DEFENSE THREAT REDUCTION AGENCY

BROAD AGENCY ANNOUNCEMENT

HDTRA1-15-EBOLA-BAA

CHEMICAL / BIOLOGICAL TECHNOLOGIES DEPARTMENT

FY2015 – FY2016 Program Build

24 OCTOBER 2014

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1. INTRODUCTION AND BACKGROUND

1.1. Introduction.

1.1.1. The Defense Threat Reduction Agency's (DTRA) mission is to safeguard the United States and its allies from Weapons of Mass Destruction (WMD) (chemical, biological, radiological, nuclear, and high yield explosives) by providing capabilities to reduce, eliminate, and counter the threat, and mitigate its effects.

1.1.2. The DTRA Chemical and Biological Defense Program (CBDP) was established by the Department of Defense (DoD) to provide state-of-the-art defense capabilities to allow military forces of the United States to operate and to successfully complete their missions in chemical and biological warfare environments. The scope of mission efforts and the priorities assigned to specific projects are influenced by changes in military and civilian Chemical and Biological Defense (CBD) science and technology, advanced developments, operational requirements, military threat assessments, and national defense strategies. To keep pace with defense capability requirements, the CBDP as part of its mission, routinely promulgates chemical and biological research. The comprehensive research program encompasses both intramural and extramural sources, and the role of each is vital to the fulfillment of the Program objectives.

2. PURPOSE

2.1. The purpose of this Broad Agency Announcement (BAA) is to solicit research proposals for Chemical and Biological Defense Program, DTRA requirements for the CBDP Ebola BAA for the FY2015-2016 program.

DTRA, with industry and government partners, has been working aggressively for the past decade to understand and counter Zaire ebolavirus (EBOV). DTRA's program is currently supporting the accelerated development of a therapeutic through preclinical Investigational New Drug (IND) enabling activities as well as the clinical evaluation for one EBOV vaccine. The program co-developed the rapid field deployable diagnostic systems currently in use in West Africa. The program has also been adapting and improving upon North Atlantic Treaty Organization (NATO) approved and high performance computing methods of modeling EBOV to perform analysis of the current EBOV outbreak. Recognizing that industry may have solutions applicable to the current EBOV outbreak in West Africa, this BAA has been released to ensure that all potential near-term solutions are considered.

The World Health Organization (WHO) currently reports an ongoing outbreak of Ebola Virus Disease (EVD) in West Africa. The West African countries currently affected include Liberia, Sierra Leone, and Guinea, with past cases occurring in Nigeria and Senegal. There are no U.S. Food and Drug Administration (FDA) approved medical countermeasures for EBOV, the causative strain of the ongoing EVD epidemic in West Africa. Although diagnostic capabilities are available and are being utilized in West Africa, limitations with these current capabilities must be addressed. Similarly, improved modeling data, methods, and/or tools are required to better understand and predict the course of the current outbreak.

The primary objective of this BAA is to support development of near-term solutions such as therapeutic and vaccine candidates; diagnostic capabilities; modeling capabilities; and data gaps. For Medical Countermeasures (MCMs), only late stage development products for EBOV that can be completed and implemented in the near-term; defined as in time to assist with the current EBOV outbreak will be considered under this solicitation.

Offerors are encouraged to develop Research & Development (R&D) collaborations with other organizations in Government, academia, and the private sector to broaden and strengthen their capabilities. Where possible, Offerors are encouraged to take advantage of specialized resources in DoD and other Government agencies such as facilities/capabilities for biocontainment, collections of biothreat pathogens, Core testing, or advanced manufacturing.

2.2. CBDP, in its continuing mission, is seeking proposals for the following topics:

2.2.1. Topic: CBM-01, Development of Medical Countermeasures and Rapid Diagnostics for EBOV

Area 1: Therapeutics:

This area specifically solicits proposals focused on late stage development of therapies for EBOV. Outcomes from these studies are intended to provide a near-term capability that can be employed under compassionate use and may ultimately lead to an FDA approved therapeutic for EBOV infection. Broad-spectrum antivirals may be submitted to this solicitation for consideration; however proposals must meet the minimum requirements specific for EBOV (i.e. must include preliminary data demonstrating efficacy *in vitro* and *in vivo* for EBOV). Proposals with extensive preliminary data demonstrating efficacy *in vitro* and *in vivo* with optimized assays and conditions in place to develop and characterize Pharmacodynamics (PD) and Pharmacokinetics (PK), cytotoxicity, Absorption, Distribution, Metabolism, and Excretion (ADME) and viral inhibition and clearance will be considered. All therapeutic modalities and platforms are encouraged and may include, but are not limited to, antibody-based therapies, Ribonucleic Acid interference (RNAi), or small organic molecules. Repurposing efforts of FDA approved therapeutics may be submitted, provided those proposals meet the minimum efficacy requirements. Specifically, DTRA is seeking products that can be accelerated towards clinical evaluation in the near-term (3 to 6 months) to provide additional MCM capabilities to mitigate the epidemic in West Africa. Efforts to produce therapeutic immune sera or immune-globulin under an IND from either EBOV vaccine-immunized subjects or from Zaire EVD survivors may be submitted. Because the purpose of this BAA is to identify near-term solutions, the following activities will **NOT** be considered:

- Target identification and host-pathogen interaction studies
- Screening of compound libraries or compound series for hit identification
- Chemical synthesis of analogs to develop structure-activity relationship profiles
- Chemical optimization of core molecular scaffolds to improve physiochemical properties and drug-like properties
- Studies that initiate with the demonstration of in vivo efficacy based upon promising in vitro data

- Repurposing platforms for the production of novel therapeutic candidates that do not possess minimum efficacy requirements for EBOV
- Formulation studies to optimize dosing, pharmacodynamics, product stability and other drug properties
- Development of device, prophylactic products or diagnostics
- Development of animal infection and/or efficacy models

Contracts awarded under this BAA may support

- *In vitro* and non-Good Laboratory Practices (GLP) *in vivo* testing for toxicity, activity, ADME
- Preclinical non-GLP efficacy testing for EBOV
- Manufacturing, characterization and release of Current Good Manufacturing Practices (cGMP) material
- Completion of IND-enabling non-clinical studies
- Development, submission, and sponsorship of an IND application
- Clinical studies in humans

Area 2: Vaccines:

DTRA has a long history of investments in the development of EBOV animal models and immune assays, as well as in the evaluation of vaccines that target EBOV. Recently, DTRA accelerated the development of a candidate EBOV vaccine, called BPSC1001, which is being developed by BioProtection Systems, a wholly owned subsidiary of NewLink Genetics of Ames, Iowa. In previous studies, BPSC1001 afforded protection in post-exposure prophylaxis (PEP) and general use prophylaxis (GUP) indications in non-human primate (NHP) models of Ebola. Currently, BPSC1001 is manufactured at a scale of 1000 – 5000 vials per lot. Although this vaccine system has the capacity to serve immediate requirements, production of BPSC1001 at large scales ($\geq$ 500,000 doses) will require process development and be laden with risk. Moreover, BPSC1001 requires a cold chain to maintain stability, which introduces complexity and risk into the use of this vaccine in austere conditions.

The purpose of this area, therefore, is to reduce risks in the current effort by identifying solutions to production capacity limitations and to develop strategies to bring MCM that present a more favorable product profile for use in austere environments. This area specifically solicits proposals focused on late-stage development of vaccine against EBOV. Outcomes from these studies are intended to provide a near-term capability that can be used under compassionate use and may ultimately lead to an FDA approved vaccine for EBOV infection. Since the purpose of this BAA is to identify near-term solutions, the following activities will **NOT** be considered:

- Vaccine antigen discovery, vaccine screening and adjuvant discovery studies
- Development of novel vaccine systems and vaccine platforms that have no track-record in viral vaccines to predict feasibility
- Development of vaccine systems or vaccine platforms that have no manufacturing process experience

Contracts awarded under this BAA may support:

- *In vitro* and non-GLP *in vivo* testing for safety toxicity, immunogenicity

- Preclinical non-GLP efficacy testing for EBOV
- Manufacturing process development, manufacturing, characterization and release of cGMP material
- Development of EBOV vaccine formulations that display thermal stability
- Completion of IND-enabling non-clinical studies
- Development, submission, and sponsorship of an IND application
- Clinical studies in humans

2.2.2. Topic: CBA-01, Diagnostics

DTRA seeks proposals for short term (<6 months) Science and Technology (S&T) efforts that will provide immediately fieldable products to address detection, diagnostics, and surveillance challenges in response to the Ebola epidemic. At a minimum, solutions should be Technology Readiness Level (TRL) 4 and above. Attractive proposals could repurpose, reconfigure or rapidly mature existing technologies to resolve a well-defined challenge within the Ebola crisis. Proposals must have existing test data to show clinically relevant performance for a comparable target, and a clear path to provide a capability against Ebola. Proposals that are submitted without supporting test data for Ebola or a relevant analogous target will be deemed non-responsive. S&T efforts might include, but are not limited to:

- Rapid, low burden, potentially Clinical Laboratory Improvement Amendments (CLIA) waivable, triage level diagnostics
- Inexpensive (<$10 per sample) multiplexed diagnostics or detection
- Exposure monitoring tools

2.2.3. Social Network and Infectious Disease Modeling

DTRA seeks proposals that will immediately support current agent based, social network modeling of EVOD or EVD in West Africa. DTRA's capabilities have been rapidly applied to West African with significant estimation to mitigate the lack of local and temporal data. Our social network modeling is being used to estimate the spread of EVD as well as efficacy of public health interventions. Requested products would assist in the population and advancement of our current program and would entail integration with the current overall developer and DTRA operational staff.

2.2.3.1. Topic: CBI-01, Road Mobility

DTRA requires road mobility modeling data, methods, and/or tools relative to weather conditions, especially rain. Many of the West Africa local roads are not improved and can become impassable during heavy rains, especially during the rainy season.

2.2.3.2. Topic: CBI-02, Estuary Mobility

DTRA requires estuary mobility modeling data, methods, and/or tools relative to weather conditions especially rain. Some estuaries may become either viable or impassable during heavy rains especially during the rainy season.

2.2.3.3. Topic: CBI-03, Human Mobility

DTRA requires human mobility data, method, and/or tools relative to each West Africa local area with temporal estimations both during normal days and estimation in time of emergency such as the EVD outbreak. This will help refine estimates disease spread and/or migration of people (e.g. to health care locations) via foot or other methods that do not use or require roads.

2.2.3.4. Topic: CBI-04, Social Networks

DTRA's social network modeling is provides a highly resolved synthetic infrastructure in which each individual's movement and social interactions are estimated over time. To support this, DTRA requires micro scale economic, marketing, and general activity data, methods, and tools for West and Central Africa.

2.2.3.5. Topic: CBI-05, Hospital Disease Transmission

DTRA requires data, methods, and tools to better simulate hospital transmission of the infectious agents as a function of level and quality of health care available for a local area, country, and/or region.

2.2.4. Ebola Characterization

The means by which Ebola virus is maintained in nature remains unclear. One reservoir of this zoonotic pathogen is believed to be in bats, but it is unknown what other natural reservoirs exist. Distinct Ebola viral sequences have been identified in infected but healthy mice and shrews. (Pourrut et al., 2005) indicating there may be other unknown reservoirs. A better understanding of Ebola persistence under a variety of environmental conditions may help us identify other possible reservoirs and hosts to research reservoirs and other modes of transmission. While current science indicates the disease can only be transmitted by contact with contaminated body fluids, it remains unclear if other transmission modes are feasible. Filoviruses are able to infect via the respiratory route and are lethal at very low doses in experimental animal models, however the infectious dose is unknown. There is minimal information on how well filoviruses survive within aerosolized particles, and in certain media like the biofilm of sewage systems. Preliminary studies indicate that Ebola is aerostable in an enclosed controlled system in the dark and can survive for long periods in different liquid media and can also be recovered from plastic and glass surfaces at low temperatures for over 3 weeks (Piercy, et al., 2010).

2.2.4.1. Topic: CBS-01, Determination and Understanding of Quantitative Infectious Dose

This topic explores the physical, biological and molecular interactions of Ebola and related filoviruses to determine which of these interactions play a key role in the determination and understanding of quantitative infectious dose. The focus is on proposed efforts that aid in determining how many viable virions are required to cause human illness. Efforts that combine both experimental and computational techniques to explore molecular and physiological interactions and biochemical pathways using non-human primate models and a systems biology approach will be given priority.

2.2.4.2. Topic: CBS-02, Persistence and decay or survival rates in the Environment

The research should generate knowledge on Ebola persistence in the environment and knowledge to help predict potential mutations or changes to the viron. Studies should determine persistence and decay or survival rates of Ebola virus and other filoviruses in the environment. Research areas may include (but are not limited to):

- Assessment under a range of controlled environmental conditions, including, but not limited to the dark, simulated solar radiation, and ranges of temperature and humidity.
- Identification of environmental factors that contribute to persistence
- Assessing persistence of Ebola on fomites/ surfaces after aerosolization
- Assessing persistence in other media such as water, sewage biofilm, and other priority surfaces

2.2.4.3. Topic: CBS-03, Molecular Determinants for Persistence

This topic focuses on understanding the molecular determinants that govern the ecology and environmental persistence of filoviruses. The research should focus on the molecular identities and mechanisms that promote environmental persistence of filoviruses. Research areas may include (but are not limited to):

- Genomic and proteomic analyses to investigate the regulation of genes and proteins upon exposure to varying environmental conditions
- Use of phylogenetics to identify potential genes involved in environmental persistence
- Elucidation of mechanisms that contribute to environmental persistence
- Metagenomic analysis of potential reservoir environments
- Elucidation of mechanisms and environmental conditions that promote mutations in animal reservoirs

References:

Pourrut, X. et al. (2005). The natural history of Ebola virus in Africa. *Microbes and Infection*. (7: 7–8), 1005–1014. DOI: 10.1016/j.micinf.2005.04.006

Piercy, T., et al. (2010).The survival of filoviruses in liquids on solid substrates and in a dynamic aerosol. *Journal of Applied Microbiology*. (109), 1531–1539. doi:10.1111/j.1365-2672.2010.04778.x

2.2.5. Topic: CBT-01, Biohazard Personal Protective Equipment (PPE)

DTRA is seeking innovative technologies that protect warfighters who are engaged in bio-hazardous epidemic response operations. Technologies are being sought that extend wear-time in hot and humid environments by reducing thermal and cognitive burden and reduce hazards especially during the doffing process. Proposed solutions must be both innovative, technically mature, and provide a significant advantage over ensembles that are commercially available. Technical maturity must be demonstrated through statistically valid testing using applicable standard test methods. Material solutions must be cost-effective and logistically sustainable within the context of applicable military operations including security, construction, medical care, non-combatant or casualty evacuation and mortuary operations. Proposals must clearly show and justify a development and testing program to qualify the technology and validate the

advantage claimed. The proposal must also consider scale-up and manufacturability as part of the overall life-cycle analysis.

2.2.6. Topic: CBT-02, Rapid Disinfection Processes

DTRA is seeking innovative technologies for rapid disinfection of interior surfaces with viral contamination. The technology must prove effective against viral contamination either deposited as an aerosol or heavy contaminated combined with body fluids (e.g. blood, vomit, feces). Responses must address the entire process, a response that only develops a disinfectant/sterilant is not sufficient. Disinfectants/sterilants must be compatible with sensitive equipment. Existing compatibility qualifications, such as registered compatibility with aircraft, is desired. The proposal must show data that demonstrates performance of the disinfectant/sterilant against pathogens similar to the Ebola virus or pathogens that are more difficult to disinfect. Material solutions must be cost-effective and logistically sustainable within the context of applicable military operations. Proposals must clearly show and justify a development and testing program to qualify the technology and validate the advantage claimed. The proposal must also consider scale-up and manufacturability as part of the overall life-cycle analysis.

3. BAA APPROACH AND OVERVIEW

3.1. This BAA remains effective for proposal selection for two years from the initial date of issuance with the ability to award contracts for three years.

3.2. The Government encourages proposals that span a wide spectrum of possible technical and business solutions. Proposed collaboration with a DoD laboratory should be clearly identified in the proposal, and must be supported with a letter of intent from that laboratory's Commander. The Government reserves the right to award any combination of approaches which offer the best overall value to the Government, and to oversee any and all processes and approaches once ongoing.

3.2.1. Offerors choosing to use the services of Government Laboratories in the performance of work proposed may be required to enter into a Cooperative Research and Development Agreement (CRADA) with the laboratory. A CRADA is not a Federal Acquisition Regulation (FAR) based agreement; it is authorized by 15 U.S. Code (USC) Section 3710(a). A CRADA will be separate from the DTRA procurement instrument, with its own unique terms, in particular related to Intellectual Property. It would be prudent for the offeror to discuss those unique terms with the laboratory prior to submitting a proposal under this BAA. DTRA will not facilitate, nor be involved in, the negotiation of the agreements with Government Laboratories.

3.2.2. In accordance with FAR 17.503(e), Department of Energy (DOE) Order 481.1C and DOE Acquisition Regulation DEARS 970.1707-3, DOE Federally Funded Research and Development Centers (FFRDC) participants must provide a copy of the written certification from the DOE sponsor authorizing its performance of the proposed effort as a subcontractor. The DOE sponsor must provide written certification that the proposed work –

(1) is consistent with or complimentary to missions of DOE and the facility to which the work is to be assigned,

(2) will not adversely impact programs assigned to the facility, and
(3) will not create a detrimental future burden on DOE resources.

DTRA will provide to the sponsoring agency confirmation that the requested work will not place the FFRDC in direct competition with domestic private industry.

3.2.3. In accordance with FAR 17.503(e), 35.017(a)(2) and 35.017-3, FFRDC participants (other than DOE FFRDCs) must provide documentation from the FFRDC sponsor authorizing its performance of the proposed effort.

3.3. A full range of flexible acquisition related statutory authority arrangements available to DTRA are possible results from this announcement, including but not limited to, contracts, task orders placed against existing Indefinite Delivery/Indefinite Quantity (ID/IQ) contracts, and Other Transaction Agreements (OTA). The government does not intend to award grants or cooperative agreements under this solicitation. Each of these procurement instruments offers different advantages, liabilities and responsibilities for the Government. Except for OTAs, the Government actions under this BAA shall adhere to the requirements of the FAR and Defense Federal Acquisition Regulation Supplement (DFARS).

3.4. The government intends to award fixed price, cost reimbursable and cost plus fixed fee type contracts.

3.4.1. R&D contracts are typically cost reimbursement contracts. In accordance with FAR 16.301-3(a)(3), cost reimbursement contracts require that the contractor's accounting system is adequate for determining costs applicable to the contract. Therefore, DTRA will request that the Defense Contract Audit Agency (DCAA) perform an audit on your proposal and accounting system prior to entering into contract negotiations. **Failure to have an adequate accounting system will preclude the offeror from receiving a cost type contract (If determined appropriate, fixed price contracts may be awarded).**

3.5. DTRA intends to create an environment where potential offerors are willing to share commercially generated research and development with the Government. The Government seeks to ultimately acquire the best products and technology in addition to offering the appropriate level of protection of corporate and institutional intellectual property rights, thus encouraging participation by a broad spectrum of leading-edge technology developers.

3.6. Funding for participation in this program is highly competitive and the cost of proposed technologies should be considered. The Government reserves the right to fund all, some, one, or none of the proposals submitted; may elect to fund only part of a submitted proposal; and may incrementally fund any or all awards under this BAA. In either case, the Contracting Officer will have the ultimate authority and responsibility to make final scope determinations for selections of proposals that will not be totally funded to ensure the portion selected meets the solicited requirements. All awards are subject to the availability of funds. Offerors that are not responsive to government requests for information in a timely manner, defined as meeting government deadlines established and communicated with the request, may be removed from award consideration.

4. ELIGIBILITY

4.1. Proposals submitted for this BAA will be considered from the following U.S. and Foreign Enterprises:

- Industrial/commercial concerns including small businesses
- Accredited degree granting colleges and universities
- Not-for-profit organizations
- Other Non-U.S. sources
- DoD sponsored FFRDCs. Specified in DFARS 235.017-1
- DOE sponsored FFRDCs provided that authorization is obtained from the DOE sponsor

4.2. The following entities may not participate as prime contractors nor furnish principal investigators in awards made under this BAA, but may act as subcontractors:

- Federal laboratories other than those DoD-sponsored and DOE-sponsored FFRDCs specified in section 4.1 above.
- U.S. Government agencies and organizations
- Academic institutions that are federal government organizations (e.g., Naval Postgraduate School)

4.3. All **Offerors proposing a cost type contract are required in accordance with FAR 16.301-3 to have an adequate accounting system for determining costs applicable to the contract.**

5. POINTS OF CONTACT

E-mail address for all BAA correspondence and questions	CB-FY15-EBOLA@dtra.mil
BAA Announcements posted in Federal Business Opportunities, FedBizOpps	http://www.fbo.gov
DTRA Proposal Submission Website (requires registration prior to proposal submission)	http://www.dtrasubmission.net
DTRA Website	http://www.dtra.mil

Questions regarding the technical and administrative content of this BAA must be addressed to the e-mail address listed above. All questions must include the BAA number in the subject line. DTRA will post questions and answers to the FedBizOpps website that are relevant to all potential offerors. It is the offeror's responsibility to periodically check the FedBizOpps website (www.fbo.gov) to view postings of questions and answers, in addition to any applicable amendments to the BAA. Please note, answers will not be provided, nor any judgment made, related to questions concerning the applicability of certain projects to the scope of this BAA.

6. PROPOSAL SUBMISSION

6.1. Evaluation Major Milestones.

Phase I Proposals that are submitted by the last calendar day of this month: January February March April May June July August September October November December	Will typically have evaluations completed and presented to the BAA Board members for a final decision no later than: March April May June July August September October November December January February	A Phase II Full Proposal invite or non-selection notification will be sent after the final decision by the BAA Board.
Phase II Proposals that are submitted by the last calendar day of this month: January February March April May June July August September October November December	Will typically have evaluations completed and presented to the Source Selection Authority for final decision no later than: April May June July August September October November December January February March	Announcement of Apparent Successful Offeror or nonselection will be sent after the Source Selection Authority makes the final determination.
Note: Actual award dates will vary based on complexity, urgency, statutory requirements, quality of proposal, pricing considerations, DCAA audits of proposed rates, type of instrument, number of awards, and other considerations. All dates are subject to change.		

6.2. Application and Submission Information.

6.2.1. Registration. All Offerors are required to register at the DTRA proposal submission website as stated in Section 5 prior to submission of Phase I proposals. Detailed registration and submission instructions are available at the site.

6.2.1.1. The Registration must be submitted by a central Business Point of Contact (BPOC) rather than individual Principal Investigator personnel. A BPOC is a person who is given the responsibility of coordinating all submissions from individual Principal Investigators at his or her work location and is the only individual who may access the DTRA proposal submission website. The intent is that all submissions from an organization be coordinated and submitted by a single, identified responsible party. Failure to register in accordance with instructions may render them ineligible for participation in this BAA.

6.2.1.2. Offerors must be aware that it is their responsibility to ensure that e-mail notifications reach the designated BPOC and that e-mail notifications are not blocked due to the use of 'spam blocker' software or other means that the recipient's Internet Service Provider may have implemented as a means to block the receipt of certain e-mail messages. Additionally, it is the responsibility of the BPOC to inform DTRA of any updates to e-mail addresses for both themselves as the registered BPOC and for the designated Principal Investigator.

IMPORTANT: Registration at the DTRA proposal submission website is NOT the same as registering at System for Award Management website or FedBizOpps websites. Failure to register at the DTRA proposal submission website will prevent an Offeror's submission of documents required and thus render the Offeror ineligible for participation in this BAA.

6.2.2. Submission Process. All proposals must be submitted electronically through the DTRA proposal submission website. Any proposal submitted by any means other than the DTRA proposal submission website will not be considered (e.g., hand-carried, postal service, commercial carrier, e-mail). Offerors are responsible for ensuring compliant and final submission of their proposals. The Offeror must verify the submission of their proposal package by printing the electronic receipt (time and date stamped) that appears on the final screen following compliant submission of a proposal to the DTRA proposal submission website.

6.2.3. Using the DTRA proposal submission website, all Offerors must prepare Proposal Cover Sheets for each Phase I and invited Phase II proposal submitted. All data point requirements must be completed in every cover sheet. Once the cover sheet is saved, the system will assign a unique proposal number for each Phase I submission and a different unique proposal number for each invited Phase II submission. Cover sheets may be edited as often as necessary until the submission period closes. All submissions must be dated.

6.2.4. Notifications to Offerors. Selection and non-selection notifications will be sent via e-mail to Offerors (specifically, the registered BPOC and the designated Principal Investigator as entered on the proposal cover page on the DTRA proposal submission website) from the DTRA proposal submission website. A debriefing summary statement will be electronically available to Offerors via the DTRA proposal submission website. Additionally, notification of apparent successful Offerors will be posted to the FedBizOpps page.

6.3. Two-Phased Submission. This BAA will be conducted in two phases as follows:

6.3.1. **Phase I** – Interested Offerors are required to complete a cover sheet using the DTRA proposal submission website, and must submit Quad Chart/White Papers in accordance with

instructions provided in this section of the BAA. Proposals will be evaluated against criteria as described in Attachment 8 of this BAA. Based on this evaluation, selected Offerors will be invited to submit full proposals for evaluation under Phase II.

6.3.1.1. Quad Chart Format: All Quad Charts should include the information indicated on the sample template located in Attachment 1.

6.3.1.2. White Paper Narrative Format. The White Paper narrative expands on the Quad Chart presentation and instructions for format, preparation and content are located in Attachment 2.

6.3.1.3. Classification: All Quad Chart/White Paper submissions must be UNCLASSIFIED.

6.3.1.4. Disclosure of Information

6.3.1.4.1. The Quad Chart portion of the submission shall not contain information deemed trade secret, confidential or proprietary by the Offeror.

6.3.1.4.2. All information provided in the White Paper that is marked appropriately will be considered proprietary information.

6.3.1.5. In the event that properly marked data contained in a white paper/proposal submitted in response to this BAA is requested pursuant to the Freedom of Information Act, 5 USC 552, the Offeror will be advised of such request and, prior to such release of information, will be requested to expeditiously submit to DTRA a detailed listing of all information in the white paper/proposal which the Offeror believes to be exempt from disclosure under the Act. Such action and cooperation on the part of the Offeror will ensure that any information released by DTRA pursuant to the Act is properly identified.

6.3.1.6. Notification to Offerors: Notifications of invitation to participate in Phase II and notifications of non-selection will be sent via e-mail to Offerors (specifically, the registered BPOC as entered on the proposal cover page on the DTRA proposal submission website) from the DTRA proposal submission website. Formal debriefings for Quad Charts/White Papers will not be provided. However, a brief synopsis of the Government's evaluation in the form of a summary statement will be electronically available to Offerors via the DTRA proposal submission website. The e-mail notifications will advise of the statement availability. Phase II proposals will be evaluated against criteria as described in Attachment 8 of this BAA.

NOTE: Any submission that does not conform to the requirements outlined in the BAA and in the invitation may not be reviewed or considered further.

6.3.2. **Phase II -** Proposal Submission and Content. The Phase II proposal must be prepared in three separate volumes: Volume I – Technical Proposal; Volume II – Cost Proposal; and Volume III – Supplemental Information, to include a Statement of Work (SOW) and an updated Quad Chart. Each volume submitted must have page numbers and date.

6.3.2.1. Volume I – Technical Proposal. The technical proposal must include the components included in the template as shown in Attachment 3 of this BAA.

6.3.2.2. Volume II – Cost Proposal. The cost proposal must include the components included in the template and instructions as specified in Attachment 4 of this BAA.

6.3.2.3. Volume III – Supplemental Information. The supplemental information must include the components included in the instructions as specified in Attachment 5 of this BAA.

6.4. Submission File Formats. Each volume of the proposal must be submitted as a separate Portable Document File (PDF) compatible with Adobe Acrobat ® version 11.0.0 or earlier. In addition to the PDF submission, the Cost Breakout section of the cost proposal shall be submitted in Microsoft Excel version 2010 or earlier and the SOW shall be submitted in Microsoft Word version 2010 or earlier. Each individual file will not exceed 2 Mbytes of storage space (uncompressed) for Phase I submission and 5 Mbytes for Phase II submission of storage space (uncompressed). Movie and sound file attachments, or other additional files, will not be accepted. If multiple proposals are being submitted by the same institution, separate cover sheets must be generated for each proposal and the full proposal files must be uploaded with the associated cover sheet, since a unique document number will automatically be assigned to each submission by the electronic proposal tracking system. All documents submitted to the DTRA proposal submission website are considered works in progress and are not eligible for evaluation until the Offeror submits the final proposal package for consideration. The final submission must be 'locked' on the DTRA proposal submission website; until a submission has been 'locked' (saved as final); the submission is not eligible for review (look for this 'lock' icon  on the DTRA proposal submission website). Offerors are responsible for ensuring compliant and final locked submission of their proposals, and can verify the submission of the proposal package with the electronic receipt that appears on the screen following submission of a proposal to the DTRA proposal submission website. Perform a virus check before uploading any proposal files. If a virus is detected, it may cause rejection of the file. Do not encrypt any files you upload.

6.5. Late Submissions and Withdrawal of Proposals.

6.5.1. Offerors are responsible for access to the DTRA proposal submission website and for submitting electronic proposals so as to be received at the Government site indicated in this BAA no later than the date specified in the invitation. When sending electronic files, the Offeror will account for potential delays in file transfer from the originator's computer server to the Government website/computer server. Offerors are encouraged to submit their proposals early to avoid potential file transfer delays due to high demand or problems encountered in the course of the submission. Offerors should also print, and maintain for their records, the electronic date/time stamped receipt that appears on the final screen following submission of a proposal on the DTRA proposal submission website. All Phase II submissions shall be fully uploaded before the cut off time/date in order to be considered – No exceptions.

6.5.2. If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the date

specified in the invitation for full proposal, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the BAA on the first work day on which normal Government processes resume.

6.5.3. Proposals may be withdrawn by written notice received at any time before award. Withdrawals are effective upon receipt of notice by the contracting officer via the e-mail address listed in Section 5.

6.5.4. The Government may reject Phase I or Phase II submissions that are deemed non-compliant, i.e., that significantly deviate from the instructions in the BAA.

7. INFORMATION TO BE REQUESTED FROM SUCCESSFUL OFFERORS

Offerors whose proposals are selected for potential award may be contacted to provide additional information required for award. Such information may include revisions to the costs or cost explanations and other information applicable to the proposed award. Offerors that are not responsive in a timely manner to Government requests for information (defined as meeting Government deadlines established and communicated with the requests) may be removed from award consideration as determined by the contracting officer. Offerors that request significant revisions to their proposals subsequent to their selection for potential award (including revisions to proposed intellectual property restrictions and proposed procurement instrument) may be removed from award consideration. Offerors may also be removed from award consideration if the Offeror and the Government fail to negotiate mutually agreeable terms within a reasonable period of time.

8. EXPORT CONTROL NOTIFICATION

Offerors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Offerors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 Code of Federal Regulations [CFR] Parts 120 – 130) and/or the Department of Commerce regarding the Export Administration Regulations (EAR) (15 CFR Parts 730-774). The Department of State publishes guidance on the ITAR at http://www.pmddtc.state.gov. Department of Commerce guidance on the EAR is located at http://www.bis.doc.gov.

9. LIMITATION ON OTHER TRANSACTIONS

Offerors are advised that an OTA may only be awarded if there is:

a. At least one nontraditional defense contractor participating to a significant extent in the prototype project, or
b. No nontraditional defense contractor is participating to a significant extent in the prototype project, but at least one of the following circumstances exists:
    i. At least one third of the total cost of the prototype project is to be paid out of funds provided by the parties to the transaction other than the federal government. The cost

share should generally consist of labor, materials, equipment, and facilities costs (including allocable indirect costs).

ii. Exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a FAR/DFARS based contract.

c. Although use of one of these options is required to use an OTA as the procurement vehicle, no single option is encouraged or desired over the others.

NOTE: For purposes of determining whether or not a participant may be classified as a nontraditional defense contractor and whether or not such participation is determined to be participating to a significant extent in the prototype project, the following definitions are applicable:

"Nontraditional defense contractor" means an entity that is not currently performing or has not performed, for at least the one-year period preceding this solicitation, any of the following for the DoD:

i. any contract or subcontract that is subject to full coverage under the cost accounting standards prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act [41 USCS §§ 1501 et sequ.] and the regulations implementing such section; or

ii. any other contract in excess of $500,000 under which the contractor is required to submit certified cost or pricing data under section 2306a of this title [10 USCS § 2306a].

"Participating to a significant extent in the prototype project" means that the nontraditional defense contractor is supplying a new key technology or product, is accomplishing a significant amount of the effort wherein the role played is more than a nominal or token role in the research effort, or in some other way plays a significant part in causing a material reduction in the cost or schedule of the effort or an increase in performance of the prototype in question.

NOTE: Offerors are cautioned that if they propose the use of an OTA, the Government reserves the right to negotiate either a FAR based procurement contract, or OTA as it deems is warranted under the circumstances.

10. TECHNICAL AND ADMINISTRATIVE SUPPORT BY NON–GOVERNMENT PERSONNEL

It is the intent of DTRA to use non-government personnel (e.g. contractor support personnel) in the review and administration of all submittals (Phase I and Phase II) for this BAA. Participation in the BAA requires DTRA J9 CBDP Advisory and Assistance Services (A&AS) support contractor employees, contract specialist contractor support, financial analyst contractor support, technical repository contractor support and proposal submission website contractor support, listed hereto, to have access to proposal information including information that may be considered proprietary. Phase II proposals, in some instances, may require other non-government personnel from Academia to serve as peer reviewers with access to proposal information including information that may be considered proprietary. All individuals in these categories having access to any proprietary data shall execute nondisclosure agreements certifying that they will not disclose any information pertaining to this solicitation including any proposal submittals, the identity of any submitters, or any other information relative to the

Offeror's proposal. The contracts for provision of support personnel contain Organizational Conflict of Interest provisions and include contractual requirements for non-disclosure of proprietary contractor information. Additionally, TASC employees in their role as an A&AS support contractor to DTRA will provide technical input in an advisory role as subject matter experts (SMEs) to the Government reviewers in addition to providing administrative support in the management of the proposals and their technical review. All offerors to this BAA consent to the disclosure of their information to the companies listed below, their subcontractors, and academia peer reviewers under these conditions.

JAB Innovative Solutions, LLC
12932 News Hollow Ct
Bristow, VA 20136

Kforce Government Solutions, Inc.
2750 Prosperity Ave, STE 300
Fairfax, VA 22031

Quanterion Solutions, Inc.
811 Court St, STE 214
Utica, NY 13502

SBG Technology Solutions, Inc.
2 Britany Ln
Stafford, VA 22554

TASC, Inc.
35 New England Business Ctr Dr, STE 200
Andover, MA 01810

11. SYSTEM FOR AWARD MANAGEMENT (SAM)

11.1. DTRA requires that all offerors be registered in the SAM database at the time of Phase I proposal submission. Contractors must keep their registration current for the life of the contract.

11.2. Offerors may register with SAM by calling the SAM Customer Service Center at 1-866-606-8220 or register online at http://www.sam.gov. Offerors will NOT be able to complete their SAM registration until SAM has confirmed the Offeror's Employer Identification Number (EIN) or Taxpayer Identification Number (TIN) with the Internal Revenue Service (IRS).

NOTE: It will take 24-48 hours for IRS to validate the TIN. According to the IRS, if Offerors do not currently have an EIN and need to apply for one over the phone or Internet, they will be given a tentative EIN, but the EIN may not become active for up to two (2) weeks. Questions regarding an EIN may be directed at 1-800-829-4933.

11.3. Representations and Certifications must be completed at the time of Phase II submission. The Offeror must complete the annual representations and certifications electronically via the SAM website at http://www.sam.gov. After reviewing the SAM information, the Offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, inclusive of the following:

- FAR 52.209-7 Information Regarding Responsibility Matters
- DFARS 252.203-7000 Requirements Relating to Compensation of Former DoD Officials
- DFARS 252.203-7005 Representation Relating to Compensation of Former DoD Officials
- DFARS 252.209-7994 Representation by Corporations Regarding an Unpaid Delinquent Tax Liability or a Felony Conviction under any Federal Law—Fiscal Year 2014 Appropriations

NOTE: The above mentioned clauses/provisions are not contained in the SAM database, the Offeror is required to acknowledge and submit in writing documentation that they have read and understand each provision.

Additionally, the Offeror is required to verify that the electronic representations and certifications are current, accurate, complete, and applicable to this BAA, including the business size standard applicable to the NAICS code referenced (541711) for this BAA, as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201).

12. PROTECTION OF HUMAN SUBJECTS

12.1. If the proposed work involves human subjects or materials, Offerors are required to outline the human use, to include the source of the human subjects or materials involved in the work. Further information may be required if the proposal is successful.

12.2. All work under any award made under this BAA involving human subjects must be conducted in accordance with 32 CFR 219, 10 U.S.C. § 980, and DoD Instruction 3216.02, and, as applicable, 21 CFR parts 11, 50, 56, Good Clinical Practice (GCP), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) as well as other applicable federal and state regulations. Contractors must be cognizant of and abide by the additional restrictions and limitations imposed on the DoD regarding research involving human subjects, specifically as regards to vulnerable populations (32 CFR 219 modifications to subparts B-D of 45 CFR 46), recruitment of military research subjects (32 CFR 219), and surrogate consent (10 U.S.C. § 980).

12.3. DTRA Directive 3216.01 of October 21, 2011 establishes the DTRA Human Subjects Protection Program, sets forth the policies, defines the applicable terms, and delineates the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing human subject research. The regulations mandate that all DoD activities, components, and agencies protect the rights and welfare of human subjects of study in DoD supported research, development, test and evaluation, and related activities hereafter referred to

as "research." The requirement to comply with the regulations applies to new starts and to continuing research.

12.4. The DTRA Directive requires that research using human subjects may not begin or continue until the DTRA Research Oversight Board (ROB) has reviewed and approved the proposed protocol. Contractors and subcontractors are required to submit a valid federal assurance for their organization (institution, laboratory, facility) that has been issued by either DoD or the Department of Health and Human Services, and documentation of review of proposed protocols by the local Institutional Review Board (IRB) to include consent forms for any planned research using human subjects to the ROB for its review through the contracting officer's representative (if assigned) or the contracting officer. The ROB review is separate from, and in addition to, local IRB review.

12.5. A study is considered to involve human research subjects if: 1) there is interaction with the subject (even simply talking to the subject qualifies; no needles are required); and 2) if the study involves collection and/or analysis of personal/private information about an individual, or if material used in the study contains links to such information.

12.6. Written approval to begin research or to subcontract for the use of human subjects under the proposed protocol will be provided in writing from the DTRA ROB, through the contracting officer. Both the contractor and the Government must maintain a copy of this approval. Any proposed modifications or amendments to the approved protocol or consent forms must be submitted to the local IRB and the DTRA ROB for review and approval. Examples of modifications/amendments to the protocol include but are not limited to:

- a change of the Principal Investigator;
- changes in duration or intensity of exposure to some stimulus or agent;
- changes in the information requested of volunteers, or changes to the use of specimens or data collected; or
- changes in perceived or measured risks or benefits to volunteers that require changes to the study.

12.7. Research pursuant to such modifications or amendments must not be initiated without IRB and ROB approval except when necessary to eliminate apparent and immediate hazards to the subject(s).

12.8. Research projects lasting more than one year require IRB review at least annually, or more frequently as required by the responsible IRB. ROB review and approval is required annually. The contractor or subcontractor must provide documentation of continued IRB review of protocols for ROB review and approval in accordance with the Contract Data Requirements List. Research must not continue without renewed ROB approval unless necessary to eliminate apparent and immediate hazards to the subject(s).

12.9. A clause regarding human subjects research will be included in all contracts involving human subjects research. Non-compliance with any provision of this clause may result in withholding of payments under the contract pursuant to the terms and conditions. The

Government shall not be responsible for any costs incurred for research involving human subjects prior to protocol approval by the ROB.

12.10. The contract clauses regarding the use of humans are:

DFARS 252.235-7004 Protection of Human Subjects

(a) *Definitions.* As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Contractor's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Contractor to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242-15 to immediately suspend, in whole or in part, work and further payment under this contract, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Contracting Officer.

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

(End of clause)

DTRA local clause 252.223-9002 Protection of Human Subjects

All research under this contract involving human subjects must be conducted in accordance with 32 CFR 219, 10 USC 980, and DoDD 3216.02, as well as other applicable federal and state regulations. Contractors must be cognizant of and abide by the additional restrictions and limitations imposed on the DoD regarding research involving human subjects, specifically as regards vulnerable populations (32 CFR 219 modifications to subparts B-D of 45 CFR 46), recruitment of military research subjects (32 CFR 219), and surrogate consent (10 USC 980). Defense Threat Reduction Agency (DTRA) Directive 3216.01 establishes the DTRA Human Subjects Protection Program, sets forth the policies, defines the applicable terms, and delineates the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing human subject research. The regulations mandate that all DoD activities, components, and agencies protect the rights and welfare of human subjects of study in DoD-supported research, development, test and evaluation, and related activities hereafter referred to as "research". The requirement to comply with the regulations applies to new starts and to continuing research.

The DTRA directive requires that research using human subjects may not begin or continue until the Defense Threat Reduction Agency's Research Oversight Board (ROB) has reviewed and approved the proposed protocol. Contractors and subcontractors are required to submit a valid federal assurance for their organization (institution, laboratory, facility) that has been issued by either DoD or the Department of Health and Human Services, and documentation of review of proposed protocols by the local Institutional Review Board (IRB) to include consent forms for any planned research using human subjects to the DTRA ROB for its review through the contracting officer's representative (if assigned) or the contracting officer. The ROB review is separate from, and in addition to, local IRB review.

Written approval to begin research or subcontract for the use of human subjects under the proposed protocol will be provided in writing from the DTRA ROB, through the contracting officer. A copy of this approval shall be maintained by both the contractor and the government. Any proposed modifications or amendments to the approved protocol or consent forms must be submitted to the local IRB and the DTRA ROB for review and approval. Examples of modifications/amendments to the protocol include but are not limited to:

1) a change of the Principal Investigator
2) changes in duration or intensity of exposure to some stimulus or agent
3) changes in the information requested of volunteers, or changes to the use of specimens or data collected
4) changes in perceived or measured risks or benefits to volunteers that require changes to the study

Research pursuant to such modifications or amendments shall not be initiated without IRB and ROB approval except when necessary to eliminate apparent and immediate hazards to the subject(s).

Research projects lasting more than one year require IRB review at least annually, or more frequently as required by the responsible IRB. ROB review and approval is required annually. The contractor or subcontractor must provide documentation of continued IRB review of

protocols for ROB review and approval in accordance with the Contract Data Requirements List. Research must not continue without renewed ROB approval unless necessary to eliminate apparent and immediate hazards to the subject(s).

Non-compliance with any provision of this clause may result in withholding of payments under the contract pursuant to the contract's payments clause(s) and/or contract termination pursuant to the contract's termination clause(s). The government shall not be responsible for any costs incurred for research involving human subjects prior to protocol approval by the ROB.

(End of Clause)

13. ANIMAL USE

13.1. If the proposed research involves the use of live nonhuman vertebrate animals, Offerors are required to describe the proposed animal use and type of animals being used. The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (ORP), must review and approve all animal use prior to the start of working with animals. Therefore, the contractor will be required to complete and submit the animal use appendix titled "Research Involving Animals", after award of contract, which can be found on the ACURO website:
https://mrmcwww.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1.
Allow two to four months for regulatory review and approval processes for animal studies. Offerors are to build the review time into their project schedules.

13.2. DoD Instruction 3216.01, dated September 13, 2010, provides policy and requirements for the use of animals in DoD-funded research. The DoD definition of animal is any live nonhuman vertebrate. All proposals that involve the use of animals must be in compliance with DoD Instruction 3216.01 and Army Regulation (AR) 40-33. For animals, the provisions include rules regarding animal acquisition, transport, care, handling, and use in: (i) 9 CFR parts 1-4, Department of Agriculture rules that implement the Laboratory Animal Welfare Action of 1966 (U.S.C. 2131-2156); and (ii) the "Guide for the Care and Use of Laboratory Animals," National Institutes of Health Publication No. 86-23.

13.3. The contract clauses regarding the use of animals are detailed below:

DFARS 252.235-7002 Animal Welfare

(a) The Contractor shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2136 and 9 CFR Subpart C, and Section 2.30, and furnish evidence of such registration to the Contracting Officer before beginning work under this contract.

(b) The Contractor shall acquire animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Subpart A, Sections 2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(c) The Contractor agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 *et. seq.* and 9 CFR Subchapter A, Parts 1 through 4).

(d) The Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract for failure to comply with the requirements of paragraphs (a) through (c) of this clause.

(1) The suspension will stay in effect until the Contractor complies with the requirements.

(2) Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this contract and removal of the Contractor's name from the list of contractors with approved Public Health Service Welfare Assurances.

(e) The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for the region in which its research facility is located. The location of the appropriate APHIS regional office, as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Federal Center Building, Hyattsville, MD 20782.

(f) The Contractor shall include this clause, including this paragraph (f), in all subcontracts involving research of live vertebrate animals.

(End of clause)

DTRA local clause 252.235-9001 Prohibition of the use of Laboratory Animals.

The contractor shall obtain approval from the US Army Medical Research and Material Command (MRMC), Animal Care and Use Review Office (ACURO) prior to conducting research on live nonhuman vertebrates. Studies involving non-human primates, dogs, cats, or marine mammals will require a site visit by an ACURO laboratory animal veterinarian as a condition of approval. DoD may also conduct site visits involving research on other animals when deemed appropriate. The animal research facility is responsible for notifying the DoD sponsor if Association for the Assessment and Accreditation of Laboratory Animal Care accreditation is lost or the facility is under USDA inspection. DoD also has the right to a site inspection under these circumstances.

The contractor (including subcontractors) is expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of MRMC ACURO.

The contractor shall complete the ACURO Animal Use Appendix for Research Involving Animals found at the following web site: https://mrmcwww.army.mil/index.cfm?pageid=Research_Protections.acuro_AnimalAppendix. Submit the completed ACURO appendix, contact information, the DTRA contract number and a copy of the contract for processing to the email address listed at the ACURO website. Once ACURO approves the effort, the contractor will receive written approval to begin animal use from the US Army MRMC ACURO by separate email. The contractor shall promptly provide a copy of the approval to the contracting officer and contracting officer representative. After approval, changes or protocol amendments must be submitted to and approved by ACURO before implementation.

The contractor, or subcontractors as appropriate, shall submit the most recent U.S. Department of Agriculture Animal Care Inspection Report annually in accordance with the CDRL.

Non-compliance with any provision of this clause may result in the termination of the contract.

(End of Clause)

14. BIOLOGICAL DEFENSE RESEARCH PROGRAM (BDRP) REQUIREMENTS: BIOSURETY AND SELECT AGENT USE; CHEMICAL AGENT USE

14.1. Proposals must specify what Select Agent work will be conducted at the Offeror's facility and what Select Agent work will be performed in other facilities. Proposals also must provide the source of the Select Agents, any appropriate registration information for the facilities, and specify the Laboratory Biosafety Level. All Select Agent work is subject to verification of information and certifications.

14.2. For those contractors conducting research with Bio-safety Levels 3 and 4 material, a Facility Safety Plan must be prepared and made available during the project award phase in accordance with 32 Code of Federal Regulations (CFR) 626.18. DTRA requires that research using Select Agents not begin or continue until DTRA has reviewed and approved the proposed agent use. The contract clause for etiologic agents is detailed below:

DTRA local clause 252.203-9004 Etiologic Agents – Biological Defense Research Program

a. For purpose of this contract etiologic agent--biological defense program is defined as: any viable microorganism, or its toxin which causes or may cause human disease, including those agents listed in 42 CFR 73, 9 CFR 121, and 7 CFR 331, of the Department of Health and Human Services and Department of Agriculture regulations, respectively, and any agent of biological origin that poses a degree of hazard to those agents and is further identified by the US Army. The contractor shall comply with the following when working with etiologic agents:
    (1) 29 Code of Federal Regulations 1910, Occupational Health and Safety;
    (2) US Department of Health and Human Services (DHHS) and US Department of Agriculture, Select Agent Program(s), 42 CFR 73, 9 CFR 121, and 7 CFR 331; and
    (3) DHHS Publication No. 93-8395, Biosafety in Microbiological and Biomedical Laboratories, latest edition.

b. Etiologic agents shall be packaged, labeled, shipped, and transported in accordance with applicable Federal, State, and local laws and regulations, to include:
    (1) 42 CFR 72 (Interstate Shipment of Etiologic Agents);
    (2) 49 CFR 172 and 173 (Department of Transportation);
    (3) 9 CFR 122 (USDA Restricted Animal Pathogens);
    (4) International Air Transport Association Dangerous Goods Regulations;
    (5) The United States Postal Service shall not be used for transportation of BDRP related etiologic agents; and

(6) If performance is outside of the United States, any additional procedures required by the nation where the work is to be performed.

(End of Clause)

14.3. Proposals that will employ the use of chemical agents, either neat agent or dilute agent, the Offeror must provide approved Facility Standard Operating Procedures that conform to Federal, State, and local regulations and address the storage, use and disposition of these chemical materials.

15. ORGANIZATIONAL CONFLICT OF INTEREST ADVISORY

15.1. Certain post-employment restrictions on former federal officers and employees may exist, including special Government employees (including but not limited to Section 207 of Title 18, United States Code, the Procurement Integrity Act, 41 U.S.C. 423, and FAR 3.104). If a prospective Offeror believes that a conflict of interest exists that relates to the above restrictions, the situation should be raised to the DTRA Contracting Officer before time and effort are expended in preparing a proposal. Send notification of potential conflict of interest via an e-mail message to the e-mailbox listed in Section 5.

15.2. All Offerors and proposed subcontractors also must affirmatively disclose whether or not they are providing Scientific, Engineering and Technical Assistance (SETA), System Engineering and Integration (SE&I), A&AS or similar support, through an active contract or subcontract, to any DTRA technical office(s), the Joint Program Executive Office for Chemical and Biological Defense (JPEO), Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ATSD-NCB), or the Office of the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs (OSA (CBD&CDP)). All disclosures must state which office(s) the Offeror supports, and identify the prime contract number. Disclosures must be furnished at the time of proposal submission. All facts relevant to the existence or potential existence of organizational conflicts of interest (FAR 9.5) must be disclosed, including facts not specifically described above. The disclosure must include a description of the action the Offeror has taken or proposes to take to avoid, neutralize, or mitigate such conflict.

16. INTELLECTUAL PROPERTY

16.1. Patents. Offerors must list any known patents, patent applications, or inventions which the Offeror may be required to license in order to perform the work described in the Offeror's proposal, or which the Government may be required to license to make or use the deliverables of the contract should the Offeror's proposal be selected for award. For any patent or patent application listed above, the Offeror must provide the patent number or patent application publication number, a summary of the patent or invention title, and indicate whether the Offeror is the patent or invention owner. If a patent or invention is un-licensed by the Offeror, identify the licensor.

16.1.1. If any listed patent, patent application or invention is owned or licensed by the Offeror, the Offeror must provide a statement, in writing, if it either owns or possesses the appropriate licensing rights to patent, patent application or invention to perform the work described in the proposal and/or to grant the Government a license to make or use the deliverables for this program. If any listed patent, patent application or invention is not owned or licensed by the Offeror, then the Offeror must explain how it will obtain a license, how the Government may obtain a license and/or whether the Offeror plans to obtain these rights on behalf of the Government.

16.1.2. Be advised that no patent, patent application or invention disclosure will be accepted if identified in the Data Rights Assertion list described in subsection 16.2 below. Government rights in patents, patent applications, and invention disclosures are addressed in the patent rights clause to be included in the contract and therefore, no assertion of limited rights in patents or patent applications will be accepted. **The list of patents, patent applications and inventions of this section must be a separate list from the Data Rights Assertion list described below**.

16.2. **Offerors responding to this BAA requesting a contract to be issued under the FAR/DFARS shall submit a Data Rights Assertions List, which shall identify all technical data and computer software, to the extent known at the time that their offer is submitted to the Government.** The Data Rights Assertions List shall describe whether the Offeror, its subcontractors or suppliers, and potential subcontractors or suppliers, will furnish to the Government with less than "unlimited rights" to use, release and disclosure in accordance with DFARS 252.227-7017, Identification and Assertion of Use, Release or Disclosure Restrictions, and DFARS 252.227-7028, Technical Data or Computer Software Previously Delivered to the Government. The Data Rights Assertion List will contain a table of data deliverables to be furnished to the Government with rights restrictions, as illustrated in DFARS 252.227-7017 (d). The table below shall be used to provide the statement given in DFARS 252.227-7017 (d), signed and dated by an official authorized to contractually obligate the Offeror. If the Offeror will deliver all technical data and computer software to the Government without restrictions, enter "NONE" in this table under the heading "Technical Data or Computer Software to be Furnished with Restrictions."

Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data or Computer Software.

> The Offeror asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data or computer software should be restricted:

Technical Data or Computer Software to be Furnished With Restrictions*	Basis for Assertion**	Asserted Rights Category***	Name of Person Asserting Restrictions****

(LIST)*****	(LIST)	(LIST)	(LIST)

*For technical data (other than computer software documentation) pertaining to items, components, or processes developed at private expense, identify both the deliverable technical data and each such item, component, or process. For computer software or computer software documentation identify the software or documentation.

**Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, enter the specific basis for asserting restrictions.

***Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited, restricted, or government purpose rights under this or a prior contract, or specially negotiated licenses).

****Corporation, individual, or other person, as appropriate.

*****Enter "none" when all data or software will be submitted without restrictions.

Date _____

Printed Name and Title _____

_____

Signature _____

16.3. Offerors responding to this BAA requesting an OTA shall specifically identify any asserted restrictions on the Government's use of intellectual property contemplated under those award instruments. For this purpose, Offerors must propose specific Intellectual Property terms and conditions and a data deliverable list. Offerors are encouraged to model their data rights assertions list to the template provided in DFARS 252.227-7017.

17. EARNED VALUE MANAGEMENT SYSTEM

All proposals which will result in a FAR based cost reimbursement type contract and have an estimated total dollar value greater than $20 million are required to have an Earned Value Management System (EVMS) in accordance with DFARS 252.234-7002. Offerors proposing

work with an estimated total dollar value greater than $20 million should not include EVMS with the Phase II proposal. Any EVMS requirements will be added during negotiations, if necessary.

18. SUBCONTRACTING

18.1. Any Offeror, other than small businesses, submitting a proposal for an award with a value more than the amount listed in FAR 19.702(a)(1) and that has subcontracting possibilities, must submit a subcontracting plan in accordance with FAR 19.7. 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 assure that prime contractors and subcontractors carry out this policy.

18.2. A subcontracting plan identifies the Offeror's approach to awarding subcontracts to small business, small disadvantaged business, women-owned small business, service-disabled veteran owned small business, and Historically Underutilized Business Zone (HUB Zone) small business concerns, on this effort. A DCMA approved master plan may be submitted in lieu of an individual contract plan. The narrative in the subcontract plan must address each element listed in FAR 19.704(a)(1)-(11). The emphasis of the plan must be to maximize small business participation to the maximum extent practicable. The FY2014 DoD subcontracting goals are as follows:

Percentage of subcontracted dollars	
Small Business	36.7%
HUB Zone Small Business	3%
Small Disadvantaged Business	5%
Women-Owned Small Business Concerns	5%
Service-Disabled Veteran Owned Small Business	3%

Note: Provide rationale if the Small Disadvantaged Business goal cannot be achieved per DFARS 219.705-4(d)

19. RECOMMENDED AWARD VEHICLE AND CONTRACT TYPE

Offerors must include a recommended award vehicle (e.g., FAR based contract, OTA) and contract type (e.g., cost, cost-plus-fixed-fee, etc.) and include rationale for their use. However, the Government reserves the right to make the final determination and award the type determined most appropriate under the specific acquisition. It is anticipated that most contracts will be FAR based contracts with a Cost or Cost-Plus-Fixed-Fee pricing arrangement.

20. AUTHORIZED NEGOTIATORS

Offerors must include the name, title, mailing address, telephone number, fax number, and e-mail address of the company, BPOC and any personnel authorized to negotiate with the Government and who is authorized to obligate the Offeror contractually.

21. STATEMENT OF CURRENT AND PENDING SUPPORT

Offerors must include a statement of current and pending support of all related work that is currently receiving or may potentially receive financial support. This information must be included for each investigator listed in the proposal.

22. MODIFIED PREAWARD CHECKLIST - SF1408

Any offeror awarded a cost type contract must be in compliance with FAR 16.301-3 "Limitations" restrictions. Specifically, the contractor's accounting system must be adequate for determining costs applicable to the contract; and will be subject to DCAA audit and surveillance during performance to provide reasonable assurance that efficient methods and effective cost controls are being used. Offeror's are required to submit a Modified Preaward Checklist (SF 1408), which will expedite the pre-award survey of the accounting system by DCAA. Refer to www.dcaa.mil for further assistance preparing an adequate cost proposal.

23. FORWARD PRICING RATE AGREEMENT

Offerors shall include a copy of any current Forward Pricing Rate Agreements with Government agencies, such as Defense Contract Management Agency (DCMA) or the Office of Naval Research (ONR). If no agreement has been made with a Government representative, provide all rates, factors, and bases by year utilized in the development of the proposal and the basis of those rates and factors.

24. CONFIRMED PROPOSAL EXPIRATION DATE

Offerors must provide written confirmation that cost proposals will remain valid for a period of one year after the Phase II date of selection. Offerors may be asked to revalidate their proposal expiration date.

25. EXHIBIT 1: CONTRACT DATA REQUIREMENTS LIST (CDRL)

The separately attached EXHIBIT 1 is a list of potential CDRLs in the form of DD Form 1423's reflecting potential deliverables under a contract awarded under this BAA. The CDRL lists those data deliverables that are required, under the terms of the contract, to be delivered to the Government in accordance with the information in the CDRL and the contract itself. The CDRL will identify the necessary information needed by the contractor to deliver acceptable data items to the Government. This includes a description of the data item, any acceptance criteria, the format of the deliverable, and any delivery information.

26. LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (DURC)

26.1. If the proposed research involves use of any of the 15-specified agents/toxins listed in the U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern; Offerors are required to evaluate the proposed project for DURC. All potential DURC projects must be outlined in detail, naming what agent(s) and what research procedure/protocol causes it to be

DURC. This information, if applicable, must be included in Volume III, Supplemental Information, of the Phase II full proposal. Further information may be required if the proposal is successful.

26.2. All proposed DURC-identified projects must be conducted in accordance with the US Government Policy for Oversight of Life Sciences Dual Use Research of Concern. Web access for this policy can be found at the following URL: http://osp.od.nih.gov/office-biotechnology-activities/dual-use-reasearch-concern-policy-information-national-science-advisory-board-biosecurity-nsabb/united-states-government-policy-oversight-life-sciences-dual-use-research-concern

26.3. If a proposal contains DURC items, the proposal (in Phase II submittals) should include a discussion of their understanding of DURC issues and risks, and a resultant proposed risk mitigation plan for ensuring DURC compliance throughout the duration of the proposed efforts

26.4. If DURC is applicable, see Attachment 10 for further instructions for the SOW and CDRLs.

27. LIST OF ATTACHMENTS/EXHIBITS:

ATTACHMENT 1 QUAD CHART TEMPLATE

ATTACHMENT 2 PHASE I WHITE PAPER FORMAT AND PREPARATION INSTRUCTIONS

ATTACHMENT 3 PHASE II TECHNICAL PROPOSAL TEMPLATE AND PREPARATION INSTRUCTIONS

ATTACHMENT 4 PHASE II COST PROPOSAL TEMPLATE AND PREPARATION INSTRUCTIONS

ATTACHMENT 5 VOLUME III SUPPLEMENTAL INFORMATION

ATTACHMENT 6 STATEMENT OF WORK TEMPLATE AND PREPARATION INSTRUCTIONS

ATTACHMENT 7 PROPOSAL SUBMISSION CHECK LIST

ATTACHMENT 8 EVALUATION CRITERIA AND SELECTION PROCESS

ATTACHMENT 9 STANDARD FORM 1408

ATTACHMENT 10 DUAL USE RESEARCH CONCERN (DURC) INFORMATION

ATTACHMENT 11 TECHNOLOGY READINESS LEVEL (TRL) DEFINITIONS

EXHIBIT 1 CONTRACT DATA REQUIREMENTS LIST (CDRL)

NOTE: Contract clauses may be accessed through:
http://farsite.hill.af.mil