item is non-applicable, then that section should be marked "non-applicable."

- Proposal Project Title:
- Project Awardee/Contractor Name and Address:
- DUNS #:
- Cage Code:
- Tax Payer ID Number:
- Business Size / Type:
- Proposal Validity Period (120 days from proposal submission):
- Agreement Type (Cost Plus Fixed Fee, Cost Reimbursement, Cost Reimbursement/Cost Share, or Firm Fixed Price):
- Facility Clearance Level:
- List of Team Members:
- Data Rights (If there is any exception to providing the Government with unlimited rights in technical data than it shall be highlighted here):

III. Table of Contents

IV. Program Management: The Offeror shall describe how their overall management approach will comply with the requirements to control, coordinate, and direct performance; organize and manage resources including the selection and management of subcontractors; describe policies and procedures that ensure the project will be effectively managed and achieve the technical/scientific requirements as established in the SOW. The Offeror's approach should address: milestones where Government information/activity is required and timeline dependencies for subsequent awardee activities; a staffing plan which ensures continuity of services, and compliance with the proposed schedule.

V. The Offeror shall describe its approach to Quality Assurance and Quality Control (QA/QC). This approach shall describe the QA/QC systems for each of the Offeror's partners/subcontractors.

VI. The Offeror shall demonstrate an understanding of risk management by identifying the relevant key technical/program/cost risks, analysis process, and providing mitigation options for each identified risk.

VII. For efforts that include biologics manufacturing activities the Offeror shall propose to use the DoD ADM. Alternatively, the Offeror shall provide clear and compelling rationale as to why it is in the DoD's best long-term interest for the Offeror not to use the DoD ADM.

VIII. Regulatory strategy. The Offeror shall describe its regulatory strategy to achieve project objectives. The description shall address adherence to FDA quality requirements and/or any other certifications.

4.4.4 Volume 2: Appendices

Appendices to the proposal are required. They provide the Offeror an opportunity to provide additional information that may enhance or supplement the management and resources proposal. Appendices that contradict each other, the technical proposal, the management and resources proposal or the cost proposal will result in unfavorable government evaluations.

A. Corporate Experience – **LIMITED TO 5 PAGES.** The Offeror shall provide evidence of corporate experience relevant to the objectives in Section 2 of the RPP. The Offeror shall provide evidence that proposed personnel have the technical, academic, and professional knowledge and experience to accomplish the objectives.

B. Resumes of Key Personnel – **NO PAGE LIMIT.** Include the resumes of key Offeror, team member, subcontractor and university personnel who will be assigned to and work on this project. Indicate what percentage of their total available work time each will devote to this project. Each resume must be no more than two (2) pages in length.

C. Facilities and Equipment – **LIMITED TO 10 PAGES**. The Offeror shall describe the facilities, staffing, equipment, operational controls and technical skills required to perform the objectives specified in Section 2 of this RPP. The description will include how these resources will be acquired (e.g. owned, rented, subcontracted, etc…). The Offeror shall provide a logical flow of performance in each facility whether at the prime or sub-awardee,

and the major equipment proposed for use in each.

D. Proprietary Data/Data Rights Assertions – **NO PAGE LIMIT**. Each proposal submitted by the Offeror in response to a RPP shall include a list of the Category A, B and C data to be used or developed under the proposal if selected (sample table below). Rights in such Data shall be as established under the terms of the Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. Based upon Government direction, the CMF will incorporate the list of Category A, B and C data and the identified rights in the award.

Technical Data or Computer Software to be Furnished with Restrictions	**Basis for Assertion**	**Asserted Rights Category (A, B, C)**	**Name of Organization Asserting Restrictions**	**Milestone # Affected**

E. Nontraditional Defense Contractor Warranties and Representations – Include signed copies of Enclosure 1 for any nontraditional defense contractor proposed.

4.6 Volume 3: Cost

The objective of the Cost Proposal is to provide sufficient information to substantiate that the overall proposed cost is realistic, reasonable and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of the cost can be conducted and reflect the best cost for the project. The cost proposal must be consistent with information provided in the realism form. **The IMS and cost proposal information shall conform to the Work Breakdown Structure (WBS) of the SOW. Offerors may add lower levels of detail as needed.** (NOTE: *Proposals that deviate substantially from these guidelines or that omit substantial parts or sections may be found unresponsive and may be eliminated from further review and funding consideration.)*

The Cost Proposal must include the requested information in the format provided below:

Volume 3: Cost

I. Cover Page (as outlined in the technical volume above)

II. Project Awardee/Contractor Information Sheet (as outlined in the technical volume above)

III. Table of Contents

IV. Cost Narrative – The Cost Narrative is used to assess various criteria. The agreements official will use this section to determine reasonableness, allowability, and allocability of proposed costs in determination of an overall fair and reasonable proposed cost. The Cost Narrative section should also give substantiation and written explanation of proposed costs. Breakdowns should be as accurate and specific as possible.

The Cost Narrative must include, at a minimum, details on the following categories for the proposed cost:

Direct Labor Rates: The Offeror shall identify the labor category for all proposed personnel, hourly rate associated with each labor category, and proposed hours for each category. Documentation to support proposed labor category rates shall be provided in the cost proposal submission in the form of Government Agreement or Recommendation or payroll records. Order of preference for supporting documentation is as follows: Government Agreement or Recommendation (DCMA FPRA or FPRR or DCAA Audit); Payroll records for proposed personnel.

Team Members/Subcontractors: For proposed team members/subcontractors of which the individual proposed price is greater than or equal to $150,000, a detailed proposal broken out by element of cost for each of the team members/subcontractors proposed must be provided in the Offeror's cost proposal submission. Team member/subcontractor proposals must be as detailed as possible, but at a minimum must include the following: labor categories and hours specified, list of material/equipment and other direct costs, travel detail, lower tier subcontractors/consultants identified, indirect costs and fee. The Offeror must also state that a cost and price analysis has been performed on all team members/subcontractors and provide documentation supporting the determination of cost/price reasonableness upon request. Offerors shall also provide a list of all team members/subcontractors and a total cost for each team member. Please identify if each team member/subcontractor is a traditional or nontraditional defense contractor.

Consultants: For proposed Consultants of which the individual proposed price is greater than or equal to $150,000, a detailed proposal broken out by element of cost (i.e. labor categories, associated hours, travel, other direct costs, etc.) for each of the Consultants shall be provided in the prime Offeror's cost proposal submission. The Offeror shall provide a list of all Consultants and a total cost for each consultant. The Offeror must also state that a cost and price analysis has been performed on all Consultants and provide documentation supporting the determination of cost/price reasonableness. Offerors shall identify if each Consultant is a traditional or nontraditional defense contractor for all Consultants no matter their proposed cost.

Material/Equipment: An itemized list of the material/equipment proposed (i.e. a bill of

materials) must be provided in the cost proposal submission. **Additionally, for each piece of proposed material/equipment with a unit cost greater than or equal to $25,000,** a copy of the basis of cost documentation (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) that indicates the item(s) being purchased, quantity and unit cost of each item) must be included in the Offeror's cost proposal.

Travel: The Offeror must provide an estimate of the travel required for the proposed effort. A basis of cost for all travel elements must be included in the proposal, to include the nature of any proposed travel, estimated number of trips required, destinations, mode and cost of transportation, and number of man-days per trip. Note: Offerors are expected to be cost-conscious regarding travel, for example, the Offeror should propose in accordance with the Joint Travel Regulation. Travel costs that are deemed excessive (e.g., first class airfares, exorbitant hotel room charges, etc.) will be adjusted to a reasonable cost.

Other Direct Costs: The Offeror must identify and provide a detailed description of any Other Direct Costs that do not fit into the cost elements above, including the basis for determining those costs (i.e., vendor quotes, catalog pricing data, company estimating procedures, etc.), in the Offeror's cost proposal submission. **Additionally, for each proposed Other Direct Cost with a unit cost greater than or equal to $25,000,** a copy of the basis of cost documentation (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) must be included in the Offeror's cost proposal.

Indirect Costs: The Offeror shall identify all proposed indirect costs (e.g., labor overhead, fringe benefits, material overhead, G&A) and associated rates and provide supporting documentation. Documentation to support proposed indirect costs shall be provided in the cost proposal submission in the form of Government Agreement or detailed rate make up for the indirect costs. If selected for award, the Offeror will be expected to submit the expense pools and allocation bases that make up the indirect rate, the previous 3 years of forecasted and actual indirect rates, and a breakdown of the costs that make up 2-3 items in each expense pool. Order of preference for supporting documentation is as follows: Government Agreement or Recommendation (DCMA FPRA or FPRR or DCAA Audit); detailed rate make up as identified above. To the extent possible, information shall be provided in working formulas in Excel. For ease this information can be provided in the Cost Formats Section.

Alternately, in lieu of providing the supporting documentation for your indirect costs within the cost proposal submission, if the Offeror can obtain appropriate Government assistance on its own, the Offeror may provide a letter from the cognizant Government audit agency stating that, based upon their review of the Offeror's proposal, the indirect rates used in the proposal are approved by a Government agency and were applied correctly in this specific proposal.

Cost of Money: If applicable, Cost of Money should be proposed on a separate line from indirect costs. If the Offeror has a Government recommendation or agreement document to support this cost element, the documentation should be provided with the cost proposal.

Profit/Fee: Proposing Profit/Fee is allowable to include in a cost proposal when cost share is not being contributed by the Offeror.

Excessive Pass Through. It is anticipated that the Government will not pay excessive pass-through charges on projects. Therefore, if the Offeror intends to subcontract more than 70 percent of the total cost of the work to be performed under the project, a description of the "added value" provided by the Offeror as related to the work to be performed by the subcontractor(s) must be included in the Cost Narrative. This provision is in effect at all tiers. "Added value" means that the Offeror performs subcontract management functions that the government determines are a benefit (e.g., processing orders of parts or services, maintaining inventory, reducing delivery lead times, managing multiple sources for requirements, coordinating deliveries, performing quality assurance functions).

V. **Basis of Estimate (BOE)** – BOEs shall provide in sufficient detail the basis, rationale, estimating methodology, and historical database used to derive the proposed labor and material estimates to support the proposed costs on tasks associated with the effort. The supporting documentation should be comprehensive enough to enable to a cost/price reasonableness and realism assessment. If the Offeror uses parametric methods as part of the estimating methodology, the Offeror shall identify the model/tool used (name and version) and provide a copy of all model inputs, default values used, rationale for setting input parameters, and model generated outputs. Offeror shall provide rationale to support model calibration and validation. If historical data is used for estimating, the Offeror shall provide a description of the comparability of projects and supporting rationale for any adjustments made to the metrics used Cost Formats – An Excel workbook shall be provided detailing each element of cost/price included in the Cost Narrative section. All elements of cost/price shall be totaled and summed up to derive an overall total cost for the proposed effort.

VI. **Cost Formats** – An Excel workbook shall be provided detailing each element of cost/price included in the Cost Narrative section. All elements of cost/price shall be totaled and summed up to derive an overall total cost for the proposed effort.

VII. **Realism** – This section provides technical evaluators with high-level cost data in order for them to determine if the proposed cost is realistic as compared to the scope of work proposed. This information must be consistent with the cost proposal. Include the following table as a summary of the cost by cost element:

Realism Form **to be completed by Offeror and evaluated by Technical Evaluators***		
Cost Element	**Total Proposed Cost**	**Description/Explanation**
Labor	*$ 100,000.00*	*750 hrs of engineering and 250 hours of program management*
Labor Hours	*1,000.0*	
Subcontractors	*$ 50,000.00*	*Sub A - $25,000; 250 engineering hours* *Sub B - $25,000; 250 hours of Testing*
Subcontractors Hours	*500.0*	
Consultants	*$ 10,000.00*	*Design engineer -supporting all tasks*
Consultants Hours	*100.0*	
Material/Equipment	*$ 75,000.00*	*steel, modeling software*
Other Direct Costs	*$ 1,000.00*	*ship testing materials to lab*
Travel	*$ 5,000.00*	*2 trips 2 day to Ft. Detrick from Charleston, for 2 people*
Indirect costs	*$ 48,200.00*	*approved by DCAA 30 Sept 15*
Total Cost	*$ 289,200.00*	
Fee	*$ 14,460.00*	*5% of Total cost*
Total Cost Plus Fee	*$ 303,660.00*	
Cost Share **(if cost share is proposed then fee is unallowable)**	*$ 0*	
Total Project Cost	*$ 303,660.00*	
*Items in italics are provided as samples only. Offeror must complete table with the applicable information.		

FOR OFFICIAL USE ONLY/ PROCUREMENT SENSITIVE

4.7 Inconsistencies

Any inconsistency between the proposed performance, cost, or price of a project should be explained in the proposal. Any significant inconsistencies, if unexplained, raise a fundamental issue of the Offeror's understanding of the nature and scope of work required and of their financial ability to perform if selected, and may be grounds for non-selection of the proposal or grounds for adjusting the probable cost to the Government. The burden of proof as to cost and technical credibility rests with the Offeror.

4.8 Proposal Preparation Cost

The cost of preparing proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

Part 5 – Selection

5.1 Proposal Source Selection

For each Sub-objective Area, the Government expects competition and will conduct a proposal source selection in accordance with the evaluation factors detailed below. It is the Government's intention to negotiate, select and fund the "best value" project(s) from the submitted prototype proposals. The Government intends on making only one (1) award but reserves the right to not make an award or award multiple proposals. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

a) Select the proposal (or some portion of the proposal) for award;
b) Place the proposal in the Basket if funding currently is unavailable; or
c) Reject the proposal (it will not be placed in the Basket).

The results of these evaluations will be forwarded to the CMF for notification of Offerors. A Basis of Selection (BOS) will document the Government's decision, and negotiations will be conducted with the Offerors who were selected for award contingent on funding availability.

5.2 Evaluation Process

The BOS will be prepared for every Sub-objective Area as a result of this RPP. The BOS will be an integrated assessment of each proposal evaluation to include the rating in accordance with the technical benefit evaluation, the cost/price evaluation, and the proposed nontraditional defense contractors/cost sharing evaluation. The selection will be based upon the following three evaluation factors, listed in decreasing order of importance:

- Technical Benefit
- Management and Resources
- Cost

The Technical Benefit and Management and Resources factor ratings will be based on an adjectival merit rating system supported by narrative justification. The Cost will be a narrative assessment. For evaluation purposes, Technical Benefit is more important than Management and Resources. Management and Resources is more important than Cost. The Government will weigh any increase in the Technical Benefit Factor Merit Rating against any additional cost to determine if the parity of the relationship warrants the paying of additional cost for higher Merit Ratings.

5.2.1 Technical Benefit Evaluation

The overall Technical Benefit merit rating will be based on an integrated assessment of the below Technical Benefit Factors. The Technical Benefit Factor will receive an adjectival rating of Excellent, Good or Poor. Based on these adjectival ratings, an overall Technical Benefit merit rating will be determined using the same adjectival ratings as follows: Excellent, Good or Poor.

If required, the government will assess Appendix I, Proof of Product Maturity, to determine if sufficient evidence to support the claim of prototype maturity has been provided. Offerors who do not submit this appendix or if the evidence is deemed insufficient will receive a poor Technical Benefit evaluation and no further evaluation of the proposal will be conducted.

The ratings for the Technical Proposal will be based on the Government's assessment of the following:

- Likelihood of the proposed solution to successfully achieve the requirements of the objective area as defined in the RPP.
- Ability to describe the efforts required to achieve the objectives in a clear, concise and complete Statement of Work (SOW).
- Ability to clearly explain the feasibility, achievability, and completeness of the technical approach that will be employed to meet or exceed the requirements of the SOW.
- The IMS will be evaluated to ensure that it includes all proposed tasks (and associated technical elements); to ensure all deliverables are included; to ensure appropriate risks have been identified and considered, and to ensure it clearly shows all tasks required to complete the effort and that their sequence and durations are appropriate.
- Alignment of the IMS, SOW, WBS, and prototype project objectives.
- Extent proposed effort is a technological breakthrough solution that is an innovative or novel approach, or is a brand new technology that is currently not readily available.

The following adjectival merit ratings will be used:

Evaluation	**Merit Rating**
The proposal demonstrates an excellent understanding of the objectives and the approach and has a high probability of achieving all or most of the requirements of the objective area. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is low.	Excellent
The proposal demonstrates a good understanding of the objectives and the approach and has a good probability of achieving most of the requirements of the objective area. Strengths outweigh any weaknesses, or are offsetting and will have little or no impact on performance. Risk of unsuccessful performance is no worse than moderate.	Good
The proposal demonstrates little or no understanding of objectives and has a low probability of achieving the objective. Proposal does not meet requirements or contains one or more deficiencies. Risk of unsuccessful performance is high.	Poor

A proposal that receives an overall Technical Benefit merit rating of Poor will be rejected and will NOT be placed in the Basket.

5.2.2 Management and Resources Evaluation

The overall Management and Resources Factor merit rating will be based on an integrated assessment of the below factors. The Management and Resources Factor will receive an adjectival rating of Excellent, Good or Poor. Based on these adjectival ratings, an overall Management and Resources merit rating will be determined using the same adjectival ratings as follows: Excellent, Good or Poor.

Ratings will be based on our assessment of the following:

- The internal management policies, processes, and organizational relationships identified are appropriate to support the prototype project.
- Technical, academic, corporate, and professional knowledge, experience and mix of the Offeror's (and any proposed teaming partners) proposed personnel to perform this project as proposed.
- The proposed quality management system is appropriate to support the prototype project.
- Knowledge and application of risk management principles to achieve project objectives.
- Appropriate facilities and equipment are sufficiently identified and available to execute the effort as proposed.
- Alignment of proposed data rights assertions with the Government's required level of data rights as stated in the project description (or the base agreement, W15QKN-16-9-1002, if specific data rights requirements are not stated in the project description). Reasonableness and affordability of data rights assertions made by the Offeror, if a cost is associated with obtaining specific data rights.
- For efforts that include biologic manufacturing activities, the proposed use of DoD ADM to achieve project objectives. **OR** the Government's acceptance of the Offeror's justification for not using the DoD ADM to meet project objectives. **Proposals that do not address this element at all will receive a poor rating.**

The following adjectival merit rating will be used:

Evaluation	**Merit Rating**
The proposal demonstrates an excellent management approach and resources to complete milestones and execute objectives in a timely manner. The proposal has strengths that will significantly benefit the Government. Risk of unsuccessful performance is low.	Excellent
The proposal demonstrates a good management approach and resources to complete milestones and execute objectives in a timely manner. The proposal contains one or more strengths that will benefit the Government. Risk of unsuccessful performance is no worse than moderate.	Good
The proposal demonstrates an unrealistic management approach or resources to complete milestones and execute objectives in a timely manner. The proposal does not clearly meet requirements or contains one or more deficiencies. Risk of unsuccessful performance is high.	Poor

5.2.3 Cost Evaluation

The Cost area will receive a narrative rating. The Government evaluation team will perform a cost realism assessment. The MCDC CMF will perform a cost analysis of the Offeror(s)' cost proposal to assess the reasonableness and completeness of the cost proposal. The Government, through the CMF, may make adjustments to the cost of the total proposed effort as deemed necessary to reflect what the effort should or will likely cost. These adjustments shall consider the task undertaken and technical approach proposed. These adjustments may include upward or downward adjustments to proposed labor hours, labor rates, quantity of materials, price of materials, overhead rates and G&A, or other related expenses.

The objective of this area of evaluation is to assess the ability of the Offeror to successfully execute the proposed project with the financial resources proposed. The Government Technical Evaluators will assess cost realism as part of the source selection process. If a proposal is selected for award and has available funding, the CMF will review the original cost proposal and the Offeror's response to a Proposal Update Letter (PUL), if applicable. Additional information or clarification will be requested as necessary. The CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government Acquisition Center will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

As part of its cost analysis, the factors of realism, completeness, and reasonableness, will be reviewed as discussed below.

Realism

Estimates are "realistic" when they are sufficient for the effort to be successfully accomplished. Estimates must be realistic for each task of the proposed project, particularly when compared to the total proposed cost. Determination will be made by directly comparing proposed costs with cost estimating relationships, comparable current and historical data, evaluator experience, and available estimates. Proposed estimates will be compared with the corresponding technical proposals for consistency. As part of the cost realism analysis each cost element will be determined either (S) Sufficient, (I) Insufficient, (E) Excessive, (U) Unable to determine.

Completeness

Estimates are "complete" based upon the degree to which the Offeror has provided all cost information requested in the RPP. Please note that rate and pricing information is required to properly perform the cost analysis of your proposal. If your company is unwilling to provide this information in a timely manner, your proposal will be lacking information that is required to properly evaluate the proposal and may result in that proposal being ineligible for award. Other important information that affects this determination is how well the cost data is reconcilable, and the substantiation of the costs for each element (e.g. supporting data and estimating rationale).

Reasonableness

Estimates are "reasonable" based upon the Offeror's cost estimate and should be developed from applicable historic cost data; fully supportable with assumptions, learning curves, equations, and estimating relationships; clearly stated; valid; and suitable for the effort proposed. The Offeror should

show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner, and should not be excessive for the effort proposed.

Definitions

Insufficient – The proposed cost is lower than what is deemed appropriate to successfully accomplish the technical effort proposed.

Sufficient – The proposed cost is deemed appropriate to successfully accomplish the technical effort proposed.

Excessive – The proposed cost is higher than what is deemed appropriate to successfully accomplish the technical effort proposed.

Unable to determine – The cost proposal does not include sufficient information for the Government to determine if the proposed cost is insufficient, sufficient or excessive.

5.3 Best Value

Projects will be awarded in Best Value sequence for each Objective Area, pending available funding. Projects that are not initially awarded will be placed in the Basket in accordance with the Basket Provision. Proposals that receive a poor subjective rating for the Technical Benefit factor will not be placed in the basket.

Basket Provision

Qualifying proposals, not eligible for current funding, may be entered into an electronic basket and subject to award for up to thirty-six (36) months. A Basket proposal may be identified for award by the Government based on Government need and availability of funding. The Government reserves the right to 1) request that the MCDC member who submitted the identified proposal, scale or otherwise adjust the original proposal, and to 2) fund all or part of the identified proposal. The MCDC member will have an opportunity to update their proposal, as applicable, if selected from the basket. The Government will review any updated information provided by the MCDC member and/or CMF. Upon the Government's decision to fund such a proposal from the Basket, the CMF will receive notification of the award decision whereupon the CMF will enter into a Project Agreement with the indicated MCDC member as required.

5.4 Proposal Funding

Not all proposals that are selected for award will be funded. If a proposal selected for award is not funded within nine (9) months from the RPP closing date, the proposal will be placed in the Basket. Decisions to fund will be based on funding availability. Proposals may be considered for funding for a period of up to three (3) years from the closing date for submission of proposals. The Government reserves the right to select for funding all, some, or none of the proposals received. Selection will be made to those Offeror(s) whose proposal(s) represent the best overall value to the Government.

Part 6 – Additional Information

6.1 Security Requirements

Information classified as “Confidential”, “Secret”, or “Top Secret” shall not be submitted or included in the prototype proposals. If classified information is submitted in a proposal, that proposal will be rejected.

Offerors should reference ARTICLE XVII: SECURITY & OPSEC of the Base Agreement for information regarding applicable Security requirements.

The Security Classification for this RPP is UNCLASSIFIED.

Offerors should expect these awards may require the generation or handling of Covered Defense Information (CDI) at times. Offerors are reminded to review the base OTA clause that addresses the safeguarding of CDI:

> The Government will identify Covered Defense Information (CDI) at the Project Agreement level and the MCDC Member will (a) on its enterprise level information systems, implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 not later than December 31, 2017 per the requirements of the Interim Clause, and (b) make reasonable best efforts regarding the same for those other areas still requiring analysis, specifically contractor's program unique systems/tools and subcontracts requiring flowdown, as applicable. After completion of such additional analysis, the MCDC Member shall notify the DoD Chief Information Officer (CIO) within 30 days of Project Agreement award of the standards which are currently not in compliance at the time of award, and immediately thereafter of any additional security requirements which have not been implemented. The MCDC Member will implement such security requirements as do not drive adverse cost or schedule impact. Implementation of requirements that will result in adverse impacts to cost or schedule shall be addressed at the Government's discretion by equitable adjustment. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) and/or DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting)).

6.2 Safety Requirements

Offerors shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non-hazardous occupational environment throughout the duration of the project.

Offerors should reference ARTICLE XVIII: SAFETY of the Base Agreement for information regarding applicable Safety requirements.

Part 7 – Points of Contact

Questions concerning contractual, cost or pricing format related to this RPP should be directed to the MCDC CMF, ATI, Attn: Ms. Mandi Ballou, 315 Sigma Drive, Summerville, SC 29486, E-mail mandi.ballou@ati.org or contracts.mcdc@ati.org. Additionally, MCDC shall encourage MCDC members to periodically visit the MCDC website for potential updates.

Warranties and Representations

Authority to use Section 815 Other Transaction Agreement

In accordance with Section 815, Amendments to Other Transaction Authority, of the National Defense Authorization Act (NDAA) for Fiscal Year 2016, which governs the authority to use a Section 815 Other Transaction Agreements to carry out 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 Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces, ***(insert organization)*** hereby provides the following Warranties and Representations:

1. Prime Contractor: The Prime Contractor *(insert Organization Name)* for the proposed program □ is a traditional defense contractor □ is a nontraditional defense contractor. *(check one)* based on the following definition:

A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the RPP, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.

Note: Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units; provided the business unit makes a significant contribution to the prototype project (i.e., is a key participant). A foreign business can be considered a nontraditional if it has a DUNS # and can comply with the terms and conditions of the Base t Agreement, specifically aspects involving ITAR/EAR.

If the prime contractor is a traditional defense contractor and proposes the use of one or more nontraditional defense contractors, the following information is required for each participating nontraditional defense contractor.

Legal Name of Nontraditional Defense Contractor:	
DUNS #:	
Address:	
Point of Contact (Name, Title, Phone #, Email):	
Please select at least one or more of the significant contribution(s) listed below that will be provided by the Nontraditional defense contractor cited above:	
☐	**A - The significant contribution involves developing, demonstrating or providing a key technology.** *Please describe what the key technology is; why it is key and what*

	makes it key.
☐	**B - The significant contribution involves developing, demonstrating or providing a new part or material that is not readily available.** *Please describe what the new part or material is and why it is not readily available.*
☐	**C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, weapon system design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program.** *Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.*
☐	**D - The use of this designated non-traditional will cause a material reduction in the cost or schedule.** *Please describe and quantify the specific cost or schedule impact to be realized*
☐	**E - The use of this designated non-traditional will increase performance or mission effectiveness.** *Please describe what the performance or mission effectiveness increase will be attained by the use of this designated nontraditional defense contractor*
II. In addition to the above please provide the following information:	
Q1	**What additional capability beyond those described in A through E above does this Nontraditional defense contractor have that is necessary for this specific effort?**
A1	
Q2	**Which task/phase(s) of the effort will the Nontraditional defense contractor be used?**
A2	
Q3	**What is the total estimated cost associated with the Nontraditional defense contractor included in the proposal?**

A3	

_____ _____

Signature of authorized representative of Offeror Date

Statement of Work Template

Statement of Work
For
NAME OF PROJECT PROTOTYPE

RPP:
Sub-Objective Area:
Consortium Member:

Title of Proposal:

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To be initially provided by the Offeror at the time of proposal submission to demonstrate a clear understanding of the requirement. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. This should not be verbatim the objective area requirement.

PROVIDE A BRIEF BACKGROUND OF THE REQUIREMENT THAT IS BEING ADDRESSED BY THIS PROTOTYPE PROJECT.

Explain WHY we are doing this and WHY it is important? Include the following:
1. Who requires this? (The U.S. Army, the Government, JPM-MCS, DTRA, e.g.)
2. Why are we doing this? (Increased performance, cost savings, regulatory compliance, e.g.)
3. Explain how the project will enhance the DoD mission?
4. Identify this as a project related to the development of state-of-the-art medical, pharmaceutical, and diagnostic-related technologies/solutions. (i.e. within scope of MCDC OTA. See Article I, Section C & D of OTA)

1.2 Scope

To be initially provided by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.

THIS SECTION DEFINES THE SCOPE AND CLEARLY ESTABLISHES THAT THIS IS A PROTOTYPE PROJECT.

The scope establishes the boundaries of the work. (What is and is not required under the Project Agreement.)

1.3 Objective

To be initially provided by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.

THIS SECTION ESTABLISHES THE OVERALL OBJECTIVE OF THE PROJECT, DEFINES THE SCOPE, AND CLEARLY ESTABLISHES THAT THIS IS A PROTOTYPE PROJECT.

Explain WHAT we are going to do? Explain the following:

1. What is the objective? (Prove out a concept or process/Integrate new technology/enhance performance/attain a TRL level, e.g.)
2. What is the prototype project? (How will a prototype be integral to achieving the stated objectives of the project?) The description of the prototype project establishes that this project can be awarded under the MCS OTA.

2.0 APPLICABLE REFERENCES

LIST ANY APPLICABLE DOCUMENTS, INCLUDING THOSE IDENTIFIED IN THE APPLICABLE SECTION 2 OF THE RPP or INSERT N/A.

To be initially provided by the Offeror at the time of proposal submission and final determination by the Government based on negotiation.

Documents that are incorporated as part of the requirements (Any documentation to be followed.)

EXAMPLES:

- Military Standards / FDA Guidelines
- Performance Specifications / Target Product Profiles
- Technical Data Packages (TDP) / Drug Master Files
- Security Classification Guides (SCG)

3.0 REQUIREMENTS

To be initially provided by the Offeror at the time of proposal submission to be finalized by the Government based on negotiations.

THIS SECTION DELINEATES THE SPECIFIC TASKS THAT WILL BE PERFORMED BY THE AWARDEE IN ORDER TO ACHIEVE THE OBJECTIVE ESTABLISHED IN THE APPLICABLE SECTION 2.0 OF THE RPP.

Specify requirements clearly to ensure that both the Government and the Awardee are in agreement about the work to be performed. Each task must be clearly defined by either specific instructions or

performance-based outcomes. Tasks shall provide the details of how the technical approach efforts will be accomplished.

This section explains HOW we are going to accomplish the OBJECTIVE.

It establishes a series of discrete tasks that:

1. Break down the steps required to achieve the objective.

2. Result in the Deliverables listed in Section 4.0 (Tasks shall culminate in a tangible deliverable.)

3. Identify/align major tasks with the IMS/WBS.

4. Will be used to establish payment milestones in Section 5.0

Prototype Requirements

- Identify which tasks will result in prototype deliverables, including types and quantities.
- The sequence of tasks must clearly detail how the prototypes will be integrated into the larger project structure, and how prototyping is being used to advance the project objective.
- All deliverable prototypes must be listed in Section 4.0, Deliverables.

Deliverables

- Defines end items (line items) to be delivered, such as prototypes, hardware, software, analyses, software validation, testing reports, etc.

Cross-Referencing

- All requirements should be cross-referenced and traceable in Section 4.0, Deliverables, and Section 5.0, Milestone Payment Schedule.
- This section should include all deliverables listed in Section 5.0

NOTE: Begin sentences indicating action to be taken, by stating “The awardee shall provide/deliver/develop/etc…”

Listed below is an example of a vaccine or drug clinical trial SOW structure. This is not to be considered a mandatory format or all inclusive, but is only provided for clarification purposes of Government expectations.

3.1 Regulatory Planning

3.2 Clinical Trial Planning

- **3.2.1 Protocols and Associated Documents**
- **3.2.2 Data Management Plan**
- **3.2.3 Randomization Plan**
- **3.2.4 Recruitment Plan**
- **3.2.5 Pharmaceutical Management**
- **3.2.6 Investigator/Kickoff Meeting**
- **3.2.7 Clinical Quality Monitoring Activities**
- **3.2.8 Protocol Safety Review Team (PSRT) or Drug Safety Monitoring Board (DSMB)**
- **3.2.9 Medical Safety Monitoring and Reporting**

3.3 Regulatory Execution

- **3.3.1 Product Sponsorship**
- **3.3.2 Investigational New Drug Filing**

3.4 Clinical Trial Execution

- **3.4.1 Site Management, Communications and Activities**
- **3.4.2 Recruitment, Screening and Enrollment**
- **3.4.3 Execution and Safety Subject Monitoring**
- **3.4.4 Quality and Data Management**

3.5.1 Clinical Trial Close Out

- **3.5.1 Subjects/ Database**
- **3.5.2 Review and Verification of Available Source Documentation**
- **3.5.3 Biostatistics and Clinical Studies Report (CSR)**
- **3.5.4 Data Archive**
- **3.5.5 Specimen Repository**

3.6 Management and Reporting

- **3.6.1 Project Management**
- **3.6.2 Technical and Financial Reporting**
- **3.6.3 Study Reporting**
- **3.6.4 Communications with the Government**

4.0 DELIVERABLES

To be initially provided by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.

LIST ALL DELIVERABLES HERE

Include references to paragraphs in section 3.0, Requirements. Recommend using the table of deliverable provided in applicable Section 2 of the RPP and include a column aligning the SOW sections to the deliverables. The table in Section 2 of the RPP is not to be considered all inclusive as the Offeror is responsible to propose the relevant deliverables based on the proposed SOW. Differentiate between data and prototype project deliverables as applicable in this section.

5.0 MILESTONE PAYMENT SCHEDULE

To be initially provided by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included below should be in editable format (i.e. not a picture).

THIS SECTION PROVIDES A PROJECT STRUCTURE TYING SPECIFIC TASKS AND/OR DELIVERIES TO THE PAYMENT SCHEDULE.

The milestone payment schedule should be developed so that it can be used as a tracking tool.

- It should reflect your anticipated funding
- Estimated dates for all milestones (month/day/year) shall align with the proposed project schedule and Statement of Work and clearly indicates the completion of cost tasks, or cost deliverables to meet the milestones.
- For firm fixed price agreements, the milestone schedule will serve as a payment schedule for any subsequent award.
- Include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due at the end of Mar, Jun, Sep, Dec), Annual Technical Report, Final Technical Report, Final Business Status Report, and Interim and Final Patent Reports. The quarterly reporting may not apply if the requirement specified in Section 2 of this RPP is for monthly reports.

NOTE: Include applicable cross-references to Section 4.0, Requirements. DO NOT simply pro-rate the cost evenly by the Period of Performance.

(A) Milestone or WBS No.	(B) Deliverable Description	(C) Due Date	(D) Total Program Funds
(E)	(F)	(G)	(H)
(I)	(J)	(K)	(L)
(M)	(N)	(O)	(P)
(Q)	(R)	(S)	(T)
(U)	(V)	(W)	(X)

(A) Milestone or WBS No.	(B) Deliverable Description	(C) Due Date	(D) Total Program Funds
		(Y) Total	(Z) $$$$

6.0 SHIPPING PROVISIONS

To be completed with Government AOR input.

LIST SHIPPING INFORMATION HERE

7.0 DATA RIGHTS AND COPYRIGHTS

To be initially provided by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.

THE AWARDEE SHALL COMPLY WITH THE TERMS AND CONDITIONS DEFINED IN THE BASE AGREEMENT REGARDING DATA RIGHTS.

Rights in such Data shall be as established under the terms of the Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The below table lists the Awardee's assertions.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category (A, B, C)	Name of Organization Asserting Restrictions	Milestone # Affected

8.0 SECURITY

To be initially provided by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.

INSERT ANY OTHER SECURITY RELATED INFORMATION HERE

The security classification level for this effort is INSERT CLASSIFICATION LEVEL HERE.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

To be initially provided by the Offeror at the time of proposal submission or may be provided by the Government during negotiations if the Government selects the proposal for funding.

IF APPLICABLE; IF NOT, INSERT N/A.

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

To be cited by the Government in Section 2 of the RPP or initially provided by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.

LIST ITEMS HERE or INSERT N/A

Provide a list of any items GFP/GFM/GFI required to perform the proposed effort.

11.0 AGREEMENTS OFFICE REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

Alternate AOR

NAME:
MAILING ADDRESS:
EMAIL:
PHONE: