JPM-MCS-BAA 15-01 Amendment 0001

The JPM-MCS-BAA-15-01 is hereby amended to include Technology Investment Agreements (TIA).

Section I, paragraph A of the JPM-MCS-BAA-15-01 is hereby amended to include:

> 5) Technology Investment Agreements: As prescribed in 32 CFR Part 37, TIA's 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. TIA's 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.
>
> 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.

Section IV. C is amended to include Technology Investment Agreements (TIA).

JPM-MCS-BAA 15-01 Amendment 0002

The purpose of this Amendment 0002 is to replace Section 845 of Public Law (P.L.) 103-160 with Section 237lb of title 10, U.S.C, and to incorporate changes to Section VII, paragraphs B.5, and C.5 as follows:

A. This amendment is hereby issued to revise:

1 Section I, paragraph A.2 is hereby deleted and replaced with the following:

2) 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 under this BAA and associated specific requirement announcements of 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 the general requirements to be competed hereunder. In general, Prototype OTA Offerors may submit a pre-proposal (i) qualifying under Section VII.A of this BAA for one or more of the Mission Areas or (ii) for specific requirements otherwise identified in this Announcement 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. Section VIII contains instructions specific to the development of, and evaluation of proposals, for prototypes.

2. Section II, “Section 845 of Public Law (P.L.) 103-160”, is hereby replaced with “Section 237lb of title 10. U.S.C.". Section 845 of Public Law (P.L.) 103-160 has been repealed by Section 815 of the FY 2016 NDAA (Public Law 114-92).

3. Section VIII, “Section 845 of Public Law (P.L.) 103-160”, is hereby replaced with “Section 237lb of title 10. U.S.C.". Section 845 of Public Law (P.L.) 103-160 has been repealed by Section 815 of the FY 2016 NDAA (Public Law 114-92).

4. Section VII, Paragraphs B.5 and C.5 are hereby revised to replace “Critical Reagent Program (CRP) with “Defense Biological Product Assurance Office, JPM Guardian”.

5. Section IV.B.5 is hereby revised to include “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 offeror's demonstrated savings in negotiating competitive pricing."

B. All other sections of MCS BAA 15-01 remain unchanged.

JPM-MCS-BAA 15-01 Amendment 0003

The JPM-MCS-BAA-15-01 is hereby amended to incorporate changes to Section II, last paragraph and Section VII.C.1.

A. This amendment is hereby issued to include:

Section II, last Paragraph is hereby replaced as follows:

"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 that are limited in applicability to procurement contracts. "Prototype. 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. In DoD, except in the cases supporting emergency use authorization, the threshold for military utility of a vaccine/therapeutic is FDA approval. As such, 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.

Section VII.C.1 is hereby replaced in its entirety as follows:

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.

1. 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.

2. 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. Prevention, treatment, or supportive care regimens for adverse reactions to prophylaxis or pretreatments against bio-warfare agents. Some vaccines or other pretreatments occasionally result in adverse reactions that require treatment themselves, such as in the case of smallpox vaccine. In such circumstances, an immune globulin or other biological or drug product is required to be part of the vaccine or product “system” to prevent or treat rare but potentially serious adverse events. FDA approval is required for these associated products.

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 single use system (SUS) manufacturing technologies and processes to facilitate transition and future production of MCM.

2. Infectious bio-warfare agents upon which the Biological Medical Prophylaxis program places its current focus include 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.

3. As stated herein, Prototype OTA Offerors may submit a pre-proposal (i) qualifying under Section VII.A of this BAA for one or more of the general Mission Areas or (ii) for prototype projects based on specific requirements otherwise identified in this Announcement or in a separate Request for Project Proposals (RPP) issued under this BAA. These pre-proposals must be 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. In general, the overall goals specific to JVAP include advanced development of products resulting in, or leading/preliminary to, FDA approved medical countermeasures to validated biological warfare threats, such as, but not limited to, Zaire ebolavirus, Sudan ebolavirus, and Marburg marburgvirus, Alphaviridae (Eastern Equine Encephalitis, Western Equine Encephalitis, Venezuelan

Equine Encephalitis), Bunyaviridae (Hantaan), Filoviridae (Tai Forest, Bundibugyo) and aerosolized recombinant Botulinum toxin serotypes A and B. Consistent with these overall goals are the following specific requirements hereby announced under this BAA.

i. Vaccine doses/material (i.e., the prototype) in advanced development for one or more of the following indications: Zaire ebolavirus, Sudan ebolavirus, and Marburg marburgvirus that 1) undergo and complete Phase 1 and/or Phase 2 trials and 2) complete proof of concept efficacy testing against virus using wild type (non-animal adapted) minimally passaged virus challenge material in a nonhuman primate aerosol exposure model.

ii. Vaccine doses/material (i.e., the prototype) employing advanced, adaptable vaccine manufacturing platforms in advanced development against one or more of the following aerosolized viruses: Eastern Equine Encephalitis Virus (EEEV), Venezuelan Equine Encephalitis Virus (VEEV), or Western Equine Encephalitis Virus (WEEV), able to support enabling studies and use in humans up through Phase 2 clinical trials.

iii. The delivery of a licensed vaccine (i.e., the prototype) against aerosolized recombinant Botulinum toxin serotypes A and B to include manufacture drug product, conduct all required safety and efficacy clinical and non-clinical trials, all requirements necessary to obtain FDA licensure, obtain product FDA licensure, and deliver the final prototype product.

JPM-MCS-BAA 15-01 Amendment 0004

The JPM-MCS-BAA-15-01 is hereby amended to incorporate changes to Section VII.

Section VII.C.2. Paragraph 5 is hereby replaced in its entirety as follows:

BDTx seeks to develop and acquire an OTA prototype consisting of an FDA approved antiviral countermeasure efficacious against one or more of the following: Filoviridae: Zaire ebolavirus, Sudan ebolavirus or Marburg marburgvirus. Accordingly, this requirement for an OTA prototype is hereby announced for competition in accordance OTA prototype competition requirements. To the extent the proposed countermeasure is efficacious against a broad spectrum of other BW agents of interest may be a consideration for military and program relevance in accordance with this announcement's evaluation section.