ARMY CONTRACTING COMMAND-ABERDEEN PROVING GROUND
EDGEWOOD CONTRACTING DIVISION
FT. DETRICK BRANCH

BROAD AGENCY ANNOUNCEMENT (BAA)
RESEARCH AND DEVELOPMENT
IN SUPPORT OF
THE JOINT PROGRAM EXECUTIVE OFFICE FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR DEFENSE (JPEO-CBRND), JOINT PROJECT MANAGER MEDICAL (JPM MEDICAL) AND JOINT PRODUCT LEAD ENABLING BIOTECHNOLOGIES (JPL CBRND EB)
FOR
EFFORTS UNDER PROCUREMENT CONTRACTS, GRANTS, COOPERATIVE AGREEMENTS, AND OTHER TRANSACTION AGREEMENTS

CBRND-BAA-22-01

W911SR-22-R-CBRN

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I. INTRODUCTION:

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) is organized into five Joint Project Management Offices (JPMO), each responsible for specific commodity areas. General information on the JPEO-CBRND and subordinate JPMOs can be obtained from the JPEO-CBD website at http://www.jpeocbd.osd.mil/. Mission areas and technical points of contact for the product management offices are shown in Section VII of this BAA. As the purpose of this BAA is to identify the best available science in the identified areas of research interest, proposals are sought from all eligible sources as specified herein, including educational institutions, nonprofit organizations, and private industry. This Broad Agency Announcement (BAA) provides general information, proposal preparation instructions, evaluation and selection criteria, and award administration.

Offerors may submit unsolicited proposals (preproposals) for consideration under the general requirements of this BAA at any time, as long as the announcement is active, in support of research and development within the mission areas identified in Section VII of this announcement. Studies related to novel solutions and improved methods to develop medical countermeasures more rapidly and with increased efficiency through enabling technologies, life cycle bioinformatics, and improved logistics tracking are of specific interest to the Government.

This announcement will also be available on the Grants.gov web portal (http://www.grants.gov/), the Contract Opportunities section of SAM.gov website (https://sam.gov) and the JPEO-CBD website (http://www.jpeocbd.osd.mil/).

From time to time, special announcements or calls for proposals referencing this BAA may be issued for specific requirements in addition to any requirements announced in Sections VII and VIII. Additionally, the application process may be amended as other electronic application processes are implemented. All amendments to this BAA will be announced respectively. To facilitate communication on both scientific and administrative matters relating to this BAA, a single email address may be used for all communication with the Government. Please send all technical and administrative questions and inquiries to usarmy.detrick.mcs.mbx.baa@mail.mil. Potential Offerors are encouraged to discuss their proposal ideas with the JPMO technical contacts listed in Section VII (B).

Administrative questions concerning the preparation of preproposals or proposals should be addressed to U.S. Army Contracting Command Edgewood Contracting Division/ Grants Officer. They should be emailed to usarmy.detrick.mcs.mbx.baa@mail.mil, ATTN: CBRND BAA 22-01.

This BAA is intended to solicit pre-proposals for:

1. Procurement Contracts,: Awarded Procurement Contracts shall apply to those parts of development not related to the development of a specific system or hardware procurement based on the Technical Readiness Level limitations described herein. As to any resultant procurement contracts, this BAA is issued under the provisions of the Competition in Contracting Act of 1984 (P.L. 98-369), as implemented in the Federal Acquisition Regulation (FAR) Part 6.102 (d)(2) and in accordance with FAR 35.016(a). The purpose of Procurement Contracts for research

and/or development placed under this BAA is to identify the best available science, and as such, there are no set-asides associated with any awards resulting from this BAA

2. Grants and Cooperative Agreements: Consistent with the regulatory authority in Code of Federal Regulation (CFR), Title 2.A, Chapter II, Part 200, funds may be awarded to stimulate or support a public purpose consistent with objectives to develop, approve, and field medical CBRN countermeasures and enabling biotechnologies, or, as defined in 31 U.S.C. 6305, to transfer a thing of value to a recipient to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government. These efforts should be intended for scientific study and experimentation directed toward advancing the state-of-the- art or increasing knowledge or understanding, rather than focusing on a specific system, product, or medical countermeasure. The purpose of grants and cooperative agreements placed under this BAA is to identify the best available science, and as such, there are no set-asides associated with any awards resulting from this BAA. This BAA operates as a competitive procedure for the award of grants and cooperative agreements.

3. Other Transactions (OTs) for Research: As prescribed in 10 U.S. Code 4021, OTs for Research are non-FAR based agreements for use in carrying out basic, applied and advanced research. The intent of an OT for Research is to spur dual-use research and development (R&D) between the Government and Industry. An OT for Research requires cost sharing between the awardee and the Government, and to the maximum extent practicable, OTs for Research should not duplicate research being undertaken under other agreements, grants, or procurement contracts. OTs for Research may only be used for a research project when the use of a standard contract, grant, or cooperative agreement for such project is not feasible or appropriate.

4. Prototype Project Other Transactions (OTs): The award of Prototype OTAs shall be for the development of prototypes in accordance with 10 USC 4022 The resultant award of any OTA using the procedures of this BAA either announced in Section VII or for a requirement announced in section VIII are NOT made or issued under the provisions of the Competition in Contracting Act of 1984 (P.L. 98-369), FAR Part 6 or any other FAR based regulation. However, solely as a matter of convenience to meet the requirement for maximum practicable competition, the mechanics of the competitive BAA process detailed in this BAA otherwise not applicable to OTAs are, as supplemented herein, adopted as the competitive procedure for entering into OTAs.

5. Technology Investment Agreements (TIAs): As prescribed in 32 CFR Part 37, TIAs are defined as a special class of assistance instruments used to support or stimulate research. A TIA may be either a kind of cooperative agreement or a type of assistance transaction other than a grant or cooperative agreement. TIAs allow for involvement of commercial firms in defense research programs and for other purposes (described in 32 CFR 37 appendix A) related to integrating the commercial and defense sectors of the nation's technology and industrial base. A TIA may be a cooperative agreement with provisions tailored for involving commercial firms (as distinct from a cooperative agreement subject to all of the requirements in 32 CFR part 34), or another kind of assistance transaction described in 32 CFR 37 Appendix B. TIAs are more flexible than traditional Government funding instruments allowing for negotiation of

provisions in areas such as audits and intellectual property rights.

6. To the maximum extent practicable, the non-Federal parties carrying out a research project under a TIA are to provide at least half of the costs of the project in accordance with 32 CFR § 37.215(b) to demonstrate its strong commitment to and self-interest in the project's success.

7. Generally, this announcement is continuously open; preliminary proposals (preproposals) may be submitted and will be evaluated for the general requirements of this BAA at any time throughout the year. The availability of funds may limit the ability of the U.S. Government to make awards in specific areas, nevertheless preproposals are sought under this BAA announcement for areas consistent with the mission areas identified in Section VII of this announcement. Medical/EB are not interested in proposals that are based on data from experiments using specific CBRN warfare agents, not surrogates, to demonstrate safety, efficacy or mode of action. (Please note that CBRN warfare agents may not be provided by the DoD for these efforts.) We are interested in studies on new and better ways to develop medical countermeasures more rapidly and with increased efficiency through enabling technologies, life cycle bioinformatics, and improved logistics tracking.

8. JPM Medical/JPL EB are not interested in Science and Technology (S&T) basic research proposals; however, we are interested in efforts directed toward the development of enabling technologies that speed up the advanced development process leading to FDA approval of countermeasures. All developmental efforts nominated to be considered by this BAA should be evaluated against the Quality Technology Readiness Levels (Q-TRL) (Attachments 1 and 2). Typically, for advanced development, the scope of work proposed under this BAA, except as proposed under Section VIII, must be limited to TRL 4 levels described at 4-M1, 4- D1 and 4-E1 for Medical Products and 4-DAM1, 4-DAS1, 4-DCS1 for Diagnostics.

9. From time to time, special announcements or calls for proposals referencing this BAA may be issued for specific requirements in addition to any requirements announced in Sections VII and VIII. Additionally, the application process may be amended as other electronic application processes are implemented. All amendments to this BAA will be announced on the websites shown above. To facilitate communication on both scientific and administrative matters relating to this BAA, a single email address may be used for all communications. Please send all technical and administrative questions and inquiries to usarmy.detrick.mcs.mbx.baa@mail.mil. Potential applicants are encouraged to discuss their proposal ideas with the Technical contacts listed in Section VII (B).

10. Administrative questions concerning the preparation of preproposals or proposals should be addressed to U.S. Army Contracting Command Edgewood Contracting Division. They should be emailed to usarmy.detrick.mcs.mbx.baa@mail.mil, ATTN: BAA W911SR-22-R-0001

11. Issues with submitting applications through the Grants.gov web portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email support@grants.gov. The Contact Center hours of operation are Monday-Friday, 7 AM to 9 PM Eastern Standard Time. The Catalog of Federal Domestic Assistance (CFDA) can be accessed online at https://www.cfda.gov. The online CFDA provides access to a database of all Federal programs available to the grant community, including state, local and tribal Governments,

academia and research institutions, commercial firms and not-for-profits. Included on the web site are contact information for the office that administers each program, instructions on how to apply for assistance, and several proposal writing guides. The CFDA number for this announcement is 12.360.

II. ACRONYMS / DEFINITIONS:

ACRONYMS:

ACC-APG-NCD
Army Contracting Command-Aberdeen Proving Ground-Edgewood Contracting Division **ACO**
Administrative Contracting Officer
ACURO
Animal Care and Use Review Office
AAO
Administrative Agreements Officer
ALINs
Agreement Line Item Numbers
AOR
Authorized Organizational Representative
BAA
Broad Agency Announcement
BLA
Biologics License Application
BWA
Biological Warfare Agent
CBDP
Chemical Biological Defense Program
CBRN
Chemical, Biological, Radiological, and Nuclear
CDRL
Contract Data Requirements List
CFDA
Catalog of Federal Domestic Assistance
CFR
Code of Federal Regulations
CLINs
Contract Line Item Numbers
cGMP
Current Good Manufacturing Processes
CWA
Chemical Warfare Agent
CWBS
Contract Work Breakdown Structure
DCAA
Defense Contract Audit Agency
DCMA
Defense Contract Management Agency
DFARS
Department of Defense Federal Acquisition Regulation Supplement
DoD
Department of Defense
D-U-N-S
Data Universal Number System
JPM-EB
Joint Program Management -Enabling Biotechnologies
EPLS
Excluded Parties List System
EFT
Electronic Funds Transfer
FAR
Federal Acquisition Regulation
FDA
U.S. Food and Drug Administration
FCCM
Facilities Capital Cost of Money
FOIA
Freedom of Information Act
FY
U.S. Government Fiscal Year, which begins October 1
GCP
Good Clinical Practices
GLP
Good Laboratory Practices
HRPO
Human Research Protection Office
IMS
Integrated Master Schedule
IND
Investigational New Drug

IAE
Integrated Acquisition Environment
JPEO-CBD
Joint Program Executive Office for Chemical and Biological Defense
JPM-CBRN MEDICAL
Joint Project Management Chemical, Biological, Radioactive and Nuclear, Medical
NDA
New Drug Application
NIOSH
National Institute of Occupational Safety and Health
OMB
Office of Management and Budget
OSD
Office of the Secretary of Defense
P.L.
Public Law
POC
Point of Contact
Q-TRL
Quantitative Technological Readiness Level
RDT&E
Research, Development, Test, and Evaluation
RFFP
Request for Full Proposal
RPP
Request for Project Proposal
R&R
Research and Related
SAM
System for Award Management
SF
Standard Form
SOW
Statement of Work
TRL
Technology Readiness Level
USC
U.S. Code
WAWF
Wide-Area Work Flow
WBS
Work Breakdown Structure

DEFINITIONS:

AGENCY: Agency means any of the military departments or defense agencies with authority to award OTAs for prototype projects.

AGREEMENTS OFFICER: An Agreements Officer has authority to enter into, administer, or terminate OTs for prototype projects and make related determinations and findings.

DEVELOPMENT: The systematic use of scientific and technical knowledge in the design, development, testing, or evaluation of potential new products, processes, or services to meet specific performance requirements or objectives. It includes the functions of design engineering, prototyping, and engineering testing. Advanced development consists of activities that plan, produce and deliver information outputs (documents, data, and records) from discovery all the way through Phase 4 post-marketing studies and surveillance.

ENABLING TECHNOLOGIES: Technologies that are not countermeasure products or systems themselves but facilitate or accelerate the development of countermeasure products or systems. Examples of enabling technologies include combinatorial chemistry, high-throughput screening, microarrays, bioinformatics and computational biology, nanotechnologies, imaging (including biosensors and biomarkers), animal models, assays, and other product development tools.

HEALTH SURVEILLANCE: The ongoing, systematic collection, analysis, and interpretation of health-related data to detect and assess CBRN warfare risks in order to plan, implement, and evaluate prevention and intervention/response programs. Included are computational models, such as expert systems and predictive models.

IMPROVED LOGISTICS TRACKING: Technologies which facilitate tracking and monitoring individual product items throughout shipping, storage, delivery to, and use by the end user (factory to foxhole). Examples include technologies which facilitate or simplify supply chain management and/or shelf life extension, such as Time Temperature Indicators (TTI), Item Unique Identification (IUID), and Radio-Frequency Identification (RFID).

JOINT PROJECT MANAGER (JPM): The designated individual with responsibility for and authority to accomplish program objectives for development, production, and sustainment to meet the user's operational needs. The JPM is accountable for credible cost, schedule, and performance reporting to the Milestone Decision Authority (MDA).

LIFE CYCLE BIOINFORMATICS: The systematic collection and analysis of data from all phases of research, development, manufacturing, and test and evaluation to enable informed decision making. Included are data obtained from preclinical studies, ensuring compliance with 21 Code of Federal Regulations (CFR) part 11.

MILESTONE DECISION AUTHORITY (MDA) (JPEO-CBD): The designated individual with overall responsibility for the Chemical and Biological Defense Program. The MDA has the authority to approve entry of an acquisition program into the next phase of the acquisition process and shall be accountable for cost, schedule, and performance reporting to higher authority, including Congressional reporting.

OTHER TRANSACTIONS FOR PROTOTYPES: The Department currently has authority under Section 4022, of title 10, U.S.C., to award "other transactions" (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the Armed Forces.

"OTHER TRANSACTIONS AGREEMENTS (OTA) for prototype projects": are acquisition instruments that generally are not subject to the federal laws and regulations governing procurement contracts. As such, they are not required to comply with the Federal Acquisition Regulation (FAR), its supplements, or laws limited in their applicability to procurement contracts. A prototype can generally be described as "a physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system." OSD, OTA Prototype Guide. While prototype's are not limited to FDA approved vaccines/therapeutics, a single vial/dose of FDA approved medical counter measure material (e.g., vaccine/therapeutic) is an end item that has been tested and evaluated as to feasibility (technical, manufacturability, and regulatory) and as to military utility

TECHNOLOGY INVESTMENT AGREEMENTS (TIAs): A TIA is a special type of assistance instrument used to increase involvement of commercial firms in DoD research, development and demonstration (RD&D) programs. A TIA, like a cooperative agreement, requires substantial Federal involvement in the technical or management aspects of the project. A TIA may be either a type of cooperative agreement or a type of assistance transaction other than a cooperative agreement, depending on the intellectual property provisions.

III. GENERAL INFORMATION:

A. AWARDS

1. **TYPE OF AWARDS:** This BAA contemplates the award of procurement Contracts, Grants, Cooperative Agreements, TIAs, and OTAs under this BAA in support of its mission to foster and/or conduct the advanced development of FDA approved medical CBRN countermeasures and to expand, and/or accelerate domestic manufacturing related to Medical Chemical and Biological Countermeasures. For awards involving research and/or development, the purpose of this BAA is to identify the best available science, and as such, there are no set-asides associated with any awards resulting from this BAA due to the impracticality of reserving discrete or severable areas/elements of development in the cited areas of interest or to inapplicability

   i. **Procurement Contracts:** Procurement contracts will be utilized to fund development activities that, while directly supporting a U.S. Government requirement, can include basic research, applied research, advanced technology development or advanced component development and prototypes. Examples of the use of a procurement contract include a Good Laboratory Practices (GLP)-compliant animal toxicology study or a Phase 1 clinical safety study.

   ii. **Grants/Cooperative Agreements:** Consistent with statutory authority, funds may be awarded by the requiring office to stimulate or support a public purpose consistent with the broad DoD objectives to develop, approve, and field medical CBRN countermeasures. Any of these efforts that involve research should be intended for scientific study and experimentation directed toward advancing the state-of-the- art or increasing knowledge or understanding, rather than focusing on a specific system, product, or medical countermeasure. By submitting a proposal and accepting an award, the recipient organization is certifying that the Project Manager and other investigators' credentials have been examined and verified to ensure that the investigators are qualified to conduct the proposed study, and if applicable, to use humans or animals as research subjects in accordance with all federal and institutional guidelines and regulations. A Cooperative Agreement is used to enter into the same kind of relationship as a grant, except that substantial involvement is expected between the DoD and the recipient when carrying out the activity contemplated by the cooperative agreement. See 31 U.S.C. 6305. Cooperative Agreements awarded to expand, and/or accelerate domestic manufacturing related to Medical Chemical and Biological Countermeasures may include substantial involvement by the Federal Government in the form of coordination of a variety of factors associated with domestic manufacturing expansion (e.g., size and location of expanded manufacturing capability and future government access to the expanded capacity). The term "Cooperative Agreement" does not include "Cooperative Research and Development Agreements" as defined in 15 U.S.C. 3710a. No fee or profit to a recipient and/or subrecipient is allowed on Grants or Cooperative

Agreements awarded by the Department of Defense.

The type of instrument used to reflect the business relationship between the recipient and the U.S. Government will be determined by the Grants, Agreements, or Contracting Officer supporting the JPMO prior to award. For the purposes of this BAA, The U.S. Army Contracting Command Aberdeen Proving Ground Edgewood Contracting Division, Fort Detrick (ACC-APG Edgewood), provides contracting support and will process proposals selected for funding. Applicants may propose the type of instrument for the proposed effort. However, the applicant's suggestion regarding suitable type of instrument does not obligate the government to employ the suggested instrument. Applicants proposing a COST type procurement contract, must have an adequate accounting system for determining costs on a government contract IAW FAR subpart 16.301-3. This is determined by the Defense Contract Audit Agency (DCAA) assigned to the applicant's business location and may take thirty (30) to forty (40) days for completion. For OTAs, TIAs and Grants/Cooperative Agreements, the determination will be made by a warranted agreements officer.

iii. **Other Transactions Agreements** – Prototype: The award of Prototype OTAs shall be for the development of prototypes in accordance with Section 2371b of title 10. U.S.C. The resultant award of any OTA using the procedures of this BAA either announced in Section VII or for a requirement announced in section VIII are NOT made or issued under the provisions of the Competition in Contracting Act of 1984 (P.L. 98-369), FAR Part 6 or any other FAR based regulation. However, solely as a matter of convenience to meet the requirement for maximum practicable competition, the mechanics of the competitive BAA process detailed in this BAA otherwise not applicable to OTAs are, as supplemented herein, adopted as the competitive procedure for entering into OTAs.

- Section VII contains areas of interest to be competed hereunder for Prototype OTA awards. Section VIII contains instructions specific to the development of, and evaluation of proposals, for prototypes.

- In general, OTA Offeror's may submit a pre-proposal (1) qualifying under Section VII.A of this BAA for one or more of the Mission Areas or (2) for prototype requirements identified in Section VIII or in a separate Request for Project Proposals (RPP) issued under this BAA. If two or more Prototype OTA Offerors submit for the same requirement, the field of competition will be narrowed by the evaluations called for under this BAA for pre-proposals used to conduct phased evaluations using one or more of the evaluation factors.

iv. Technology Investment Agreements: As prescribed in 32 CFR Part 37, TIAs are defined as a special class of assistance instruments used to support or stimulate research. A TIA may be either a kind of cooperative agreement or a type of assistance transaction other than a grant or cooperative agreement. TIAs allow for involvement of commercial firms in defense research programs and for other

purposes (described in 32 CFR 37 appendix A) related to integrating the commercial and defense sectors of the nation's technology and industrial base. A technology investment agreement may be a cooperative agreement with provisions tailored for involving commercial firms (as distinct from a cooperative agreement subject to all of the requirements in 32 CFR part 34), or another kind of assistance transaction described in 32 CFR 37 Appendix B. TIAs are more flexible than traditional Government funding instruments allowing for negotiation of provisions in areas such as audits and intellectual property rights.

v. To the maximum extent practicable, the non-Federal parties carrying out a research project under a TIA are to provide at least half of the costs of the project in accordance with 32 CFR § 37.215(b) to demonstrate its strong commitment to and self-interest in the project's success.

2. CONTRACTOR MANPOWER REPORTING:

IAW AFARS 5137.91, all procurement contracts awarded under this BAA may include the requirement to report contract manpower in the Enterprise-wide Contractor Manpower Reporting Application (eCMRA). Contracts subject to manpower reporting will include a separate line item in Section B. Reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

3. BASIC AWARD PROCEDURES:

i. To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The ACC-APG Edgewood Contracting Division uses the System for Award Management (SAM) to exclude recipients ineligible to receive federal awards.

ii. Applicants should meet certain minimum standards pertaining to institutional support, financial resources, prior records of performance, integrity, organization, experience, operational controls, facilities and conformance with safety and environmental statutes and regulations in accordance with CFR Title 2, Part 200 or FAR subpart 9.1.

iii. Investigators are cautioned that awards are made to organizations, not individuals. A Project Manager must submit a proposal through, and be employed by, an organization in order to receive support. Should the Project Manager of a funded project leave the recipient institution, both the Project Manager and institution must contact ACC-APG Edgewood Contracting/Grants Officer as soon as possible to discuss options for continued support of the project. Every effort should be made to notify ACC-APG Edgewood prior to the Project Manager leaving the institution. By submitting a proposal and accepting an award, the recipient organization is certifying that the Project Manager and other investigators' credentials have been examined and verified to ensure that the investigators are qualified to conduct the

proposed study, and if applicable, to use humans or animals as research subjects in accordance with all federal and institutional guidelines and regulations.

iv. Applicants located outside of the U.S. may submit in response to the BAA, however, it is the organizations' responsibility to ensure that the project staff is able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the United States. In addition, the U.S. Government will not provide funds to support scientists from countries which support terrorism, or otherwise determined not acceptable.

v. Funding may be provided incrementally during the life of the award. Under cost-reimbursement type awards, payments are made in response to monthly vouchers or invoices submitted by the awardee. Grants/cooperative agreement funds are generally awarded via cost-reimbursement or periodic scheduled payments, in accordance with the negotiated payment schedule included in the award document.

vi. The primary basis for the selection of proposals is based upon evaluation of technical merit, programmatic relevance, and the availability of funds.

vii. Detailed information on proposal evaluation and selection is located in section V, "Evaluation and Selection."

B. CONFLICT OF INTEREST:

There are certain post-employment restrictions on former Federal officers and employees as defined in 18 USC 207 and FAR 3.104-4(c). If a submitter believes a post-employment restriction or conflict of interest exists, the situation should be discussed with the JPMO legal staff (telephone 301-619-8444) prior to expending time and effort in preparation of a proposal.

C. DISCLOSURE OF INFORMATION OUTSIDE THE U.S. GOVERNMENT:

Proposals may be disclosed to U.S. Government contractor support personnel deemed subject matter experts for the sole purpose of technical and programmatic evaluation as part of the determination to fund a proposal. The Government obtains a written agreement from the contractor evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release. Any information considered proprietary or otherwise not available for disclosure to other than a warranted contracting officer should be marked accordingly.

D. U.S. GOVERNMENT OBLIGATION:

Only a warranted Contracting, Grants, or Agreements Officer may obligate the U.S. Government to the expenditure of funds for awards under this BAA. The U.S.

Government does not fund preparation of proposals or support work efforts or tasks that are inferred from discussions with technical project officers.

E. INFORMATION SERVICE:

Applicants should use the technical reference facilities of the Defense Technical Information Center (DTIC) to acquire information of U.S. Government funded projects to avoid duplication of scientific and engineering effort. DTIC is responsible for collecting all scientific or technological observations, findings, recommendations, and results derived from Department of Defense endeavors. Requests for eligibility and registration information should be addressed to DTIC Registration, 8725 John J. Kingman Road, Ft. Belvoir, VA 22060-6218, or may be obtained at http://www.dtic.mil/dtic.

F. PREPROPOSALS:

1. Organizations are strongly encouraged to explore the JPMO's interests by submitting a preliminary proposal (preproposal). Preproposals may be submitted at any time describing a specific idea or project pertaining to any of the areas of interest outlined in this BAA. Preproposals should be no longer than eleven (11) pages, and include a description of the relevant technology including supporting data, the scope of the proposed effort including a high-level Work Breakdown Structure (WBS), and a description of the applicant's research, development, manufacturing, past performance, or other special qualifications, in addition to any IP restrictions. The preproposal should include an anticipated cost for the efforts described in the preproposal. Preproposals may be submitted to the following email address: usarmy.detrick.mcs.mbx.baa@mail.mil.

Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a preproposal. All preproposals will be assigned and an email will acknowledge receipt of a preproposal. Usually, the applicant's Project Manager should receive a decision letter or email regarding the preproposal within 60-90 days of submission.

2. In accordance with the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC) released 29 March 2012, research being proposed which falls under the definition of DURC, "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety agricultural crops and other plants, animals, the environment, materiel, or national security", must be identified in the applicant's preproposal. If a full proposal is then requested by the Government, risk mitigation of this concern shall be included as part of the Risk Management Plan of the Technical proposal section (see section V.B.3.e) of this document.

For research involving animals, the JPMO requiresa second tier review for the use of

animals prior to implementation. Therefore, the applicant's Project Manager must address all pertinent issues relating to the use of animals in the proposed work effort. The preproposal should include the required assurances, approvals, forms and description in the proposal addenda entitled "Research Involving Animals," as specified on the Animal Care and Use Review Office (ACURO) website https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro.

Projects funded under this BAA that generate preclinical safety data intended to support a research or marketing permit for products regulated by the FDA must be in conformance with GLP. Full proposals may be submitted without protocols for animal use; however, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments. The contracting office may grant exceptions in situations where animal use is not expected to occur until after the first year of the project.

G. FULL PROPOSALS:

1. If the preproposal for a procurement contract is accepted, ACC-APG Edgewood Contracting Division will send a Request For Full Proposal (RFFP) and any additional requirements, including suggested Contract Line Item Numbers (CLINs), a Contract Data Requirements List (CDRL), clauses, terms, and conditions. Full proposals shall be submitted within 45 days after being requested. The U.S. Government reserves the right to reject submissions received more than 45 days after the request for a full proposal from the U.S. Government. Receipt of full proposals will be acknowledged by email.

2. If the preproposal for a grant/cooperative agreement is accepted, ACC-APG Edgewood Contracting Division will send a RFFP to the applicant. Full proposals for grants and cooperative agreements must be submitted through grants.gov. The forms will be available under the announcement, and, must be completed and included as part of the submission for a full proposal. Full proposals may be submitted without protocols for human and animal use. However, protocols with required institutional approvals must be submitted not later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The contracting office may make exceptions in situations where human and/or animal use is not expected to begin until after the first year of the award. In such cases, a time frame for submission of the appropriate protocols should be established during discussions/negotiations, prior to award.

3. There are no specified funding limitations identified for the proposals submitted under this BAA. The applicant's proposed budget should be commensurate with the nature and complexity of the proposed effort. An award decision should be forwarded by the U.S. Government within 180 days after submission. Be advised that at the time of publication of this BAA there are no funds identified for award, and any award(s) are predicated on the availability of funds**.**

4. **Intructions for full proposal submissions for potential OTA's are provided in Section VIII of this announcement.**

IV. FULL PROPOSAL APPLICATION INSTRUCTIONS:

A. GENERAL FORMATTING GUIDELINES:

Unless otherwise specified, full proposal submissions shall be submitted electronically. All applications must be clear, legible, and conform to the following general formatting guidelines:

a. Elaborate proposals with high-gloss paper, vivid colors, detailed artwork, or other embellishments are unnecessary and not desired.

b. Pages shall be 8.5 x 11 inches, single sided, with each page numbered "X of Y pages."

c. Margins: Minimum of 1 inch on all sides.

d. Type Font: 12 point Times New Roman, single spaced.

e. Contract Work Breakdown Structure (CWBS) and Integrated Master Schedule (IMS)/Gantt Charts: The minimum CWBS expected is Level 4. The IMS shall document the critical path and predecessor tasks. In addition to a high level presentation in PDF format as part of the Program Management submission, the applicant shall submit an electronic copy with schedule data in Microsoft Project file that shows all formulas and links, compatible with MS Project 13. The files shall be virus and malware free. All passwords shall be removed.

f. Acronyms: Spell out all acronyms the first time they are used. One page of the proposal body is allocated to spell out acronyms, abbreviations and symbols.

g. Language: English.

h. Electronic file format: PDF, compatible with Adobe Acrobat Reader v. 11.0. File size less than 20 MB.

B. SPECIFIC INSTRUCTIONS FOR CONTRACTS:

1. If a RFFP for a contract is sent to the organization submitting the preproposal, applicants shall use the following guidance as to the scope of the proposal response.

2. The applicant's proposal shall be submitted electronically. The proposal shall conform to the general formatting guidelines, see above section (IV) (a). The proposal shall include the following sections, which shall conform to the following page limits:

a. Cover Page (1 page):

i. BAA number

ii. Name of Lead Organization submitting proposal including their Unique Entity Identifier.

iii. Type of business, selected among the following categories: "Large Business," "Small Disadvantaged Business," "Other Small Business," "HBCU," "MI," "Other Educational," or "Other Nonprofit"

iv. Contractor's reference number (if any)

v. Proposal Title

vi. Technical point of contract to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail address (if available)

vii. Administrative point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail address (if available)

viii. Date proposal was prepared

b. Technical Section (20 pages):

i. Acronyms, Abbreviations, and Symbols

ii. Project objective. Describe what will be accomplished if the U.S. Government funds the proposal. Describe how it fulfils an area of interest described by this BAA.

iii. Background data. Include, for example, data supporting the safety and efficacy of the proposed technology, the validity of models used to test and evaluate the technology, and Applicant compliance with GLP, current Good Manufacturing Practices (cGMP), and/or Good Clinical Practices (GCP) compliance, as appropriate.

iv. Proposed technical approach. Describe in a comprehensive manner the technical approach proposed to accomplish the project objective. Describe the proposed technical approach in sufficient detail so that the U.S. Government may determine that the proposed approach is of acceptable risk.

c. Project Management Section (20 pages):

i. Statement of Work (SOW). The Applicant shall submit a SOW which shall describe the work to be performed by the applicant (and any subcontractors). The final proposed SOW, when accepted by the U.S. Government, shall be incorporated into the contract or Prototype OT at the time of award. For this reason, the SOW shall be a stand-alone document. Applicants should use the

DoD Handbook for Preparation of Statement of Work (MIL-HDBK-245D) as a guide found at: https://assist.daps.dla.mil/quicksearch/

ii. CWBS and CWBS dictionary. The applicant shall submit a CWBS and CWBS dictionary using MIL-HDBK-881 as a guide (http://quicksearch.dla.mil/qsDocDetails.aspx?ident_number=36026). The minimum CWBS expected is Level 4. However, the Applicant shall extend CWBS elements as needed to obtain the depth and breadth required to define the contract scope and to accurately describe the proposed effort. The CWBS shall correlate with the SOW and CLINs. The CWBS shall conform to instructions regarding font size.

iii. IMS. The IMS shall document the critical path, major milestones, tasks/activities, duration, lead/lag/slack time, and schedule relationships. The IMS shall be directly traceable to the SOW, CLINs, and the CWBS. The IMS is intended to be used as a tool for day to day tracking of the program/project. Tasks/activities should roll-up to increasingly higher summary levels. All tasks/activities in the IMS should be logically linked together showing predecessor/successor relationships. The tasks/activities shall be sufficient to account for the entire program/project under contract. Dates delineated in the IMS and Section F shall become contractually binding, and will be adjusted accordingly, based on actual contract award date. The applicant shall also submit an electronic copy of the schedule for submission of schedule data in "Read Only" format that shows all formulas and links for review. The data file shall be in the Microsoft Project 2013 format.

iv. Project Management Approach. The approach to managing and integrating the various aspects of the required work shall be described in sufficient detail so that the U.S. Government may assess associated risks. The applicant shall identify significant milestones, decision points, and the processes that will be used to evaluate program status and progress. The applicant shall include a description of any functional oversight. The applicant shall present mechanisms for interactions/communications between Program Management and the U.S. Government, to include how processes will be updated (e.g., managing and interfacing with key Subcontractors and the U.S. Government). The applicant shall include a description of management relationships or techniques that will be used to supplement day-to-day processes and procedures.

v. Risk Management Plan. The Applicant shall identify potential risks and describe the implementation of an integrated and proactive risk management plan as part of an overall management scheme (e.g., risk planning, risk assessment, risk handling, risk monitoring and documentation). The risk management plan shall discuss integrated methods for identifying, analyzing, prioritizing, and tracking risk drivers and include plans for adequate

resources for risk mitigation. The Applicant shall describe tools or methodologies used in the integrated risk management and risk assessment processes.

d. Past Performance Section (10 pages):
Information shall be provided for the Applicant as well as all proposed first-tier subcontractors. The Applicant shall list ongoing and previous U.S. Government contracts held during the past three years, which are relevant and demonstrate ability to perform the effort required by the proposal. The Applicant shall explain the relevance of previous efforts with respect to the effort described in the proposal. If the Applicant has limited U.S. Government contracting experience, a description of similar contracts with commercial entities, local and/or state governments should be included, if relevant. Information furnished concerning these efforts shall be similar to that requested of U.S. Government contracts. The Government may send Past Performance questionnaires to any Reference(s) listed, whether for U.S. Government contracts or for contracts with other entities. For that reason, the applicant must provide current contact information of all References listed in this section, to include: POC name, address, phone number, fax number, email address, Unique Entity Identifier (UEI) number. Past performance information should be a separate document to allow the Government to restrict evaluation to Government personnel only.

e. Cost Section:
The Cost Proposal shall be an integrated and comprehensive estimate with descriptions of estimating techniques and allocation methods that correlate in sufficient depth with the SOO, SOW, CWBS, IMS and CLINs when applicable. Estimating technique(s) (basis of estimate) used to create the proposal shall be clearly identified. Reasonable and supportable allocation techniques may be used to spread hours and/or cost to lower levels of the CWBS.

While it is intended that Applicants shall use their own format for providing the information requested in these instructions, failure to submit all information requested may result in rejection of a proposal. It is highly suggested that the Cost Proposal Spreadsheet be used by Applicants. The Cost Proposal Spreadsheet can be requested from the BAA POC. Instructions for completion have been embedded into the spreadsheet. Spreadsheet submission must include all formulas and be free from any protection.

Any proposed options that are identified in the Technical Proposal but are not fully priced out in the Cost Proposal Spreadsheet will not be included in any resulting contract or other transaction. If proposing options, they must be separately priced.

For proposed subcontracts, Applicants must provide a separate fully completed Cost Proposal Spreadsheet in support of the proposed costs. This spreadsheet, along with supporting documentation, must be emailed directly to the Business

Point of Contact at the same time the prime proposal is submitted. The e-mail shall identify the proposal title, the prime Applicant and that the attached proposal is a subcontract. Applicants should also familiarize themselves with the subcontract reporting requirements set forth in Federal Acquisition Regulation (FAR) clause 52.204-10, Reporting Executive Compensation and First-Tier Subcontracts Awards. Any newly awarded subcontract must be reported if the prime contract award amount was $25,000 or more.

Fee for travel, direct costs for equipment, Government entities, or cost share contracts is not allowed. In addition, fee applied to Other Direct Costs will be considered based on the application of overhead and the types/quantities of Other Direct Costs, and the Applicant's demonstrated savings in negotiating competitive pricing.

f. **Representations, Certifications, and other Statements of Applicants**: Prospective applicants shall complete electronic annual representations and certifications at SAM accessed via https://www.acquisition.gov as a part of required registration (see FAR 4.1102). Prospective applicants shall update the representations and certifications submitted to SAM as necessary, but at least annually, to ensure they are kept current, accurate, and complete. The representations and certifications are effective until one year from date of submission or update to SAM.

g. **Appendices: (no page limit)**

h. **Key Personnel Qualifications:**
The proposal shall include a Curriculum Vitae (CV) and bibliographic data for the Program Manager and other Key Personnel such as Directors (or equivalent) of Regulatory Affairs, Quality Assurance/Quality Control (QA/QC), Manufacturing, and Risk Management detailing their qualifications to perform the work. If the Applicant does not presently employ Personnel in the positions identified as Key, the Applicant must present a description of the terms of the commitment(s). The Applicant shall provide technical, regulatory, and management staffing plans, specifically addressing vacancies and maintaining Key Personnel. The Applicant shall also provide the CVs and/or resumes and list proposed duties of key subcontractor personnel and consultants (if any) who are proposed for this effort. The Applicant shall provide specific details of all assigned personnel explaining their appropriateness, scientific qualifications, depth and breadth of expertise and credentials relative to the projects. The Applicant shall describe the proposed labor hours and labor categories relating to the performance of the SOW of Key Personnel.

i. **Other documentation that may be requested by the U.S. Government in the RFFP:**
Subcontracting Plans (if applicable): Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. 637(d)), it is the policy of the Government to enable

small business and small disadvantaged business concerns to be considered fairly as subcontractors to contractors performing work or rendering services as prime contractors or subcontractors under Government contracts, and to ensure that prime contractors and subcontractors carry out this policy.
Applicants, other than small businesses, seeking an award of greater than $700,000, who submit a contract proposal including subcontractors are required to submit a subcontracting plan IAW FAR 19.702(a)(1) and (2) with the proposal submission package. The plan format is outlined in FAR 19.704.

As submitted under this BAA, subcontracting plans will be reviewed for adherence to regulations cited in FAR Part 19 and its supplements and not necessarily for evaluation as a specific evaluation criterion. However, an Applicant's refusal to submit a subcontracting plan is grounds for the government to not negotiate award of an Applicant's BAA proposal. A sample small business subcontracting plan template may be provided upon request, but should follow the requirements prescribed in FAR 19.704.

a. .

C. SPECIFIC INSTRUCTIONS FOR GRANTS, COOPERATIVE AGREEMENTS, and TECHNOLOGY INVESTMENT AGREEMENTS (TIA):

1. The Federal Financial Assistance Management Improvement Act of 1999, also known as P.L. 106-107, was enacted on November 20, 1999. The purposes of the Act are to (1) improve the effectiveness and performance of Federal financial assistance programs, (2) simplify Federal financial assistance application and reporting requirements, (3) improve the delivery of services to the public, and (4) facilitate greater coordination among those responsible for delivering services.

2. In compliance with P.L. 106-107, full proposals submitted for a grant award in response to the BAA shall be submitted through Grants.gov. This requires that applicants register in Grants.gov to submit proposals through the Grants.gov portal. Individual Project Managers DO NOT register; however, the Authorized Organizational Representative (AOR) is required to register. The registration process can take several weeks, so please register as soon as possible.

3. Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between grant applicants and the Federal agencies that manage grant funds. The grant community, including state, local and tribal governments, academia and research institutions, commercial firms and not-for-profits, can access the annual grant funds available across the Federal Government through one website, Grants.gov. In addition to simplifying the grant application process, Grants.gov also creates avenues for consolidation and best practices within each grant-making agency. Further information regarding registering with Grants.Gov is available at: http://www.grants.gov/web/grants/applicants.html.

4. Organizations that submit a preproposal or "white paper" under the BAA, and are subsequently invited to submit a full proposal for a grant, may be directed to submit through Grants.gov. Early planningwill facilitate this process and issues in submitting applications through the Grants.gov portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email support@grants.gov. The Contact Center hours of operation are Monday-Friday, 7 AM to 9 PM Eastern Standard Time.

5. The following actions are required as part of the registration process:

   a. Applicants who do business with the Federal Government on a continuing basis, likely have already completed some of the actions, e.g., obtaining a Data Universal Number System (D-U-N-S®) D-U-N-S® Number. A D-U-N-S® Number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B) and is required as part of the registration process. If an organization does not have a D-U-N-S® Number, an authorized official of the organization can request one by calling 1-866-705-5711 Monday- Friday from 7 AM to 8 PM Central Standard Time or online via http://fedgov.dnb.com/webform. Organizations located outside of the United States, can request and register for a D-U-N-S® Number online via http://fedgov.dnb.com/webform.

   b. An organization must be registered with the System for Award Management (SAM) before submitting a grant application through Grants.gov or receiving an award from the Federal Government. SAM validates applicant information and electronically shares the secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). Applicants can register with SAM on line at https://sam.gov. Online registration will take about 30 minutes to complete, depending upon the size and complexity of the organization, but allow 7-10 days after submission before receipt of an active SAM registration. Applicants are encouraged to register as soon as possible after receiving this BAA announcement.

V. EVALUATION AND SELECTION:

A. EVALUATION FACTORS:

1. Proposals received as a result of the BAA shall be evaluated in accordance with evaluation criteria specified therein through a peer or scientific review process. Evaluation of OTA's specified in Section VIII. Written evaluation reports on individual proposals will be necessary but proposals need not be evaluated against each other since they are not submitted in accordance with a common work statement. The primary basis for selecting proposals for acceptance shall be technical, importance to agency programs, and fund availability. Cost realism and reasonableness shall also be considered to the extent appropriate.

2. Full proposals will be evaluated by JPMO scientists, other Federal Agency Representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof and assigned scores based on the following factors (in descending order of importance):

   a. **Technical Merit:** The proposed plans, methods, techniques, and procedures must be feasible, clear, valid, adequately referenced, and state-of-the-art. The proposed schedule must be reasonable. Literature searches are recommended for documenting the strengths of the proposed project.

   b. **Military and Program Relevance:** Projects must support the development of medical CBRN countermeasures and Enabling Biotechnologies, to include Special Projects, and Developmental Initiatives Supporting Medical CBRN Countermeasures and Enabling Biotechnologies, as described in the "Areas of Interest" portion of this BAA and subsequent amendments. Proposals should address an outstanding requirement and balance or reduce programmatic risk of the current development programs. Explain how the results of this project are expected to impact the intended beneficiaries.

   c. **Funds Availability:** JPMO must have funds available to support the proposed work.

   d. **Technology Readiness Level (TRL):** Except RFFPs for grants and OTA's, the technology proposed typically must meet TRL 4. See section IX for a full description of TRLs (Q-TRLS).

   e. **Project Objectives:** The stated objectives must be clear, valid and logical. Projects that demonstrate an innovative approach are desired.

   f. **Regulatory compliance:** The proposal will be evaluated for compliance with FDA guidelines for current cGMP, GLP, and GCP.

g. **Support of other U.S. Government requirements**. The proposal will be evaluated for alignment with other DoD requirements and the medical CBRN Medical Countermeasure and Enabling Biotechnology development efforts of the Department of Health and Human Services, the Department of Veterans Affairs, or the Department of Homeland Security.

h. **Key Personnel Qualifications:** Document the qualifications, capabilities and experience of the proposed Project Manager and other key personnel in sufficient details to demonstrate that the proposed staff has the knowledge and skills to achieve the proposed objectives.

i. **Facilities:** Describe the proposed facilities and equipment, or unique combinations of these, in detail to demonstrate that the organization has the necessary facilities required for the accomplishing the proposed objectives.

j. **Budget/Cost:** The budget must reflect the actual needs of the proposed work and be fully justified so that the U.S. Government can evaluate and determine the cost to be fair and reasonable and commensurate with the complexity and nature of the work proposed.

k. **Past Performance:** Documented satisfactory performance record. In the case of an applicant without a record of relevant past performance or for whom information on past performance is not available, the applicant will receive neither a favorable nor unfavorable evaluation.

B. SELECTION:

Any proposal received may be negotiated. After evaluation, proposals recommended for funding will be prioritized. A prioritized listing of alternates may also be prepared when warranted. Subsequent awards depend upon the availability of funds and fulfillment of requirements and priorities determined to exist at the time of award.

In some cases, funding priorities may change as certain scientific tasks are addressed and new mission assignments arise. Awards may also be dependent upon demonstration by the applicant that they have adequately addressed the following requirements, if applicable to the efforts being proposed:

a. Research involving Human Subjects/Anatomical Substances (if proposed)
b. Research involving Animals (if proposed).
c. Facility Safety Plan.
d. Certificate of Environmental Compliance.
e. Evidence of GLP Compliance (if appropriate).
f. Evidence of cGMP Compliance (if appropriate).
g. Evidence of GCP Compliance (if appropriate).
h. All required Representations and Certifications are completed and on file.

VI. AWARD ADMINISTRATION:

A. PAYMENT:

1. CONTRACTS/GRANTS/OTAs:

In accordance with DFARS Clause 252.232-7003, Electronic Submission of Payment Requests, the contractor shall submit invoices electronically. Invoices shall be made using the DoD's Wide Area Workflow (WAWF) system, Web Invoicing System, or system acceptable to the contracting or agreements officer. Information about WAWF can be found at https://wawf.eb.mil/. Contractors must be able to electronically receive payment funds.

B. INFORMATION RELEASE:

The Government must approve the release of information pertaining to projects funded by this BAA. Approval must be sought through the cognizant Contracting, Grants, or Agreements Officer. Statement a. shall be included in all such information releases; Statements b. – e. shall be included if relevant to the work being conducted.

a. "This work was supported by the Joint Project Manager (Select One) Medical Countermeasure Systems, Enabling Biotechnologies under the Army Contracting Command – Aberdeen Proving Ground – Edgewood Contracting Division – Ft. Detrick, Award No….. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army."

b. In conducting research using humans and/or human anatomical substances, the investigator is required to include approvals, forms and information specified on the HRPO website: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo

c. "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, forms and information specified on the ACURO website https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro

d. "In the conduct of research utilizing recombinant DNA, the investigator adhered to National Institutes of Health (NIH) Guidelines for research involving recombinant DNA molecules." (http://www.nih.gov)

e. "In the conduct of research involving hazardous organisms, the investigator adhered to the Centers for Disease Control (CDC)-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories."

(http://www.cdc.gov/od/ohs/biosfty/biosfty.htm).

f. "Information" includes, but is not limited to, news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and presentations or posters at scientific conferences, workshops, and symposia.

C. FREEDOM OF INFORMATION ACT REQUESTS:

1. The Freedom of Information Act (FOIA) (5 U.S.C. 552) provides a statutory basis for public access to official U.S. Government records. "Records" are defined to include documentation received by the U.S. Government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act http://www.usdoj.gov/oip.

2. When a FOIA request asks for information contained in a successful proposal that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by ACC-APG Edgewood in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of ACC-APG Edgewood's intent to release and will be provided a reasonable opportunity to assert available action.

D. SITE VISITS:

Government personnel may visit the award recipients during the project. All visits shall be coordinated with the cognizant Contracting, Grants, or Agreements Officer and are intended for technical discussion and monitoring of progress of the funded project.

E. REPORTS / MEETINGS / KNOWLEDGE DISSEMINATION:

Reports are necessary for continuation of funding. Reporting requirements are determined by the Contracting, Grants, or Agreements officer and reflect the type of award (grant, procurement contract; firm fixed price or cost-reimbursable). Each request for full proposal will state the necessary reports that will be required. The Applicant must price all reports and deliverables.

Reporting requirements may include the following:

1. Monthly or quarterly reports that outline the accomplishments and progress for that period.

2. Quarterly In-Process Reviews to discuss findings, accomplishments and direction for the program.

3. SF 425, Federal Cash Transaction Report, filed quarterly when grants with scheduled payments are made.

4. SF 270, Financial Status Report. Required for grants either annually or at project termination.

5. Annual reports that consist of detailed summaries of scientific issues, accomplishments and animal research usage during the project.

6. Final report that details the findings and issues of the completed project.

7. Disclosure of subject inventions in accordance with 37 CFR 401 using DD Form 882.

8. Copies of all scientific publications as a result of funding.

9. Abstracts suitable for publication in relation to planned meetings.

10. A Program Review may be held annually at the Government's site in which the Recipient will be required to provide briefing charts and an oral presentation on their efforts achieved as a result of Government awarded funding.

F. AUDITS AND COST PRINCIPLES:

Organizations receiving grants and cost-reimbursable contracts must be audited. See below for the governing cost principles for each award/business type.

a. COST-REIMBURSABLE CONTRACTS:

The awardee's accounting system must be approved by the cognizant Administrative Contracting Officer (ACO). The following cost principles apply:

b. GRANTS:

Recipients are to periodically have independent financial and compliance audits subject to CFR, Title 2, Section 200.

VII. JPMO MISSION STATEMENTS AND AREAS OF INTEREST:

A. SCOPE OF PROPOSALS SOUGHT:

The Government is interested in proposals that are based on data from experiments using specific CBRN warfare agents, to demonstrate safety, efficacy or mode of action. (Please note that CBRN warfare agents will not be provided by the DoD for these efforts.) The JPMO is interested in studies on new and better ways to develop medical CBRN countermeasures more rapidly and with increased efficiency through enabling technologies, life cycle bioinformatics, and improved logistics tracking. The JPMO is not interested in proof-of-concept, applied or basic research proposals. Efforts directed toward the development of enabling technologies, and those technologies that speed up the advanced development process leading to FDA approval are of interest as well. All developmental efforts nominated to be considered by this BAA should be evaluated against the Quality Technology Readiness Levels (Q-TRL) for Medical Product Development (Appendix A).

B. JPMO JOINT DEPUTY PRODUCT MANAGERS, ORGANIZATIONAL MISSION STATEMENTS AND BAA TECHNICAL POINTS OF CONTACT:

1. **BIO 1:** Provide the warfighter with capabilities to protect against know, unknown, and emerging CBRN threats through the advanced development efforts of repurposing FDA licensed or late-stage therapeutics and development of platform vaccines. .

   BIO 1 Technical POC: Mr. Andrew Glenn
   Email: andrew.m.glenn7.civ@army.mil

2. **Chemical Defense Pharmaceuticals (CDP):** Provide the Warfighter robust & affordable FDA-approved lifesaving medical countermeasure drug capabilities against chemical, radiological and nuclear threats.

   CDP Technical POC: Dr. Renae Malek
   Email: renae.l.malek.civ@army.mil

3. **BIO 2** Provide US military forces safe, effective, innovative, and affordable therapeutic solutions to counter traditional, emerging and engineered biological threats.

   BIO 2: Technical POC: Rachel Overman
   Email: rachel.l.overman.civ@army.mil

4. **Diagnostics (DX):** Develop and integrate chemical, biological, radiological, and nuclear (CBRN) technologies to enable early warning, identification, and continued situational awareness of potential global health threats.

   Diagnostics Technical POC: Dr. Jason Opdyke

Email: jason.a.opdyke.civ@army.mil

5. Enabling Biotechnologies (EB): Develop, mature, and maintain a portfolio of technical approaches, capabilities, reagents, medical countermeasures and manufacturing infrastructure to increase efficiency, reduce the product developmental risk, and ensure preparedness in the face of a changing complex and broad CBRN threat environment.

EB Technical POC: Dr. Chris Earnhart, Chief Technology Officer
Email: christopher.g.earnhart.civ@army.mil

C. MISSION AREAS:

1. MEDICAL BIOLOGICAL PROPHYLAXIS:

a. Biological Medical Prophylaxis provides medical countermeasures against biological warfare agents. These countermeasures include specialized medical materiel (e.g., vaccines and immuno-therapeutics) as well as other biological products (e.g., immunoglobulins) designed to be effective as prophylaxis or, to treat rare but serious adverse events from other prophylaxis treatments. Biological Medical Prophylaxis countermeasures must be FDA-approved to provide the Joint Force with the ability to protect Warfighters from the debilitating and life threatening health threats of biological warfare agents (bacteria, viruses, and biotoxins) prior to the appearance of symptoms, thereby protecting Warfighters, conserving the strength of forces, and reducing the impact on the medical care system.

b. Biological Medical Prophylaxis countermeasures should protect against battle space challenge of biological warfare agents (BWA) (e.g., aerosol exposure), be deliverable by minimally invasive means in as few doses as feasible, provide protection as quickly as possible, maintain protection as long as possible, be effective against a broad spectrum of agents, and be flexible enough to respond to a wide range of agents, including genetically altered agents. Biological Medical Prophylaxis countermeasures should limit the logistic burden on the force through limited special storage or handling requirements, reduced dosing, administration, and monitoring requirements. These capabilities should also provide for insertion of technology upgrades and commonality of components to address changing threats.

c. Overarching priorities of the Biological Medical Prophylaxis program include:

i. Develop prophylaxis or pretreatment systems to protect Warfighters from the effects of biological warfare agents prior to the appearance of symptoms. Primary prevention through vaccination is generally preferred as a long term goal, where possible and supported by the nature of the agent. Vaccine development is historically a difficult, expensive, and time-consuming effort. Vaccines are agent, and frequently subtype specific. For these reasons, there is particular interest in broad spectrum protection and multi-agent medical products.

I. Vaccine development which focuses on protection from agents in aerosol exposure, molecular approaches for development of vaccines, measurement of relevant cellular and humoral protective immune responses, and expression or production of protective antigens using recombinant technology.

II. Vaccine development for specific toxins and disease agents which could involve the generation, selection and characterization of attenuated strains or inactivated purified antigen preparations, to include polyvalent vaccines that are more broadly effective.

ii. Safer means of passive immunization, such as production of human monoclonal or modified antibodies that are despeciated.

d. Monoclonal Antibodies (mAbs) have the potential to provide rapid pre-exposure protection and post-exposure prophylaxis. mAbs do not replace the long-term prophylaxis provided by vaccines; however, they do offer a unique alternative in situations where Warfighters require rapid-onset protection or treatment.

e. Enabling technologies that support, facilitate, or accelerate the development or licensure of Biological Medical Prophylaxis countermeasures.

i. Identification of correlates of protection for the agents described above and development of assays to assess such protection.

ii. Development/characterization of relevant animal models to meet FDA licensing requirements for biodefense biologics.

iii. Development of improved methods for delivery of vaccines, including adjuvants, nucleic acid vaccines, methods for oral or nasal immunization with inactivated, live and subunit antigens; sustained release formulations; and methods for delivery of antigens for specific induction of mucosal immunity and development of methods to enhance appropriate immune responses to include co- delivery of cytokines.

iv. Development of improved methods to characterize vaccine products, including potency, identity, and purity.

v. Development of manufacturing technologies and processes to facilitate transition and future production of MCM.

f. Infectious bio-warfare agents and diseases upon which the Biological Medical Prophylaxis program places its current focus include, but not limited to, Ebola virus, Marburg virus, poxvirus models of variola virus and those agents causing Venezuelan equine encephalitis, western and eastern equine encephalitis, Tularemia, Plague, Q-

fever, and Brucellosis. Bio-warfare toxins of interest include those from plants (ricin), bacteria (Staphylococcal enterotoxins, botulinum toxin serotypes A, B, C, D, E, F, G), and membrane damaging toxins.

2. MEDICAL CHEMICAL AND BIOLOGICAL COUNTERMEASURES:

a. Pre exposure/post exposure Prophylactic/pretreatment and therapeutic pharmaceuticals; to include, non-vaccine pharmacological or biological products and medical devices used to prevent, treat, or diagnose patients exposed to either chemical warfare agents (CWA), biological warfare agents (BWA) or infectious diseases. Therapeutic pharmaceuticals could be administered pre- or post-exposure. The products are of the type that are to be licensed or approved by the FDA for their intended use, potentially to include juvenile, geriatric, or immunocompromised patients, subject to type of funding. Treatment of chemical and biological casualties depends on effective use of multiple medical capabilities in an integrated manner. Warfighters may use self- administered pharmaceuticals or may administer pharmaceuticals to another Warfighter. Health care providers must have appropriate pharmaceuticals, tools to diagnose and monitor response of casualties, and appropriate means to protect themselves from chemical and biological hazards. We are particularly interested in developing medical countermeasures that are active against a broad spectrum of chemical or biological agents. Any follow on production contract or other transaction as described in section VIII.A.11 may be for a quantity of up to 10 million course of treatment based on the product and requirements of the DoD.

b. Chemical agents of concern fall under the broad categories of nerve, blister, blood, pharmaceutical-based agents and pulmonary agents. Biological agents of concern include, but not limited to, bacterial, toxin and viral threat agents. Bacterial warfare threat agents of interest include *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis, Burkholderia pseudomallei*, and *Burkholderia mallei*, to include emerging, genetically altered, and multi-drug resistant strains. Toxin threat agents of interest include Botulinum Neurotoxin (BoNT), Ricin, and Staphylococcal Enterotoxins (SE). Viral threat agents of interest include Alpha viruses (i.e., Venezuelan Equine Encephalitis virus [VEE], Western Equine Encephalitis virus [WEE] and Eastern Equine Encephalitis virus [EEE]), Orthopoxvirus (i.e., Variola and Monkey pox), Filoviruses (i.e. Ebola virus and Marburgvirus), Arena viruses (Junin virus and Lassa virus), Bunya viruses (Hantaan virus and Rift Valley Fever virus). Of interest is science focusing on characterizing the nature of the threat to identify key targets for intervention or disruption of the agents and their effects. Gene or nucleotide therapeutics and protein-based therapeutics targets are identified as promising areas/products for investment by Department of Defense (DoD). Metabolomics technology is also identified as a way to discover and develop new countermeasures against biological warfare threats.

c. The JPM CBRN Medical is seeking to develop and deliver a U.S. FDA approved

antiviral and antibacterial countermeasures to protect the warfighter against viral and bacterial (BWAs).

d. One goal is to develop and provide an FDA approved antiviral countermeasure that is efficacious against Filoviruses: Zaire ebolavirus, Sudan ebolavirus, and Marburg marburgvirus. Additional viruses of interest include: Alphaviridae (Eastern Equine Encephalitis, Western Equine Encephalitis, Venezuelan Equine Encephalitis), Bunyaviridae (Hantaan), and Filoviridae (Tai Forest, Bundibugyo).

e. Overarching goals of the Medical Chemical and Biological Countermeasures projects include:

i. Develop systems that support maintenance or restoration of pre-CWA or pre-BWA exposure health and that allow Warfighters to complete their mission. This includes medical CWA or BWA countermeasures that prevent, reverse, or significantly mitigate the effects and negative operational impact of CWA or BWA. Medical countermeasures may block, stop or reverse the direct effects of these agents, or prevent or treat the pathology and symptoms of these agents.

ii. Develop medical countermeasures that provide broad-spectrum prevention or treatment for classes of chemical or biological agents and a range of exposure routes. Threats from chemical agents are likely to become more complex in the future as a result of increased agent variety and sophistication. The effects of biological agents are likely to be more difficult to mitigate as a result of genetic engineering and the natural evolution of multidrug resistance. Therefore, the products should be flexible enough to respond to a wide range of warfare agents, including traditional and emerging agents. Medical CWA countermeasure systems might also include developing therapies and protocols for treatment that mitigate agent persistence or special effects of new threat agents, such as those that can potentially penetrate protective clothing.

iii. Evaluate and leverage enabling technologies to enhance/prolong the shelf life of nerve agent countermeasures currently in the military arsenal. Areas of focus include developing new container-closure systems, wet-dry auto injectors or formulation development.

3. MEDICAL RADIOLOGICAL COUNTERMEASURES:

The goal of the Medical Radiological Countermeasures (MRADC) projects are to select, develop, and manufacture FDA-approved drugs, biologics and diagnostics (e.g., biodosimetry) to increase survival and decrease incapacity by treating or detecting the incipient or manifest radiation injury following exposure to radiation from nuclear or radiological weapons so that Warfighters can maintain operational effectiveness.

MRADC must be safe, efficacious, free of performance-degrading side effects, compatible with current military CBRN countermeasures, and usable while in combat or garrison, during medical evacuation, and in hospital. Desired, but not mandatory, product attributes include ease of administration (e.g., auto injector) and administrable to subjects wearing military protective gear, efficacy with a single dose or short course of treatment, and retained efficacy even if delivered more than four hours after radiation exposure. MRADC should not require refrigeration or have other significant logistical burdens and should have a relatively long shelf life. Excluded from consideration under this Announcement are candidate MRADC next generation antibiotics and probiotics, blocking, decorporation, and purgative agents, blood (or blood component) replacements or substitutes, antiemetics and other comfort or supportive measures.

4. MEDICAL DIAGNOSTIC AND SURVEILLANCE SYSTEMS:

The DoD has a need for technologies for the prediction, detection, identification, and clinical diagnosis of disease caused by warfare pathogens, chemical agents, biological toxins and radiation exposure. Sensitivity, specificity, ease of use, and deployability (size, weight, power requirements, and reduced consumables) are critical features of such systems. Platform systems with a wide breadth of commercial medical diagnostic applications increase the overall utility to the military. An integrated system using multiple technology approaches that will reduce the potential for misdiagnosis of a BWA or other disease agent in clinical samples will provide the solution for future diagnostic capabilities. The DoD is interested in developmental efforts that improve the ability of DoD entities to perform identification and characterization of infectious disease and biological warfare threat agents associated with veterinary, arthropod vector, and environmental surveillance samples.

5. ENABLING BIOTECHNOLOGIES AND RESPONSE SYSTEMS

The Enabling Biotechnologies (EB) office was created to respond to emerging, altered, or wholly novel threats in an operationally relevant timeframe through a combination of reagent and medical countermeasure candidate preparedness against known priority threats and implementation of a comprehensive rapid response system. In order to meet those mission goals, EB operates on the cutting edge of technologies for response and drug development. The office has four distinct units that each uniquely contribute to fulfilling the overall mission of the office.

- Defense Biologics Assurance Office (EB/DBPAO): DBPAO develops, produces, integrates and distributes biological threat agent reference materials and detection/diagnostic assay and maintains DoD-accredited data infrastructure for: 1) genomic sequences, 2) assay data packages, 3) microbial data, and 4) analytical tools. Potential funding opportunities for DBPAO include improvement assay and reagent quality (e.g., antibodies), enhancement of DBPAO reference material holdings in the Unified Culture Collection (UCC), improvement of antibodies and expansion of immunoassays and reagents, development of new molecular assays, and development of software/artificial intelligence/machine learning tools such that constantly monitor assay

performance and countermeasure effectiveness.

- Advanced Technology Platforms (EB/ATP): ATP matures and implements platform approaches intended to increase efficiency, and reduce costs and developmental risk throughout the drug development life cycle. ATP manages active programs in computational drug design and optimization, rapid antibody development, broadly neutralizing vaccine approaches, rapid fielding for polyclonal antisera, and innovative delivery systems and formulations to facilitate use of medical countermeasures by the Warfighter in adverse conditions. ATP manages not only the standup and de-risking of platform technologies but implements those technologies to develop medical countermeasures across broad threat space. ATP is also responsible for implementation of rapid response systems. Areas of interest span innovations in drug discovery, design, manufacturing and testing that enable efficient and rapid development and aid in management of predictable drug development risks.

- Advanced Development and Manufacturing Capabilities (EB/ADMC): ADMC manages a portfolio of enabling biologics development and manufacturing capabilities and technologies; and stabilizes both supply chain and biologics manufacturing infrastructure to ensure the ability of EB to efficiently develop products and rapidly respond to unanticipated events. Example areas of interest include innovative manufacturing and testing technologies that increase product quality, yield, and shelf life. Other areas of interest include implementing process efficiencies that decrease cost per dose and drug substance/product release testing time. Facility-wide approaches in manufacturing cybersecurity and supply chain risk reduction are also of interest.
- Advanced Clinical Technologies (EB/ACT): ACT implements innovative technological solutions to enable field-forward execution of clinical trials during outbreaks or biological or chemical warfare events. These technologies include innovative approaches to clinical sample collection and processing, development of technologies to detect and track biomarkers related to efficacy and safety, management and processing of clinical data in adverse environments, and regulatory science to enable rapid implementation of clinical trials while maintaining rigor and appropriate data collection.

VIII. SPECIFIC INSTRUCTIONS FOR OTHER TRANSACTION (OT) AGREEMENTS:

A. GENERAL INFORMATION

1. This Announcement is intended to solicit pre-proposals for JPM Medical/JPL EB for the development of prototypes in accordance with Section 4022 of title 10. U.S.C. Mission areas and technical points of contact for the product management offices within the JPM/JPL are shown in Section VII of the BAA.

2. All developmental efforts considered by this Announcement should be evaluated against the Quality Technology Readiness Levels (Q-TRL) (Attachments 1 and 2). To facilitate communication on both scientific and administrative matters relating to this Announcement, a single email address may be used for all communications. Please send all technical and administrative questions and inquiries to usarmy.detrick.mcs.mbx.baa@mail.mil.

Potential applicants are encouraged to discuss their proposal ideas with the appropriate technical contacts listed in Section VII (B). Administrative questions concerning the preparation of preproposals or proposals should be emailed to usarmy.detrick.mcs.mbx.baa@mail.mil, with subject heading: Edgewood Contracting Division -Fort Detrick BAA 17-01.

3. The JPM Medical/JPL EB contemplates the award of agreements under this Announcement in support of its mission to foster and/or conduct the advanced development of FDA- Approved Medical CBRN Countermeasures. As stated herein, OTA Offerors may submit a pre-proposal for prototype projects based on specific requirements otherwise identified and called out in Sections VII and VIII of this Announcement or in a separate Request for Project Proposals (RPP) issued under this BAA.

4. There are certain post-employment restrictions on former Federal officers and employees as defined in 18 USC 207 and FAR 3.104-4(c). If a submitter believes a post-employment restriction or conflict of interest exists, notification should be sent to the Agreements Officer prior to initiating efforts on a full proposal.

5. Proposals may be disclosed outside of the U.S. Government subject matter experts for the sole purpose of technical and programmatic evaluation. The requiring office obtains a written agreement from the evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

6. The FOIA (5 U.S.C. 552) provides a statutory basis for public access to official U.S. Government records. "Records" are defined to include documentation received by the U.S. Government in connection with the transaction of public business. Certain types of information submitted to the Government in a process having the potential for award of an OT are exempt from disclosure requirements of 5 U.S.C. 552 (the Freedom of Information Act-FOIA) for a period of five (5) years from the date the Government receives the information. The types of information listed above may continue to be exempted, in whole or in part, from disclosure after the expiration of the five (5) year period if it falls within an exemption to the FOIA such as trade secrets and commercial or financial information obtained from a person and privileged or confidential. Offerors should mark business plans and technical information that are to be protected for five years from FOIA disclosure with a legend identifying the documents as being submitted on a confidential basis.

7. Only a warranted Agreements Officer may obligate the U.S. Government to the expenditure of funds for awards under this Announcement. The U.S. Government does not fund preparation of proposals or support work efforts or tasks that are inferred from discussions with technical project officers.

8. The Offeror will not be reimbursed for any costs incurred prior to the effective date of the agreement.

9. The Government is prohibited from soliciting and awarding actions to contractors that have engaged or are suspected to have engaged in criminal, fraudulent, or seriously improper conduct.

10. Prospective contractors shall complete electronic annual representations and certifications at SAM as described in the BAA.

In accordance with 10 U.S.C. § 4022(f), the Government may award a follow-on production

contract or Other Transaction (OT) for any OT awarded under this BAA if: (1) that participant in the OT, or a recognized successor in interest to the OT, has successfully completed the prototype project; and (2) the OT provides for the award of a follow-on production contract or OT to the participant, or a recognized successor in interest to the OT. A transaction for a prototype project is completed upon the written determination of the appropriate approving official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project; (2) satisfied success metrics incorporated into the Prototype OT; or (3) accomplished a particularly favorable or unexpected result that justifies the transition to production. The scope of anticipated follow-on activity will be defined for each individual Prototype Project, but in general may include activities that are necessary for further development of technology through FDA licensure and any post-marketing commitments or requirements, as well as purchase of successful prototypes in a quantity sufficient to meet the fielding needs of the requiring activity.

11. SUBMISSION PROCEDURES:

1. PREPROPOSALS:

a. Preproposals may be submitted at any time describing a specific idea or project that pertains to advanced development prototype requirements identified in Section VII, specifically announced in this Section VIII, or by separate RPP issued under this BAA. Preproposals should be no longer than eleven (11) pages, and include a description of the relevant technology including supporting data, the scope of the proposed effort including a high-level Work Breakdown Structure (WBS), and a description of the proposer's research, development, manufacturing, past performance, or other special qualifications. The preproposal should include an anticipated cost for the efforts described in the preproposal. Preproposals shall be submitted to the following email address: usarmy.detrick.mcs.mbx.baa@mail.mil.

b. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a preproposal. All preproposals will be assigned an identification number and an email will acknowledge receipt of a preproposal. Usually, the Project Manager of the submitting organization should receive a decision letter or email regarding the preproposal within 60-90 days of submission.

c. In accordance with the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC) released 29 March 2012, research being proposed which falls under the definition of DURC, "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security", must be identified in the Offeror's preproposal. If a full proposal is then requested by the Government, risk mitigation of this concern shall be

included as part of the Risk Management Plan of the Technical proposal section of this document.

2. FULL PROPOSALS:

a. If a preproposal submitted in response to this BAA is accepted by the U.S. Government, a Request for Full Proposal (RFFP) will be sent to the organization submitting the preproposal. The following is general guidance as to the scope of the proposal for an Agreement.

i. PROPOSAL GUIDELINES:

1. <u>Cover Page (1 page) "Proposal for Prototype OTA":</u>

A. BAA number

B. Name of Lead Organization submitting proposal including Commercial and Government Entity code (CAGE) and Data Universal Number (DUNS).

C. Type of business, selected among the following categories: "Large Business," "Small Disadvantaged Business," "Other Small Business," "HBCU," "MI," "Other Educational," or "Other Nonprofit"

D. Contractor's reference number (if any)

E. Proposal Title

F. Technical point of contract to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail address (if available)

G. Administrative point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail address (if available)

H. Date proposal was submitted

2. <u>Technical Section (20 pages)</u>

A. Acronyms, Abbreviations, and Symbols

B. Project objective. Describe the prototype and what will be accomplished if the U.S. Government funds the proposal. Describe how it fulfils an area of interest described by this Announcement.

C. Background data. Include, for example, data supporting the safety and

efficacy of the proposed technology, the validity of models used to test and evaluate the technology, and Offeror compliance with GLP, current Good Manufacturing Practices (cGMP), and/or Good Clinical Practices (GCP) compliance, as appropriate.

D. Proposed technical approach. Describe in a comprehensive manner the technical approach proposed to accomplish the project objective. Describe the proposed technical approach in sufficient detail so that the U.S. Government may determine that the proposed approach is of acceptable risk.

3. Project Management Section (20 pages).

A. Statement of Work (SOW). The Offeror shall submit a statement of work that formally captures and defines the work activities, deliverables, and timeline, for the prime contractor and any subcontractors, necessary to execute performance or development of the prototype. The SOW should include detailed requirements with standard regulatory and governance terms and conditions to sufficiently conceptually overlap with the contract.

B. WBS and WBS dictionary. The offeror may submit a Work Breakdown Structure (WBS) and use extended WBS elements as needed to define the contract scope and to accurately describe the proposed effort. The WBS should correlate with the SOW and Agreement Line Items (ALINs).

C. IMS. (Optional) The IMS should document the critical path, major milestones, tasks/activities, duration, lead/lag/slack time, and schedule relationships. The IMS should be directly traceable to the SOW, ALINs, and the WBS. The IMS is intended to be used as a tool for day to day tracking of the program/project. Tasks/activities should roll-up to increasingly higher summary levels. All tasks/activities in the IMS should be logically linked together showing predecessor/successor relationships. The tasks/activities should be sufficient to account for the entire program/project under contract. Dates delineated in the IMS would become legally binding, and will be adjusted accordingly, based on actual award date. The IMS should be submitted electronically in "Read Only" format that shows all formulas and links for review. The data file shall be in the native format of the commercially off the shelf software.

D. Project Management Approach. The approach to managing

and integrating the various aspects of the required work shall be described in sufficient detail so that the U.S. Government may assess associated risks. The Offeror shall identify significant milestones, decision points, and the processes that will be used to evaluate program status and progress. The Offeror shall include a description of any functional oversight. The Offeror shall present mechanisms for interactions/communications between Program Management and the U.S. Government, to include how processes will be updated (e.g., managing and interfacing with key Subcontractors and the U.S. Government). The Offeror shall include a description of management relationships or techniques that will be used to supplement day-to-day processes and procedures.

E. Risk Management Plan. The Offeror shall identify potential risks and describe the implementation of an integrated and proactive risk management plan as part of an overall management scheme (e.g., risk planning, risk assessment, risk handling, risk monitoring and documentation). The risk management plan shall discuss integrated methods for identifying, analyzing, prioritizing, and tracking risk drivers and include plans for adequate resources for risk mitigation. The Offeror shall describe tools or methodologies used in the integrated risk management and risk assessment processes.

4. **Past Performance Section (10 pages).** Information shall be provided for all proposed first-tier subcontractors with whom the Offeror is teaming as well as the Offeror. The Offeror shall list ongoing and previous U.S. Government and commercial contracts held during the past three years, which are relevant and demonstrate ability to perform the effort required by the proposal. The Offeror shall explain the relevance of previous efforts with respect to the effort described in the proposal. The Government may send Past Performance questionnaires to Reference(s) listed. For that reason, the offeror must provide current contact information of all references listed in this section, to include: POC name, address, phone number, fax number and email address. Offerors shall provide notification to the Government pertaining to all contracts with commercial or Government entities that have been terminated for default in whole or in part, for any reason, during the past two years.

5. **Cost or Pricing Section.** Proposals may be submitted on a firm fixed price basis. If during evaluation, or at any time prior to award,

the Government determines that a firm fixed priced based agreement is not suitable for the particular effort, the parties will negotiate a cost based arrangement. At such time, cost proposal requirements will be provided to the Offeror by the Government.

i. If Offeror's proposal is submitted in response to a particular RPP, all pricing shall be in accordance with the pricing template attached to that RPP.

ii. If Offeror's proposal is submitted as a cost reimbursement in response to this Announcement and not in response to a particular RPP, all pricing shall be submitted on a separate Price Proposal in a "Read Only" Microsoft Excel file, showing all formulas and links. The depth and breadth of the cost proposal shall be determined based on the complexity of the requirement. Instructions for submission shall be provided in the RFFP.

6. **Security Requirements.** Although not to be evaluated, the Offeror shall identify existing or describe capability of obtaining personnel/facilities security clearances. DoD security management and handling requirements outlined in regulations such as DoD 5200.1-R and DoD 5400.7-R apply to prototype other transactions.

7. **Key personnel qualifications.** The proposal shall include a Curriculum Vitae (CV) and bibliographic data for the Program Manager and other Key Personnel such as Directors (or equivalent) of Regulatory Affairs, Quality Assurance/Quality Control (QA/QC), Manufacturing, and Risk Management detailing their qualifications to perform the work. If the Offeror does not presently employ Personnel in the positions identified as Key, the Offeror must present a description of the terms of the commitment(s). The Offeror shall provide technical, regulatory, and management staffing plans, specifically addressing vacancies and maintaining Key Personnel. The Offeror shall also provide the CVs and/or resumes and list proposed duties of key subcontractor personnel and consultants (if any) who are proposed for this effort. The Offeror shall provide specific details of all assigned personnel explaining their appropriateness, scientific qualifications, depth and breadth of expertise and credentials relative to the projects. The Offeror shall describe the proposed labor hours and labor categories relating to the performance of the SOW of Key Personnel.

8. **Subcontractor Management.** The Offeror shall propose a subcontracting management approach to include analysis of subcontractor selection (i.e. list selection criteria), choice of subcontract

types, and the plan for incentivizing contractors and assuring subcontractors meet cost, schedule, and performance requirements. The Offeror shall describe how subcontract competition will be sought, promoted, and sustained throughout the course of the cost reimbursement component of the acquisition, identify any known barriers to increasing subcontract competition and how to overcome any such barriers. Prior to Agreement execution, the Offeror shall submit with its proposal the first tier subcontractors' letter(s) of consent allowing the Government to disclose the subcontractors' past performance to the Offeror during negotiations.

9. **Company Financial Statements.** Offerors shall provide copies of their annual financial statements for the last three years.

10. **Research Involving Animals.** Awards funded by the DoD require a second tier review for the use of animals prior to implementation. Therefore, the Project Manager must address all pertinent issues relating to the use of animals in the proposed work effort. Include the required assurances, approvals, forms and description in the proposal addenda entitled "Research Involving Animals," as specified on the Animal Care and Use Review Office (ACURO) website:https://mrmc.amedd.army.mil/index.cfm?pageid=research_protecti ons.acuro. Projects performed under DoD sponsorship that generate preclinical safety data intended to support a research or marketing permit for products regulated by the FDA must be in conformance with GLP. Full proposals may be submitted without protocols for animal use; however, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments. The contracting office may grant exceptions in situations where animal use is not expected to occur until after the first year of the project. In such cases, a time frame for submission of the appropriate protocols should be established during discussion/negotiations.

11. **Other.** Other documentation that may be requested by the U.S. Government in a RPP.

C. EVALUATION:

1. EVALUATION FACTORS FOR PROTOTYPE AGREEMENTS:

a. Proposals may be submitted in response to this Announcement or separate RPPs for particular requirements.

b. Full proposals will be evaluated by scientists, other Federal Agency Representatives, outside scientists with diverse expertise, clinicians,

consumers, or combinations thereof will evaluate proposals. At a minimum, the following will be considerations during the evaluation (in no particular order):

i. Technical Merit: The proposed plans, methods, techniques, and procedures must be feasible, clear, valid, adequately referenced, and state-of-the-art. The proposed schedule must be reasonable. Literature searches are recommended for documenting the strengths of the proposed project.

ii. Military and Program Relevance: Projects must support the development of medical CBRN countermeasures, to include Countermeasure Prototypes, Special Projects, and Developmental Initiatives Supporting Medical CBRN Countermeasures and Enabling Technologies. Proposals should address an outstanding requirement and balance or reduce programmatic risk of the current DoD countermeasure development program.

iii. Funds Availability: JPM Medical/JPL EB must have funds available to support the proposed work. JPM Medical/JPL EB funds are for purposes of warfare defense against JCS validated CBRN warfare threats.

iv. Technology Readiness Level (TRL): The technology proposed must meet TRL 4 or above. See the attached for a full description of TRLs (Q-TRLS).

v. Project Objectives: The stated objectives must be clear, valid and logical. Projects that demonstrate an innovative approach are desired.

vi. Regulatory compliance. The proposal will be evaluated for compliance with FDA guidelines for current cGMP, GLP, and GCP.

vii. Support of other U.S. Government requirements. The proposal will be evaluated for alignment with, and unnecessary duplication of, other DoD requirements and the medical CBRN Medical Countermeasure development efforts of the Department of Health and Human Services, the Department of Veterans Affairs, or the Department of Homeland Security.

viii. Key Personnel Qualifications: Document the qualifications, capabilities and experience of the proposed Project Manager and other key personnel in sufficient details to demonstrate that the proposed staff has the knowledge and skills to achieve the proposed objectives.

ix. Facilities: Describe the proposed facilities and equipment, or unique combinations of these, in detail to demonstrate that the organization has, or may access, the necessary facilities required for the accomplishing the

proposed objectives.

x. **Budget/Cost:** The budget must reflect the actual needs of the proposed work and be fully justified so that the U.S. Government can evaluate and determine the cost to be fair and reasonable and commensurate with the complexity and nature of the work proposed.

xi. **Best value:** Contract award will be made to that Offeror whose proposal offers the best overall value to the Government based on an integrated assessment of the non-cost and cost related factors.

xii. **Past Performance:** Documented satisfactory performance record. In the case of an offeror without a record of relevant past performance or for whom information on past performance is not available, the offeror may not be evaluated favorably or unfavorably on past performance.

D. SELECTION FOR AWARD OF PROTOTYPE AGREEMENTS:

Any proposal received may be negotiated. After any evaluation and selection, an award will be made to the successful proposal. Subsequent awards depend upon the availability of funds and fulfillment of requirements and priorities determined to exist at the time of award. In some cases, funding priorities may change as certain scientific tasks are addressed and new mission assignments arise. Award may also be dependent upon demonstration by the offeror that they have adequately addressed the following requirements, if applicable to the efforts being proposed:

1. Research involving Human Subjects/Anatomical Substances (if proposed).
2. Research involving Animals (if proposed).
3. Facility Safety Plan.
4. Certificate of Environmental Compliance.
5. Evidence of GLP Compliance (if appropriate).
6. Evidence of cGMP Compliance (if appropriate). Evidence of GCP Compliance (if appropriate).
7. All required Representations and certifications are completed and on file.

E. AWARD ADMINISTRATION:

1. **PAYMENT**:
   Payment process and terms will be set forth in any resultant agreement.

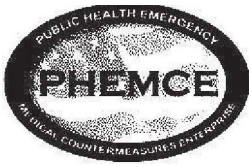
2. **AUDITS AND COST PRINCIPLES:**

a. Agreements will require that adequate records be maintained to account for federal funds received and cost-sharing, if any.

b. Section 801 of the National Defense Authorization Act for Fiscal Year 2000 establishes a requirement that an OT for a prototype project that provides for payments in a total amount in excess of $5,000,000 include a clause that provides Comptroller General access to records. Because this is a mandatory requirement that has a substantial impact on the public, the Interim Rule implementing this law was published in the Federal Register, became effective July 5, 2000, is codified in Part 3 of Section 32 of the Code of Federal Regulations, Subtitle A, Chapter I, and is attached as Appendix 4. Section 804 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 provides clarification that limits access in certain situations.

IX. ATTACHMENTS AND APPENDICES

ATTACHMENT 1



FINAL - For PUBLIC USE

Harmonized Q-TRL List for Medical MCMs

The US Department of Health and Human Services (HHS) and the Department of Defense (DoD) are engaged in the development of medical countermeasures (MCM) for Chemical, Biological, Radiological and Nuclear (CBRN) threats. The DoD and HHS utilize harmonized Technology Readiness Levels (TRLs) as a common method to understand at a general level the maturity of MCM development products in development across the USG. TRLs consist of nine progressive levels of milestones over a product development lifecycle.

Quantitative Technological Readiness Levels (Q-TRLs) expand the nine high-level TRLs to a much more detailed level to provide key development milestones and activities specific to vaccine, small molecule, biologics and diagnostics. These Q-TRLs are not intended to be a requirement for each project but rather to provide a selection of milestones and activities throughout the development lifecycle from discovery through post-approval.

Naming Conventions

For the Q-TRL naming conventions the first number denotes TRL level, second letter denotes functional areas, last number is sequential number of Q-TRL in a functional area. For Medical MCMs the letter R is Regulatory, C is clinical, D is non-clinical development, E is non-clinical efficacy and M is CMC.

Q-TRL List

TRL Level	Sub Level	Product Development Area	Q-TRL Description
1		Overview	**Review of Scientific Knowledge Base**. Active monitoring of scientific knowledge base to identify countermeasure candidates. Scientific findings are reviewed and assessed as a foundation for characterizing approaches to intervene in disease.
	1-R1	Regulatory	No Activity.
	1-M1	CMC	Establish consultant contacts with target/candidate experts (if applicable)
	1-D1	Non-Clinical Development	No Activity.
	1-E1	Non-Clinical Efficacy	Identify threat agent challenge agent and make link.
	1-E2		Perform natural/case history studies of threat agent.
	1-E3		Pathogenesis, and pathophysiology studies to relate to humans.
	1-C1	Clinical	Review the pathology of human disease.
2		Overview	**Development of Hypotheses and Experimental Designs** Develop research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Focus on practical applications based on basic principles. Use of computer simulation or other virtual platforms to test hypotheses may be used.
	2-R1	Regulatory	No Activity.
	2-M1	CMC	Review scientific literature, and design theoretical synthesis processes that may be evaluated in the laboratory to yield the selected bulk drug substance (BOS) candidate.
	2-D1	Non-Clinical Development	No Activity.
	2-E1	Non-Clinical Efficacy	Identify and characterize threat agent.
	2-E2		Generate hypotheses for types of animal models.
	2-E3		Perform exploratory studies.
	2-E4		Summarize the description of the human disease.
	2-C1	Clinical	No Activity.
3		Overview	**Target/Candidate Identification and Characterization of Preliminary Candidates(s)** Begin research, data collection, and analysis in order to test hypothesis. Explore alternative concepts, identify and evaluate critical technologies and components, and begin characterization of candidate(s). Preliminary efficacy demonstrated in vivo. **3A** Identify target and/or candidate. **3B** Demonstrate in vitro activity of candidate(s) to counteract the effects of the threat agent. **3C** Generate preliminary in vivo proof-of-concept efficacy data (non-GLP[Good Laboratory Practice])
	3-R1	Regulatory	No Activity.
	3-M1	CMC	Perform laboratory scale experiments to test feasibility of lab scale manufacturing

Q-TRL List

TRL Level	Sub Level	Product Development Area	Q-TRL Description
			Hypothesis. Explore alternative synthesis/manufacturing approaches to enhance yield and purity and document processes.
	3-M2		Identify the candidate or prototypes.
	3-M3		Lab-scale production of candidate product.
	3-M4		Formulate an experimental drug product (EDP) for preliminary animal studies.
	3-M5		Initiate development of appropriate and relevant preliminary assays to evaluate lab-scale product
	3-M6		Establish reference materials with document histories
	3-M7		Complete Research tech transfer report
	3-M8		Complete tech transfer from Research to Development
	3-D1	Non-Clinical Development	Conduct in-vitro testing to determine pre-clinical baseline (Therapeutic Index e.g. MIC, ED50, including in-vitro safety: genotoxicity)
	3-E1	Non-Clinical Efficacy	Select type strain candidate(s) or physical/physiochemical forms of challenge agent.
	3-E2		Complete pathology studies of the animals that were exposed to the challenge agent.
	3-E3		Identify facilities for physical agent exposure.
	3-E4		Complete dose ranging with challenge agent, monitoring clinical endpoints (non-invasive).
	3-E5		Determine the mechanism of action through pathogenesis & exploratory studies.
	3-E6		Identify critical parameters and outcomes in probable animal models.
	3-E7		Conduct initial proof-of-concept animal efficacy studies in one probable animal model (small animals are acceptable).
	3-C1	Clinical	No Activity.
4		Overview	**Candidate Optimization and Non-GLP In Vivo Demonstration of Activity and Efficacy** Initiation of animal model development. Non-GLP in vivo toxicity and efficacy demonstration in accordance with the product's intended use. Initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies. **4A** Demonstrate non-GLP in vivo activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration, and route of threat agent challenge) **4B** Conduct initial non-GLP toxicity studies and determine pharmacodynamics and pharmacokinetics and/or immune response in appropriate animal models (as applicable)" **4C** Initiate experiments to determine assays, parameters, surrogate markers, correlates of protections, and endpoints to be used during non-clinical and clinical studies to further evaluate and characterize candidate(s).
	4-R1	Regulatory	Request and conduct pre-pre-IND meeting, if necessary including discussions of the concept for animal models.

Q-TRL List

TRL Level	Sub Level	Product Development Area	Q-TRL Description
	4-M1	CMC	**Demonstrate Capability to Produce the Technology in a Lab Environment.** Prepare laboratory-scale non-GLP/non-cGMP quantities of BOS to further refine manufacturing process. Formulate an experimental drug product (EDP) for preliminary animal studies. Evaluate BOS and EDP for conformance to preliminary specifications.
	4-M2		Conduct physical-chemical characterization of BOS.
	4-M3		Expand on preliminary development of appropriate and relevant assays and associated reference standards/reagents for the desired formulations. Demonstrate suitability for use in pilot scale GMP manufacturing.
	4-M4		Conduct non GMP stability of BOS and EDP.
	4-D1	Non-Clinical Development	Conduct non-GLP safety studies to include early toxicity in animal models consistent with product's intended use (e.g. route of administration and dose range (small animals may be used).
	4-D2		Conduct early dose-range PK/PD/biodistribution studies
	4-E1	Non-Clinical Efficacy	Expand on initial proof of concept studies to develop relevant animal model(s). Demonstrate relevance to threat being addressed.
	4-E2		Demonstrate non-GLP in vivo activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration, and route of threat agent challenge)
	4-E3		Initiate assay development to evaluate critical outcomes in both animals and humans.
	4-E4		Evaluate potential biomarkers for measuring efficacy.
	4-C1	Clinical	No Activity.
5		Overview	**Advanced Characterization of Candidate and Initiation of GMP Process Development** Continue non-GLP in vivo studies, and animal model and assay development. Develop a scalable and reproducible manufacturing process amenable to GMP. **Animal Models:** Continue development of animal models for efficacy and dose-ranging studies. **Assays:** Initiate development of in-process assays and analytical methods for product characterization and release, including assessments of potency, purity, identity, strength, sterility, and quality as appropriate. **5A** Demonstrate acceptable Absorption, Distribution, Metabolism, and Elimination characteristics and/or immune responses in non-GLP animal studies as necessary for IND filing. **5B** Continue establishing correlates of protection, endpoints, and/or surrogate markers for efficacy for use in future GLP studies in animal models. Identify minimally effective dose to facilitate determination of "humanized" dose once clinical data are obtained. *** Changes in formulation require re-evaluation activities to be undertaken at lower TRL levels.
	5-R1	Regulatory	Submit Pre-IND package to FDA and conduct Pre-IND meeting

Q-TRL List

TRL Level	Sub Level	Product Development Area	Q-TRL Description
	5-R2		Prepare draft TPP (Target Product Profile). Questions of shelf life, storage conditions, and packaging should be considered to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from the FDA.
	5-M1	CMC	Complete development of a pilot scale process for BOS that is amenable to GMP manufacturing
	5-M2		Complete process development for a clinical drug product (CDP) suitable for early clinical studies
	5-M3		Complete development of in-process assays and analytical methods for characterization and release of pilot scale BOS and CDP, including assessments of identity, potency, impurities, sterility, and quality, as appropriate.
	5-M4		Produce BOS and FOP at pilot scale (non GMP) and establish specifications for BOS and CDP.
	5-M5		Initiate stability studies of reagents and reference standards
	5-M6		Perform Tech Transfer to GMP facility (if applicable).
	5-D1	Non-Clinical Development	Measure absorption, distribution, metabolism, and elimination characteristics and/or immune responses in non-GLP animal studies
	5-D2		Complete non-GLP dose-range PK/PD/biodistribution studies
	5-D3		Complete refinement of assays for in vivo PK/PD/biodistribution
	5-E1	Non-Clinical Efficacy	Complete development -of assays that will be used to assess biomarkers.
	5-E2		Optimize drug performance in-vitro.
	5-E3		Optimize drug performance in-vivo.
	5-E4		Demonstrate efficacy (and dose-response) in at least one relevant animal model
	5-C1	Clinical	Develop phase 1 clinical trial protocol synopsis
6		Overview	**GMP Pilot Lot Productions, IND Submission, and Phase 1 Clinical Trial(s)** Manufacture GMP-compliant pilot lots. Prepare and submit investigational New Drug package to FDA and conduct Phase 1 Clinical trial. **Animal Models:** Continue animal model development via toxicology, pharmacology, and immunogenicity studies. **Assays:** Qualify assays for manufacturing quality control and immunogenicity, if applicable **6A** Conduct GLP non-clinical studies for toxicology, pharmacology, and immunogenicity as appropriate. **6B** Prepare and submit IND package to FDA to support initial clinical trial(s). **6C** Complete Phase 1 clinical trial(s) that establish an initial safety, pharmacokinetics and immunogenicity assessment as appropriate.
	6-R1	Regulatory	Prepare and submit investigational New Drug (IND) to FDA. Include: Elements of the FDA Animal Rule, Conceptual design for efficacy studies
	6-R2		Update Target Product Profile as appropriate.
	6-R3		Conduct end of Phase 1 Meeting with FDA. (only available to Fast Track products)

Q-TRL List

TRL Level	Sub Level	Product Development Area	Q-TRL Description
	6-M1	CMC	**Capability to Produce Systems, Subsystems, or Components in a Production Representative Environment** Manufacture, release, and conduct stability testing of GMP-compliant bulk (BOS) and formulated product (FDP) in support of the IND and clinical trial(s).
	6-M2		Qualify assays for manufacturing Quality control and potency, as applicable
	6-M3		Qualify candidate reference reagents for these assays
	6-M4		Initiate development of Final Drug Product (FOP) for Phase 2-3 clinical trials.
	6-D1	Non-Clinical Development	Conduct GLP toxicity and PK/PD testing (repeat dose, acute, etc).
	6-E1	Non-Clinical Efficacy	Qualify appropriate critical assays used to assess physicochemical, in vitro and in vivo animal efficacy, PK/PD and/or immunogenic characteristics of the product.
	6-E2		Establish reproducibility of relevant animal model(s) with respect to achieving endpoints.
	6-C1	Clinical	Begin subject enrollment for Phase 1 clinical trial(s) to establish an initial safety, pharmacokinetics and immunogenicity assessment.
	6-C2		Complete last subject last visit for Phase 1 clinical trial(s)
	6-C3		Deliver final clinical study report for Phase 1 clinical trial(s)
7		Overview	Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s) Conduct animal efficacy studies as appropriate. Conduct Phase 2 clinical trial(s). **Animal Models:** Refine animal model development in preparation for pivotal GLP animal efficacy studies. **Assays**: Validate assays for manufacturing quality control and immunogenicity, if applicable. **7A** Conduct GLP animal efficacy studies as appropriate for the product at this stage. **7B** Complete expanded clinical safety trials as appropriate for the product (e.g. Phase 2).
	7-R1	Regulatory	Update Target Product Profile as appropriate.
	7-R2		Conduct End of Phase 2 Meeting with FDA.
	7-R3		Submit amendment(s) for expanded clinical trials.
	7-R4		Approve label for product shipped to SNS.
	7-R5		Submit Special Protocol Assessment for pivotal efficacy studies
	7-M1	CMC	Complete development of final process for licensure/approval conduct engineering runs and GMP runs at scale compatible with USG requirements
	7-M2		Complete stability studies of the GMP product in a formulation, dosage form, and container consistent with the Target Product Profile in support of label expiry dating.
	7-M3		Perform appropriate shipping validation
	7-M4		Obtain QA approval of process validation plan
	7-M5		Validate assays used to assess product quality and complete assay validation package

Q-TRL List

TRL Level	Sub Level	Product Development Area	Q-TRL Description
	7-D1	Non-Clinical Development	Conduct reproductive toxicology studies (small animals may be used).
	7-E1	Non-Clinical Efficacy	Validate assays used to assess critical outcomes in clinical trials and in animal efficacy studies.
	7-E2		Complete refinement of animal model development in preparation for pivotal GLP animal efficacy studies
	7-E3		Transfer animal models to GLP facility, if necessary, and conduct studies sufficient to demonstrate successful transfer.
	7-C1	Clinical	Begin subject enrollment for expanded human clinical trials - Phase 2 studies (as needed).
	7-C2		Complete last subject last visit for Phase 2 clinical trial(s)
	7-C3		Deliver final clinical study report for Phase 2 clinical trial(s)
	7-C4		Evaluate human biologic outcomes in Phase 2 clinical studies using validated assays and properly qualified reference QC reagents
8		Overview	**Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials, and FDA Concurrence or Licensure** **Finalize GMP manufacturing process**. Complete pivotal animal efficacy studies or clinical trials (e.g. Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit NDA/BLA. **8A** Complete pivotal GLP animal efficacy studies or pivotal clinical trials (e.g. Phase 3), and any additional expanded clinical safety trials as appropriate for the product. **8B** Prepare and submit New Drug Application (NOA) or Biologics License Application (BLA) to the FDA. **8C** Obtain FDA Approval or licensure.
	8-R1	Regulatory	Finalize Target Product Profile in preparation for FDA Approval/Licensure.
	8-R2		Obtain FDA concurrence on animal model(s) for pivotal animal efficacy studies and Phase 3 studies
	8-R3		Conduct Pre- New Drug Application (NOA) or Biologics Licensing Application (BLA) meeting with the FDA.
	8-R4		Prepare and submit New Drug Application (NOA) or Biologics License Application (BLA) to the FDA.
	8-R5		Obtain FDA approval or licensure.
	8-M1	CMC	Complete GMP validation for manufacturing quality control, potency, and produce consistency lots or registration lots at a scale compatible with USG requirements and/or required for licensure.
	8-M2		Continue long term stability studies to extend expiry dating.
	8-M3		Produce initial product stockpile quantities
	8-M4		Complete appropriate shipping validation
	8-D1	Non-Clinical Development	No Activity.
	8-E1	Non-Clinical Efficacy	Conduct pivotal animal GLP efficacy studies using final product formulation and use appropriate statistical to meet the requirements of the BLA/NDA submission.
	8-C1	Clinical	Begin subject enrollment for Phase 3 clinical trial
	8-C2		Complete last subject last visit for Phase 3 clinical trial

Q-TRL List			
TRL Level	**Sub Level**	**Product Development Area**	**Q-TRL Description**
	8-C3		Deliver final clinical study report for Phase 3 clinical trial
	8-C4		Evaluate critical biologic outcomes In Phase III clinical trials using validated assays and properly qualified reference and QC reagents.
9		Overview	**Post-Licensure and Post-Approval Activities** **9A** Commence post-licensure/post-approval and Phase 4 studies (post-marketing commitments) **9B** Maintain manufacturing capability as appropriate.
	9-R1	Regulatory	Commence post-licensure/post-approval and Phase 4 studies (post marketing Commitments) such as safety surveillance, studies to support use in special populations, and clinical trials to confirm safety and efficacy as feasible and appropriate.
	9-R2		Re-label investigational product in SNS with approved/licensed labeling
	9-M1	CMC	Complete delivery of contracted amount of approved or licensed product to stockpile
	9-M2		Transfer and cross-validate assays in additional facilities, if necessary.
	9-M3		If using challenge potency assays, identify alternatives, compare and validate new assay.
	9-M4		Maintain manufacturing capability as appropriate
	9-01	Non-Clinical Development	No Activity.
	9-E1	Non-Clinical Efficacy	Transfer animal model to additional facilities, if necessary.
	9-C1	Clinical	Begin subject enrollment for Phase 4 studies
	9-C2		Complete last subject last visit for Phase 4 studies
	9-C3		Deliver final clinical study report for Phase 4 studies

ATTACHMENT 2

FINAL - For PUBLIC USE

Harmonized Q-TRL List for Diagnostics MCMs

The US Department of Health and Human Services (HHS) and the Department of Defense (DoD) are engaged in the development of medical countermeasures (MCM) for Chemical, Biological, Radiological and Nuclear (CBRN) threats. The DoD and HHS utilize harmonized Technology Readiness Levels (TRLs) as a common method to understand at a general level the maturity of MCM development products in development across the USG. TRLs consist of nine progressive levels of milestones over a product development lifecycle.

Quantitative Technological Readiness Levels (Q-TRLs) expand the nine high-level TRLs to a much more detailed level to provide key development milestones and activities specific to vaccine, small molecule, biologics and diagnostics. These Q-TRLs are not intended to be a requirement for each project but rather to provide a selection of milestones and activities throughout the development lifecycle from discovery through post-approval.

Naming Conventions

For the Diagnostics Q-TRL naming conventions the first number denotes TRL level, D denotes diagnostics, the second letter denotes functional areas, last number is sequential number of Q-TRL in a functional area. DPM is Program Management, DR is Regulatory , DREQ is Requirements, ORES is Research & Dev, DAS is Animal Studies, DCS is Clinical Studies, DAD is Assay Dev, DID is Instrument Dev, DQ is Quality, DAM is Assay Mfg and DIM is Instrument Mfg.

Q-TRL List for Diagnostics

TRL Level	Sub Level	Product Development Area	Q-TRL Description
1		**Overview**	**Review of Scientific Knowledge** - Active monitoring of scientific knowledge base to identify clinical pathological markers for diagnostic countermeasure candidates. Scientific findings are reviewed and assessed as a foundation for characterizing approaches to intervene in disease. Basic research needs identified.
	1-DPM1	Program Management	No activity.
	1-DR1	Regulatory	No activity.
	1-DREQ1	Requirements	Assess clinical and/or public health needs.
	1-DRES1	Research & Dev	Review the clinical pathology of human disease (or specific medical conditions) attributed to specific threat agents and documented experience with diagnostic testing for both clinical management and for public health, National security objectives (e.g., early recognition).
	1-DRES2	Research & Dev	Review natural/case history studies and available data/information.
	1-DAS1	Animal Studies	No activity.
	1-DCS1	Clinical Studies	No activity.
	1-DAD1	Assay Dev	No activity.
	1-0101	Instrument Dev	No activity.
	1-DQ1	Quality	No activity.
	1-DAM1	Assay Mfg	No activity.
	1-DIM1	Instrument Mfg	No activity.
	1-DIV1	Integration & Verification	No activity.
2		**Overview**	**Concept Generation and Development of Experimental Designs** - Develop research plans to answer specific questions and experimental designs for addressing the related scientific issues and to establish feasibility. Focus on practical applications based on basic principles.
	2-DPM1	Program Management	Conduct feasibility phase readiness review and prepare approval report.
	2-DR1	Regulatory	No activity.
	2-DREQ1	Requirements	Prepare preliminary design inputs, test and instrument performance specifications and user needs assessment (ISO 9001 and 1345).
	2-DRES1	Research & Dev	Conduct and evaluate a market survey (currently existing solutions) and a literature search (state of the art).
	2-DRES2	Research & Dev	Characterize threat agent and clinical parameters to verify disease etiology; identify candidate diagnostic targets.
	2-DRES3	Research & Dev	Develop a product concept.
	2-DRES4	Research & Dev	Document feasibility regarding use of existing technological platform/methodology to meet preliminary requirements.
	2-DAS1	Animal Studies	Perform non-GLP small animal studies to support research (if needed).
	2-DAS2	Animal Studies	Demonstrate relevance of animal models to defined human disease threat(s).
	2-DCS1	Clinical Studies	No activity.

	2-DAD1	Assay Dev	Develop/Identify candidate assay technologies to support test system concept.
	2-DID1	Instrument Dev	Develop/Identify candidate instrument / automation technologies to support test concept. [high risk without first establishing assay feasibility.]
	2-DQ1	Quality	No activity.
	2-DAM1	Assay Mfg	No activity.
	2-DIM1	Instrument Mfg	No activity.
	2-DIV1	Integration & Verification	No activity.
3		**Overview**	**Characterization of Preliminary Candidates(s) and Feasibility Demonstration** - Begin R&D, data collection, and analysis in order to verify feasibility. Explore alternative concepts, identify and evaluate critical technologies and components, and begin characterizing specifications required. Demonstrate the performance of candidate diagnostic targets and high risk components. Develop a business case for the proposed product.
	3-DPM1	Program Management	Conduct product feasibility review and prepare approval report [would be requirement/gate to move to TRL4].
	3-DPM2	Program Management	Prepare estimate of each system critical component, non-critical component cost & price and development cost along with projected timelines.
	3-DPM3	Program Management	Identify key development team organizations, both internal and external. Initiate commercial discussions with external team members.
	3-DPM4	Program Management	Prepare Intellectual Property report detailing initial patentability, freedom to operate, and licenses needed.
	3-DR1	Regulatory	Prepare initial regulatory strategy document including intended use statement, analytical and clinical study plans, and specimen requirements.
	3-DREQ1	Requirements	Define preliminary high level test system requirements & critical component and assay specifications.
	3-DRES1	Research & Dev	Research and characterize diagnostic targets and identify chemistries, reagents needed to detect or quantify.
	3-DRES1	Research & Dev	Prepare body of data to demonstrate feasibility of final test system concept with preliminary experiments to detect, quantify selected diagnostic targets.
	3-DRES1	Research & Dev	Determine preliminary development risks.
	3-DAS1	Animal Studies	Perform GLP studies to validate a potential diagnostic target's usefulness.
	3-DCS1	Clinical Studies	Conduct experiments with archived clinical samples [pre-clinical studies (if applicable)] to demonstrate diagnostic targets assay feasibility.
	3-DAD1	Assay Dev	Develop high level assay design based on requirements.
	3-DAD2	Assay Dev	Demonstrate feasibility of high technical risk assay components and technologies for laboratory experiments.
	3-DID1	Instrument Dev	Develop high level device/instrument architecture; assess engineering, SW risks if OTS components not available, require customization, redesign.
	3-DID2	Instrument Dev	Demonstrate feasibility of high technical risk device/instrument components and technologies with prototypes demonstrating feasibility of throughput and limit of detection, or obtain OTS critical components. Produce non-GMP prototypes.
	3-DQ1	Quality	Identify reagents, materials and test methods that will be used for assessing specifications.

	3-DAM1	Assay Mfg	No activity.
	3 DIM1	Instrument Mfg	No Activity.
	3-DIV1	Integration & Verification	No activity.
4		**Overview**	**Optimization and Preparation for Assay, Component, and Instrument Development -** Prepare for test system development. Finalize diagnostic target(s) and methods for detecting or quantitating target(s). Develop detailed plans and finalize critical design requirements. Execute commercial agreements with key external development partners. Identify manufacturing resources, vendor sourcing, and experimental designs.
	4-DPM1	Program Management	Develop a detailed project plan.
	4-DPM2	Program Management	Negotiate commercial agreements with external team members for product development activities.
	4-DPM3	Program Management	Finalize system architecture and freeze requirements for initial development.
	4-DPM4	Program Management	Conduct system development readiness review and prepare approval report.
	4-DR1	Regulatory	Prepare a detailed regulatory strategy document, including draft intended use statement, analytical and clinical study plans and specimen requirements.
	4-DQ1	Quality	Develop and begin implementation of a Quality Management System.
	4-DREQ1	Requirements	Begin detailed requirements definition, hardware, software, assays.
	4-DREQ2	Requirements	Initiate user's interface definition.
	4-DRES1	Research & Dev	Finalize diagnostic targets assays (mechanism for detecting selected diagnostic targets through focused experiments.
	4-DRES2	Research & Dev	Complete tech transfer from Research to Development.
	4-DAS1	Animal Studies	Continued animal studies, as required, to support assay development and assay design finalization.
	4-DCS1	Clinical Studies	Continued pre-clinical studies, as required, to support assay development and diagnostic targets finalization.
	4-DAD1	Assay Dev	Finalize Assay requirements and specification.
	4-DID1	Instrument Dev	Finalize initial instrument/ device/ software architecture.
	4-DID2	Instrument Dev	Define design inputs/ outputs and architectures for modules/ subsystem.
	4-DAM1	Assay Mfg	Support assay architecture development, providing input on manufacturability of proposed product.

	4-DIM1	Instrument Dev	Support Instrument/device architecture development, providing input on manufacturability of proposed product. [if concurrent engineering, need to have bridging studies to assay or reiterative approach with experiments and verification studies using the test systems in final design form]
	4-DIV1	Integration & Verification	No activity.
5		**Overview**	**Product Development- Reagents, components, subsystems and modules -** Develop reagents and buffers. Build and test non-GLP prototypes of components and subsystems. Code and unit test software. Begin pilot scale manufacturing preparations. Develop protocols for assay and integration testing Initiate reagent stability testing. Hold pre-IDE meeting with FDA.
	5-DPM1	Program Management	Conduct integration readiness review and prepare approval report.
	5-DR1	Regulatory	Hold pre-IDE meeting with FDA (May occur at earlier TRL, FDA encourages pre-IDE meeting as early as possible)
	5-DR2	Regulatory	Finalize risk management plan and determine effectiveness of mitigations.
	5-DREQ1	Requirements	Finalize user's interface specification.
	5-DREQ2	Requirements	Update requirements and interface control documents as design progresses. Update specifications as components are tested.
	5-DRES1	Research & Dev	No activity.
	5-DAS1	Animal Studies	Provide samples as needed to support assay development (pre-clinical).
	5-DCS1	Clinical Studies	Provide samples as needed to support assay development (pre-clinical).
	5-DAD1	Assay Dev	Produce initial assay lots with quantities sufficient to initiate stability studies.
	5-DAD2	Assay Dev	Demonstrate sensitivity and specificity of prototype assay when performed manually or with standard laboratory methodologies.
	5-DAD3	Assay Dev	Initiate real-time stability studies of reagents with available development lots.
	5-D1D1	Instrument Dev	Build and test components and subsystems.
	5-DID2	Instrument Dev	Make preparations for and build Alpha instruments in a non-GMP environment.
	5-D1D3	Instrument Dev	Code and unit test software modules.
	5-DID4	Instrument Dev	Produce user's interface simulator and evaluate user's interface. Finalize user's interface definition [may be incorporated at later stage with less risk].
	5-DID5	Instrument Dev	Build 1st release of instrument software for integration testing.
	5-DQ1	Quality	Freeze design documents for alpha instrument/device build and laboratory assay production.
	5-DQ2	Quality	Initiate Design History File and Device Master Record [this would be done only when all priority requirements are met for both instrument and assay, reagents].
	5-DAM1	Assay Mfg	Make preparations (documents, process, procedures, etc.) for scaled development lots in a GMP compliant process with concurrent document development. Initiate design controls. [gateway to TRL6J.

	5-DIM1	Instrument Mfg	Identify/build pilot instrument/device manufacturing facility, Make preparations (documents process, procedures, etc.) for pilot Mfg build of beta instruments and components at pilot scale in a GMP compliant process. Order tooling and equipment necessary.
	5-DIV1	Integration & Verification	Prepare protocols and test procedures for assay/ system integration and testing. Prepare for alpha instrument testing.
6		**Overview**	**System integration & testing** - Integrate and test alpha and beta instruments/devices, software and assays, evaluating performance and updating specifications. Implement design improvements to address defects discovered during testing. Produce and evaluate pilot lots of reagents and beta (pilot) instruments. Increase the maturity of software. Prepare for clinical testing. Complete short term stability testing of reagents.
	6-DPM1	Program Management	Conduct analytical verification readiness review and prepare approved report.
	6-DR1	Regulatory	Hold pre-IDE discussion with FDA/CDRH to finalize regulatory strategy and pathway, e.g., clearance (510k), approval (PMA), pre-authorization (ore-EUA), or CLIA Waiver.
	6-DR2	Regulatory	Submit preliminary filings to the FDA to determine class of diagnostic (e.g., Class I, II, III) and what route of submission (e.g., clearance (510k), approval (PMA), etc.) is required.
	6-DREQ1	Requirements	Update product specifications to ensure requirements are met.
	6-DRES1	Research & Dev	No activity
	6-DAS1	Animal Studies	If applicable, prepare protocols, apply/receive IACUC approvals for further studies.
	6-DCS1	Clinical Studies	Prepare clinical study protocols; identify test sites, IRB approval and informed consent as required.
	6-DAD1	Assay Dev	Support integration testing. Evaluate/ resolve design defects discovered.
	6-DAD2	Assay Dev	Finalize test QC materials and protocols.
	6-DAD3	Assay Dev	Complete assay testing & characterization studies. Complete short term testing of reagents.
	6-D1D1	Instrument Dev	Support integration testing. Evaluate/ resolve design defects discovered.
	6-DQ1	Quality	Evaluate documentation and pilot manufacturing processes to ensure GMP compliance.
	6-DAM1	Assay Mfg	Produce pre-clinical lots of reagents in per process under document control.
	6-DIM1	Instrument Mfg	Produce beta instrument per process under document control.
	6-DIV1	Integration & Verification	Complete hardware/software/assay integration and verification testing.
	6-DIV2	Integration & Verification	Prepare protocols for analytical and pre-clinical testing.
		Overview	**Analytical Verification and Preparation for Clinical Studies** - Evaluate assay and integrated diagnostic system performance utilizing contrived, retrospective human and animal samples. Make preparations for clinical evaluation_ Begin preparation for full scale production of instruments and assays.
7	7-DPM1	Program Management	Perform review and approval of design verification report.
	7-DPM2	Program Management	Conduct clinical readiness review and prepare approval report.

	7-DR1	Regulatory	Develop and approve labeling including IFU for investigational test system.
	7-DR2	Regulatory	Obtain FDA feedback on clinical validation (use of animal samples as applicable, animal rule does not apply to Dx).
	7-DREQ1	Requirements	Track verification activities per product validation matrix.
	7-DRES1	Research & Dev	No Activity.
	7-DAS1	Animal Studies	Provide animal samples as required to support analytical verification testing.
	7-DCS1	Clinical Studies	Provide human samples as required to support analytical verification testing.
	7-DCS1	Clinical Studies	Complete identification, sourcing and distribution of clinical test lots. Distribute clinical test protocols and site binders, monitor progress.
	7-DAD1	Assay Dev	Support analytical verification testing. Evaluate/ resolve/document design defects discovered.
	7-DID1	Instrument Dev	Support analytical verification testing. Evaluate/ resolve design defects discovered.
	7-DQ1	Quality	Monitor analytical testing results. Ensure design controls Under Quality Systems Regulations.
	7-DAM1	Assay Mfg	Produce additional clinical lots with real-time stability.
	7-DAM2	Assay Mfg	Perform appropriate shipping validation.
	7-DIM1	Instrument Mfg	Produce additional beta instruments for clinical evaluations, if required.
	7-DIM2	Instrument Mfg	Perform appropriate shipping validation.
	7-DIV1	Integration & Verification	Verify that the diagnostics system meets it specifications and requirements through testing of contrived, retrospective human, normal human and animal samples through execution of a design verification protocol (containing defined study endpoints).
		Overview	**Clinical Studies and/or evaluation with Animal Studies, FDA Clearance or Approval, Finalize GMP manufacturing preparations** - Complete clinical evaluations. Prepare and submit FDA filing. **End of TRL8:** Acquire FDA approval, or clearance.
8	8-DPM1	Program Management	Conduct FDA filing readiness review and prepare approval report.
	8-DR1	Regulatory	Compile clinical validation and animal study data (where applicable).
	8-DR2	Regulatory	Prepare regulatory filing.
	8-DR3	Regulatory	Submit filing to FDA when ready and approved.
	8-DR4	Regulatory	Coordinate activities with FDA. Coordinate response to FDA questions/ notifications. Obtain Approval, Clearance, or pre-authorization, or CUA Waiver.
	8-DREQ1	Requirements	Finalize product specifications.
	8-DRES1	Research & Dev	No Activity.
	8-DAS1	Animal Studies	Perform pivotal GLP animal studies per approved protocols to validate system performance.
	8-DAS2	Animal Studies	Complete final animal study CSR.
	8-DCS1	Clinical Studies	Perform clinical evaluation per approved protocols to validate diagnostic system performance. Manage clinical sites.

	8-DCS2	Clinical Studies	Complete final human clinical study CSR.
	8-DAD1	Assay Dev	Support pivotal animal studies and clinical evaluations. Evaluate/resolve design defects discovered.
	8-DID1	Instrument Dev	Support pivotal animal studies and clinical evaluations. Evaluate/ resolve design defects discovered.
	8-DQ1	Quality	Monitor clinical and animal study processes and documentation to ensure Regulatory compliance.
	8-DAM1	Assay Mfg	No activity.
	8-DIM1	Instrument Mfg	Develop maintenance, other tech support.
	8-DIV1	Integration & Verification	Support pivotal animal studies and clinical evaluations. Evaluate / resolve design defects discovered. Instruct clinical sites on use of the diagnostic system.
		Overview	**Post-Clearance / Post-Approval Activities** Perform post market surveillance, field studies in designated sites; monitor performance, reliability, fitness for use. Establish and maintain appropriate Quality Systems compliant manufacturing capability/inventory Deliver USG ordered product if applicable.
9	9-DPM1	Program Management	No activity.
	9-DR1	Regulatory	Establish acquisition mechanism for monitoring, Post Marketing Data Performance (if required), complaint handling.
	9-DR2	Regulatory	Perform post marketing surveillance as required.
	9-DREQ1	Requirements	No activity.
	9-DRES1	Research & Dev	No activity.
	9-DAS1	Animal Studies	No activity.
	9-DCS1	Clinical Studies	No activity.
	9-DAD1	Assay Dev	Continue long term stability studies to extend expiry dating.
	9-DID1	Instrument Dev	No activity.
	9-DQ1	Quality	Fully implemented Quality Management System.
	9-DQ2	Quality	QMS monitoring of manufacturing processes to ensure GMP compliance.
	9-DAM1	Assay Mfg	Identify/build full scale GMP compliant assay manufacturing capacity, if pilot capacity insufficient. Validate processes and performance.
	9-DAM2	Assay Mfg	Produce initial assay stockpile quantities.
	9-DAM3	Assay Mfg	Maintain manufacturing capability as appropriate.
	9-DAM4	Assay Mfg	Provide field support.
	9-DIM1	Instrument Mfg	Identify/build full scale GMP compliant instrument/device manufacturing capacity, if pilot capacity insufficient, Validate all processes and performance.
	9-DIM2	Instrument Mfg	Produce initial instrument/device stockpile quantities.
	9-DIM3	Instrument Mfg	Maintain manufacturing capability as appropriate.
	9-DIM4	Instrument Mfg	Provide sustaining engineering field support.
	9-DIV1	Integration & Verification	No Activities.