Department of Homeland Security (DHS) Science and Technology Directorate (S&T) Chemical and Biological Defense Division (CBD) OBAA 14-003/Call 0017

1. **Announcement Number:** Open Broad Agency Announcement Number (OBAA) 14-003/Call 0017

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

3. **Call 0017 Event Dates/Time (Local Eastern Time):**

- Notification to Submit Full Proposals– April 13, 2016
- Full Proposal Due Date–May 13, 2016 **(3:30 PM EST)**
- Notification of Selection/Non Selection of Full Proposals– June 17, 2016

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. Proposals are not to be sent to the Contracting Officer. They must be submitted through the DHS BAA Portal at the following link:

https://baa2.st.dhs.gov/portal/BAA/

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 14-003/Solicitation HSHQDC-14-R-B0009 was posted on Federal Business Opportunities on June 16, 2014. See Link.

https://www.fbo.gov/spg/DHS/OCPO/DHS-OCPO/HSHQDC-14-R-B0009 /listing.html

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 offerors. Once the Full Proposal review process has been completed, offerors will be notified via email, 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:**

The following Technical Topic Areas (TTAs) are representative only. They are provided to help interested offerors understand the classes of needs and their potential scope.

Chemical and Biological R&D Areas of Interest

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, multiple target types), and agent characterization of chemical or biological materials.

CBD.02 – Surveillance and Detection: Advance the capability to provide early warning and detection of a chemical or biological incident in a cost-sustainable way. Effective surveillance provides essential information to decision authorities on a timescale that allows them to take actions towards mitigating or responding to the threat. Efforts in this area include bioinformatics, open area and facility surveillance through sensing and data integration, and development or improvement of chemical and biological sensors.

4.1. Research Opportunity Description

4.1.1. DHS S&T: **R**apid, **I**nexpensive, **S**mall, **I**nstrumentless, **M**ultiplexed **M**olecular **D**iagnostic **D**evice (RISIMMDD)

Background

The U.S. Department of Homeland Security (DHS) is committed to using cutting-edge technologies and scientific talent in its mission 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 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/or chemical threat. The Chemical and Biological Defense (CBD) Division 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.

A goal of the Federal Interagency Biosurveillance projects has been the early detection of biothreat agents to prevent or decrease mass civilian or military casualties. A heightened concern regarding the entry of travelers into the United States with potentially infectious viral diseases (*e.g.*, Ebola, SARS, MERS, Zika Viruses, *etc.*) has revealed gaps in the rapid detection and point-of-contact diagnostic capabilities areas. Advancement in decentralized diagnostic testing in point-of-contact and resource poor environments has become a critical capability gap and globally recognized need. As the world population is increasing in both number and mobility, the frequency of naturally occurring outbreaks of dangerous infectious diseases that were once isolated can now spread incredibly quickly throughout the entire planet. Sometimes these epidemics begin in resource limited areas of the world which are on the frontline in the fight against infectious diseases. Lack of healthcare, public works, and educational infrastructure both facilitates the spread of infections and prevents the use of the most current and powerful diagnostic techniques.

The current Ebola virus threat and most recent Zika virus outbreak are examples where a need for rapid, decentralized testing has quickly emerged. Both viruses have spread outside of their traditional range and have

threatened the United States for the first time. The mosquito borne Zika virus has been preliminarily associated with devastating birth defects and the Ebola virus is one of the most deadly viruses known. The CDC is currently spending considerable resources in epidemiological field studies to confirm the association between the viral infection and infant microcephaly. The Ebola outbreak has been expensive both in terms of lives lost and money spent to control the outbreak. Over 28,000 people have been infected worldwide and the United States alone has spent $2.4 billion dollars to fight the outbreak.

Addressing these types of issues could be accomplished by developing a rapid, inexpensive, small-hand-held, instrumentless molecular diagnostic platform that could test for a multiplexed panel of pathogens from a single finger stick blood sample or similar biological sample. The platform should be cost effective, battery operated, and disposable, *i.e.,* devices that give quick, on-screen results and relay results to a central or mobile workstation, and capable of providing rapid testing of multiple pathogen threats outside of the clinical laboratory. This type of system is best suited for real time screening and monitoring of infectious virus outbreaks, allowing for the quickest pathogen identification and therapeutic intervention possible. While the system will solve many of the issues with field testing, this type of architecture is also amenable to laboratory environments where high throughput, but random access testing is required, thus making this a system and device that can be scalable across the diagnostic market segments.

It has been documented for over 20 years that electrochemical nucleic acid detection offers the potential for low power, low cost, multiplexed diagnostics. Highly multiplexed electrochemical detection of nucleic acid amplification has been demonstrated in the laboratory, but current challenges involving the implementation of a low cost, low power traditional polymerase chain reaction (PCR) amplification; but progress involving classical thermo-cycling with electrochemical detection have been significantly hampered.

One method to circumvent the issues involving classical thermo-cycling could be isothermal amplification of signatures. Isothermal amplification offers two big advantages that can overcome these obstacles. Achieving amplification with a single moderate temperature simplifies consumable design and significantly lowers power requirements for the system. Traditional PCR involves power intensive thermal cycling, which is difficult and expensive to achieve using a disposable battery. Using a constant lower temperature allows for placing the Nucleic Acid modified electrodes directly in the amplification reaction. The chemistries used most widely for electrode biomodification will not survive multiple temperature spikes to >90°C. This has been a key hurdle to real time electrochemical PCR detection and has resulted in having to design separate chambers in a consumable for amplification and detection. This results in increased cost and complexity of the disposable device. Isothermal amplification overcomes these problems and allows for low cost, single-chamber, multiplexed detection.

In may be possible to combine isothermal amplification with electrochemical detection, thus demonstrating an important advance to achieve a commercially viable product. The preferred amplification assay will show very fast amplification and generate small single stranded products that can hybridize efficiently to the electrode surfaces. These attributes are satisfied by the recently developed technique known as NEAR. **Nicking enzyme amplification reaction (NEAR)** employs a strand-displacing DNA polymerase initiating at a nick created by a nicking enzyme, rapidly producing many short nucleic acids from the target sequence. This process is extremely rapid and sensitive, enabling detection of small target amounts in minutes. NEAR is commonly used for pathogen detection in clinical and biosafety applications, and is usually completed in approximately ten minutes.

4.1.2. Description Technical Topic Areas

The offeror shall first *develop* and then *validate* a novel, NEAR-based amplification assay chemistry which utilizes as a reporter the electrochemical (not dye-based or optical) detection methods that best qualify to create such a system as described above; a rapid, inexpensive, small-hand-held, instrumentless molecular diagnostic platform that could test for a multiplexed panel of pathogens from a single finger stick blood sample or throat/nasal swab. The device shall have a built-in sample preparation chamber, capable of processing common biological samples. To show proof-of-concept, the platform should be cost effective, battery operated, and disposable, *i.e.,* devices that give quick, "on-screen" results and relay results to a central or mobile workstation, and capable of providing rapid testing of multiple pathogen threats outside of the clinical laboratory. The developmental objectives of combining NEAR with electrochemical detection will provide the core technology that will allow for a cost effective, rapid, instrumentless molecular diagnostic platform. Once the device has been developed, an initial target panel (supplied later by the Government) will be utilized to evaluate the prototype for further development and validation. Recent advances in cheap, low power electronics should allow for disposable on board operations and communication components. Successful commercialization of the platform described in this call could result in a paradigm shift in molecular testing, bringing state-of-the-art detection and diagnosis to a wide variety of end users, including point-of-entry personnel.

The offeror will work with Government guidance to validate the final device and assays according to Public Health Actionable Assays requirements. DHS may also conduct 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, and surveillance.

The attributes of this proposed platform would include the following:

1. Field deployable (low resource environment)
2. Easy to use (untrained user can operate)
3. Disposable, single-use
4. Instrumentless, stand-alone device, based on NEAR-Electrochemistry methods
5. Low cost
6. Specific as gold standard (RT-PCR)
7. Sensitive as gold standard (RT-PCR)
8. Robust
9. Digital readout
10. Can relay data to central database, e.g., via *Bluetooth* connection
11. Small sample volume-finger stick or oral swab washings processed on device
12. Fast
13. Multiplexed
14. No upfront capital investment for user (no readers or instruments)
15. If compared to instrumented solution, this must have a low risk of cross-contamination/cross-infection due to unclean equipment
16. Patients could potentially test themselves

17. Self-monitoring cartridge will prevent erroneous results due to expiration or environmental exposure during storage

Proposal shall be written to respond to each attribute described, and include the tasks needed to accomplish each one, *e.g.*, what is required to address each topical area. The costs of doing the work, and the proposed schedule for completion shall be included in the proposal.

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. The proposal will be reviewed by a panel of Government 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.

Note also that the emphasis with respect to past performance for the topic area will be based on demonstrated and prior experience as judged by reviewers to yield the highest possible quality of performance 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 criterion shown in the Evaluation Criterion section.

5. **Number of Selections:** DHS S&T expects to make one award using its FY 2016 funds

6. **Anticipated Ceiling:** Although subject to official fiscal appropriation and availability, it is anticipated that approximately $500,000 of Fiscal Year (FY) 2016 funds will be available for any resultant awards under this OBAA Call. Follow-up funding of another $500,000 of Fiscal Year (FY) 2017 is possible at the discretion of the Government should successful results be forthcoming from the first iteration of the funding. **The Government will reserve the right to incrementally fund any resultant contracts awarded from this OBAA 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 a base effort with additional option years.

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 Fixed Price or Interagency Agreements (IAs) 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 4rd Quarter of Fiscal Year 2016 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 Call.

10. **Full Proposal Instructions:** Offerors shall submit their Full Proposals in accordance with OBAA 14-003, Section 5.4 - Format and Content of Full Proposals. See FBO link above for access to OBAA 14-003/Solicitation Number HSHQDC-14-R-B0009.

11. **Evaluation Criteria:** The evaluation of Full Proposals will be accomplished through an independent technical review using the following 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 the proposal must enumerate the 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.

Criterion II: Sound Technical Approach: Of importance is how the proposed technology 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 or government market and what the intended use, or concept of operations, would be). 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 other competing approaches should be clearly delineated.

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 successful performance in developing related solutions and technologies. Specific considerations will include:

- The Offeror must possess clear and convincing qualifications and must have a proven record of performance and experience, including successful production of and authorship on peer reviewed publications, or patents related to projects associated with the creation, and assessment of performance of select agent detection assays, and novel detection chemistries and hand-held detection methods.
- The Principle 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 technical requirements associated with the specialized development and genetic analysis of bacterial and viral select agents involved in this effort.
- Offeror's knowledge of current and in-use biological and electrochemical detection methods and systems.

- Offeror's team is sufficiently complete: key personnel are identified with the required range of competencies to execute this effort and the team includes appropriate experience and publication record.
- Experience or knowledge in commercialization of diagnostics devices for sale to the general public; not merely developing prototypes or proof-of-concept devices is desirable.

Criterion V: Cost Realism/Reasonableness: 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 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 in accordance with OBAA 14-003 Section 8.3. Any such restrictions shall be reviewed on an individual award basis.

13. **iDURC Requirements:** The offeror and any proposed sub-offeror(s) working under any award resulting from this BAA Call shall conduct all research involving agents and toxins identified in sections III.1 and 6.2.1 of the USG Policy for Oversight of Dual Use Research of Concern and USG Policy for the Institutional Oversight of Dual Use Research of Concern, respectively, in accordance with both policies referenced above and in accordance with any additional requirements set forth in related DHS policies and instructions. Each offeror and any sub-offeror(s) planning to perform research involving agents and toxins identified in sections III.1 and 6.2.1 of the USG DURC policies under this award must attest at the time of seeking funding that they are in compliance with all aspects of the Policies.

14. **Questions**: Any questions concerning this call must be submitted via email to the Contracting Officer at Michael. Jones@hq.dhs.gov no later than **April 29, 2016 3:30 PM EST** in the following format:

Question #	Reference	Contractors' Question
1	General (if there is no specific document reference)	
2	(Example) OBAA 14-003, page 15, Section 5.2, first paragraph, second sentence	
3	(Example) OBAA 14-003/Call 0017, page 2, Section 9, first sentence	

Please include "Questions for OBAA 14-003/ Call 0017" 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.