Department of Homeland Security (DHS) Science and Technology Directorate (S&T) Chemical and Biological Defense Division (CBD) BAA 14-003/Call 0007

1. **Announcement Number:** Open Broad Agency Announcement Number (OBAA) 14-003/Call 0007

2. **FBO Solicitation Number:** HSHQDC-14-R-B0009

3. **Solicitation Event Dates/Time (Local Eastern Time):**

    - Call Opening Date – March 3, 2015
    - Full Proposal Due Date– March 31, 2015

Full proposals are due by 4:00 pm EST on the closing date. There will be no exceptions to the time and date on which responses are due, unless determined otherwise by the Government. Full Proposals received after the designated closing date/time will not be considered.

Note: This Call will be conducted in accordance with the Single-Phased Evaluation Process as described under Section 1.6 of the OBAA. The OBAA Solicitation HSHQDC-14-R-B00009 was posted on Federal Business Opportunities on June 16, 2014. See Link https://www.fbo.gov/index?mode=form&id=59fb4fd55df126478cb38df3945696f2&tab=ntype

This Call will consist of the consist of the solicitation, receipt, and evaluation of a Full Proposal, limited to 30 pages, excluding the Formal Transmittal Letter, Cover Page, Summary of Costs and Related Information, Table of Contents and resumes/biographical information for proposed performers. Once the Full Proposal peer/scientific review process has been completed, Offerors will be notified via e-mail, or in writing, that its proposal has been selected, selected but not funded, or not selected for award.

4. **OBAA Call Technical Topic Area (TTA) of Interest:**

Chemical and Biological Research and Development CBD.01 – Diagnostics and Agent Characterization: Research to develop rapid, robust, and affordable diagnostic tools to support detection, response, recovery, and real-time bio-surveillance and situational awareness. CBD's interest in diagnostics includes efforts in the areas of biological assays, sample preparation, advanced diagnostics (e.g. multiplex, high throughput, low-cost, field-deployable, complex sample matrices (environmental, milk, blood, oral/nasal, sputum), multiple target types, pathogen agnostic diagnostics), and agent characterization of chemical or biological materials. CBD's interest includes new or improved rapid diagnostic tests that facilitate foreign animal disease (FAD) outbreak surveillance, response, and recovery in livestock.

4.1. Research Opportunity Description

4.1.1. DHS S&T: Testing, Evaluation, and Validation of Rapid Clinical Assays for Ebola, Anthrax, Glanders, and Melioidosis

Background

The U.S. Department of Homeland Security (DHS) is committed to using cutting-edge technologies and scientific talent in its quest to make America safer. The DHS Directorate of Science and Technology (S&T) is tasked with researching and organizing the scientific, engineering, and technological resources of the United States and leveraging these existing resources into technological tools to help protect the homeland. The Chemical and Biological Defense Division (CBD) of S&T supports this mission by identifying and developing technologies for the DHS operational components that are needed to reduce the probability and potential consequences of a biological pathogen or a chemical attack on the nation's civilian population, its infrastructure, or its agricultural system.

DHS's mission space includes preventing, detecting, responding to, and recovering from intentional or accidental introduction of biological and chemical agents which present a threat against the Nation's human population and critical infrastructure. To support this mission, DHS and its state and local partners have a need to quickly collect reliable information to enable a swift and confident response to a biological and chemical threat. CBD, within DHS S&T, is working toward developing and transitioning technologies that ***demonstrate significant improvements*** to current analytical approaches in sensing and identifying chemical or biological contaminants in all types of environmental samples (solid, vapor, liquid, serum, blood, growth media) with high confidence.

First responders and public health officials require validated detection assays to analyze suspected biothreat samples and enable them to take appropriate actions in the interest of public safety (e.g., evacuating a building) and public health (e.g., distributing antibiotics). The BioAssays Project enables capabilities to rapidly screen and detect high consequence biological pathogens and toxins that can have a significant Public Health impact. The project develops, tests, evaluates and validates nucleic acid detection assays (TaqMan PCR), antigen detection assays (immunoassays) and rapid antimicrobial susceptibility assays (based on microculture and PCR), using the Government Unique Standards for the Implementation of Public Health Actionable Assays (PHAA) for deployment and employment through the Centers for Disease Control and Prevention Laboratory Response Network and other federally-sponsored laboratory response networks. These assays are intended to be dual use assays that can be used for environmental sample analysis as well as clinical specimen analysis. This project encompasses developing bio-informatics resources, reference strain repository, antibody repository, and the appropriate standards. Finally, the PHAA and BioAssays Project will also evaluate novel approaches to recognize and identify emerging, advanced, and enhanced threat agents.

This project seeks to build on the legacy of successful DHS S&T Public Health Actionable Assay development projects. The agent detection assays and rapid point of care diagnostic tests

for the select biological agents will be used in the clinical and public health laboratories as well as point-of-care settings. A thorough test, evaluation, and validation of these assays will be completed on the prototypes by the performer via the use of Government required panels of pre-clinical and clinical samples. The use of clinical human samples will be part of the validation process, and some spiking studies with target agents and near neighbors will be conducted for the validation studies. Respondents should be able to demonstrate skill, knowledge, experience, and commercialization successes in similar types of tasks, *i.e.*, in the creation, testing, evaluation, and validation of clinical assays against these agents. A successful history of creating these types of assays and commercializing them, assumes the performer would have most if not all these reagents already in possession, and is close to testing mature prototypes. This factor is an important consideration to the Government, as there is a time factor involved in the accelerated delivery of these assays. Therefore, experience in similar projects is a plus, as is a previous history of successful transitions of viable and cost effective commercial assays of the types described. Full proposals shall be accepted, no white papers necessary.

4.1.2. Description Technical Topic Areas

The performer will test, optimize, evaluate, and characterize prototype assays for further validation against the panel of Government determined inclusivity and exclusivity materials. The performer will work with Government guidance to validate the final assays, and shall have the capability of commercially and rapidly producing them for sale to other designated end users. DHS may also conduct internal, follow-on specialized and specific analysis, test, evaluation, and validation of assays to help characterize and deploy the assays for use by DHS customers with areas of responsibility for biological defense, detection, surveillance, and response. Prototype assays for this purpose will be included in the final deliverables of the assays.

The Government has established metrics for assessing the capabilities and qualifications of the proposer to successfully meet the requirements of the task. The criteria shown in the Evaluation Criteria Section will be given **equal** weight in determining the final decisions of the source selection committee. An Offeror may submit a **full** proposal to this technical topic area.

Note also that the emphasis with respect to funding considerations for the topic area will be based on demonstrated and prior experience as judged by reviewers to yield the highest possible quality of performance and best value to the Government to assist the DHS in its biological detection and surveillance portfolio. Offerors are encouraged to submit brief and concise plans to execute the tasks, and to include information that will allow the reviewers to judge against the criteria shown in the Evaluation Criteria section. The proposal will be reviewed by a panel of subject matter experts for several criteria as described below in Evaluation Criteria section. Failure to address each criterion fully will result in rejection of the proposal as non-responsive.

Specific elements of the major task areas will also include:

1) Test and evaluation of in-house clinical assays specific for the detection of *Ebola virus* antigen, *Bacillus anthracis* antigen, and *Burkholderia spp*. antigens. Creation and characterization of novel monoclonal antibodies specifically recognizing these agents should already be completed to properly address this task.
2) Demonstrated ability to support test, evaluation, and validation studies in the performer's laboratories. This task will involve the laboratory testing of clinical samples and materials for the detection of the specific agents described. Proposer should include brief descriptions of physical plan and laboratory capabilities to perform the work.
3) Ability to manufacture the assays using the in house reagents into lateral flow assays or suspension bead-based assay chemistries. Production of reagents and assembly of reagents for test kits to support test, evaluation, and validation studies.
4) Ability to work with select agents for live testing to assess the functionality of each assay alone (Lateral Flow Assay (LFA)) and in combination with other agents in the case of bead-based assays should also be possible if the prototype assays are deemed to be functional. For Ebola virus, the use of analogues and recombinant alternatives will be judged on an individual basis. However, testing against live BSL-4 agent in clinical samples will be required later in the process; how this will be accomplished should be addressed somewhere in the proposal. You will need access to a BSL-3 at a minimum.
5) Ability and successful history of performance of Quality Assurance / Quality Control (QA/QC) of reagents in kits prior to initiation of test and evaluation studies.
6) Conduct appropriate studies to support reagent stability and test sample stability for test and evaluation studies.
7) Development of IDA 510K package for FDA approval for in vitro diagnostics.

5. **Number of Selections:** It is anticipated that multiple selections may be made depending on the quality of the Proposals and availability of funds.

6. **Anticipated Ceiling:** Although subject to official fiscal appropriation and availability, it is anticipated that approximately $900,000.00 of Fiscal Year (FY) 2015 funds will be available for any resultant awards under this BAA Call. **The Government will reserve the right to incrementally fund any resultant contracts awarded from this BAA Call as provided by the FAR 52.232-22, "Limitation of Funds."** Contracts or other agreements that obligate funds will not have an initial period of performance that exceeds 24 months from the date of contract award. However, Offerors will be able to propose optional periods beyond the 24 month base period.

7. **Anticipated Award Type:** Award type is anticipated to be in the form of Cost Reimbursement type contracts However the Government reserves the right to award firm-fixed price contracts, cooperative agreements, Other Transactions (OTs) (if authorized by

law at time of award), or interagency agreements to appropriate parties should the situation warrant.

In the event an offeror or subcontractor is a Federally Funded Research and Development Center (FFRDC), Department of Energy National Laboratory, or other Federally funded entity, DHS/S&T will work with the appropriate sponsoring agency to issue an interagency agreement pursuant to the Economy Act (31 U.S.C. 1535) or other appropriate authority.

8. **Anticipated Award Dates:** The 3rd Quarter of Fiscal Year 2015 is when the government anticipates making any resultant contract awards under this Call for those Proposals are selected. However, the award date for any resultant contract award may vary based on the quality of the proposals received and the availability of funds.

9. **White Paper Instructions:** NA – No white papers are being requested in response to this solicitation.

10. **Full Proposal Instructions:** Offerors shall submit their Full Proposals in accordance with BAA 14-003, Section 5 – Application and Submission Information.

11. **Evaluation Criteria:** Full Proposals will be evaluated in accordance with the following evaluation criteria.

Criterion I: Scientific Merit: The Offeror must demonstrate understanding of the critical technology and scientific challenges required to achieve the desired performance metrics and strategy as described elsewhere within this announcement. The research approach should be scientifically sound, practical, and technically defensible. The technical approach is innovative and has advantages over other solutions, if successfully implemented. The research must contribute to scientific knowledge in the topic area and must enumerate potential benefits of the proposed research. The proposal shall demonstrate an awareness of the state-of-the-art. The proposal should be well-prepared with supportive information that is self-explanatory. All critical scientific and technical issues and risks are clearly identified, and the planned development approach and risk mitigation efforts are clearly defined and feasible. The merit of the technical approach over the other competing approaches should be clearly delineated.

Criterion II: Sound Technical Approach: Of importance is how the proposed technology or deliverable will meet or exceed the performance requirements for this program and be commercially applicable (how the proposed technology will be transitioned into a sustainable commercial market and what the intended use, or concept of operations, would be).
Criterion III: Sound Management Approach: Presentation of a sound managerial approach to the proposed work, including a demonstrated understanding of the issues and challenges associated with achieving the goals of the topic, and a strategy to address those

issues and challenges. A successful team will possess multidisciplinary expertise to address the complexity of the effort.

Criterion IV: Capability to Perform and History of Performance: Demonstration of a capability to perform the proposed work, including history of previous performance in developing related solutions and technologies. Specific considerations will include:

- The Offeror must possess clear and convincing qualifications with respect to public health operations and requirements, and must have a proven record of performance and experience, including authorship on peer reviewed publications related to projects associated with the assessment of performance of detection assays for biothreat agents.
- The Offeror (Principal Investigator) must possess at a minimum, a doctoral level degree from an accredited university.
- The Offeror must have an expert understanding and knowledge of assay development and requirements.
- Offerors knowledge of chemical/biological detection systems.
- Offerors teams is sufficiently complete: key personnel are identified with the required range of competence to execute this effort and the team includes appropriate experience.

Criterion V: Presentation of accurate, well-founded and reasonable estimates of all costs related to performance of the proposed effort, including an appropriate allocation of labor resources. Members of the Peer Review panel will be looking for overall best value to the government.

12. **Foreign Concerns**: Foreign persons are advised that their participation may be subject to Export Control restrictions. Any such restrictions shall be reviewed on an individual award basis.

13. **Questions**: Any questions concerning this call must be submitted via email to the Contract Specialist at brigetta.weatherington@hq.dhs.gov and copy the Contracting Officer at Michael. Jones@hq.dhs.gov no later than **March 26, 2015 4:00 PM EST** in the following format:

Question #	Reference	Contractors' Question
1	General (if there is no specific document reference)	
2	(Example) BAA 14-003, page 15, Section 5.2, first paragraph, second sentence	
3	(Example) BAA 14-003/Call 0007, page 2, Section 9, first sentence	

Please include "Questions for BAA 14-003/ Call 0007" in the subject line. All questions and responses will be posted on the Federal Business Opportunities website http://www.fbo.gov and https://baa2.st.dhs.gov . Questions will only be accepted or answered electronically.