

**Department of Homeland Security (DHS) Science and Technology
Directorate (S&T) Chemical and Biological Defense Division (CBD)
OBAA 14-003/Call 0018**

1. **Announcement Number:** Open Broad Agency Announcement Number (OBAA) 14-003/Call 0018
2. **FBO Solicitation Number:** HSHQDC-14-R-B0009
3. **Call 0018 Event Dates/Time (Local Eastern Time):**
 - Notification to Submit Full Proposals: December 28, 2016
 - Full Proposal Due Date: January 31, 2017
 - Notification of Selection/Non Selection of Full Proposals: February 28, 2017

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 14-003/Solicitation HSHQDC-14-R-B0009 was posted on Federal Business Opportunities (FBO) on June 16, 2014. See below link.

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

This Call will 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 0018 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.

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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: Characterization of Extensively Multi-drug Resistant Gram-negative Isolates for the Development and Production of Detection/Characterization Assays

Background

The U.S. Department of Homeland Security (DHS) is committed to employing 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 supporting the development of technologies for the DHS operational components, which are required to reduce the probability and/or mitigate the 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 that are a threat to the Nation's human population and critical infrastructure. To support this mission, DHS and its state and local partners must quickly collect reliable information to swiftly and confidently respond 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, identifying, and characterizing chemical or biological contaminants in all types of matrices (solid, vapor, liquid, serum, blood, growth media) with high confidence.

Carbapenems are the most potent class of β -lactam antibiotics, and with the emergence of carbapenem-resistant strains, treatment options have become extremely limited. Carbapenem-resistant Enterobacteriaceae (CRE) represents a family of emerging pathogens that has compromised the ability to treat infections with currently available antibiotics and will compromise the U.S. healthcare system if hospitals have to institute drastic measures or close down units or entire facilities to stop nosocomial spread of these organisms. For example, the U.S. NIH Clinical Center had a carbapenem-resistant *Klebsiella pneumoniae* outbreak in 2011 that affected 18 people and resulted in 11 deaths (61% fatality). This fatality rate is greater than what

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was observed during the 2001 anthrax attacks. The mechanism of carbapenem resistance is plasmid-mediated. These plasmids can be spread naturally or introduced nefariously into a wide variety of Enterobacteriaceae, including *Escherichia coli*, *Salmonella* spp., *Shigella* spp., and other bacterial species that can cause food- or water-borne infections, which can impact a significant proportion of the population through direct infection and/or through the generation of widespread fear and need for critical public health and infection control measures. *K. pneumoniae* is of particular importance because it can colonize the gastrointestinal tract of patients without causing overt signs of infection. These individuals act as silent transmission vectors allowing an outbreak to develop covertly over a period of time as occurred during the 2011 NIH outbreak. Over the past decade, multidrug resistant (MDR) Gram-negative bacterial pathogens have increased in incidence at an alarming rate throughout the world. These Enterobacteriaceae (often referred to as “new Superbugs”) were first reported in 2010 in India and Pakistan. They are now recognized as a critical and urgent global threat because isolates have been reported worldwide, primarily due to the global travel of humans who may be asymptotically carrying these organisms. These “new Superbugs” have generated a great deal of public alarm primarily due to a newly identified mechanism of resistance to carbapenems (which are the antibiotics that are often the last line of defense for the treatment of infections caused by MDR organisms), involving what is referred to as New Delhi Metalloprotease-1 or NDM-1. Carbapenem-resistant Enterobacteriaceae (CRE) that harbor the NDM-1 or other mechanism(s) of resistance, such as *K. pneumoniae* carbapenemase (KPC), are typically found in certain geographic areas throughout the world. The NDM-1-producing CRE’s are most commonly isolated in countries in the Middle East and Asia, and especially in Pakistan and India. While NDM-1-producing CREs isolates are very uncommon in the United States at present, there have been cases reported over the past few years, and the number of cases is on the rise, which underscores that CREs are an emerging pathogen in the United States. Given that mechanism(s) for CRE resistance, and specifically NDM-1-mediated carbapenem resistance, are plasmid-mediated and transmissible between Enterobacteriaceae, a wide variety of bacterial species can acquire these resistance determinants, including those that are typically associated with food-borne infections such as *E. coli*, *Salmonella* spp., *Shigella* spp., etc. In fact, such bacterial species that harbor carbapenem resistance determinants have already been isolated at the Aga Khan University (AKU) Clinical Microbiology Laboratory in Pakistan. Overall, the experience at AKU Clinical Microbiology Lab since 2013 is that approximately 24-27% of Gram-negative isolates are CRE’s (typically NDM-1 producers), and bacterial species isolated that are CRE include: *K. pneumoniae*, *Enterobacter* spp., *E. coli*, *Salmonella* spp., and *Shigella* spp.. Since 2013, a number of *K. pneumoniae* CRE isolates have been found to exhibit a shift in antimicrobial resistance from being not only resistant to carbapenems but also colistin resistant upon initial testing (not necessarily after prolonged or repeated infections). Colistin is typically the very last antibacterial therapy choice for treating CRE’s. Unfortunately, there have been a sharp increase in the number of colistin resistant cases, and these isolates have recently been isolated in the U.S. Loss of colistin susceptibility means the infection is essentially untreatable. Therefore, the urgency for characterizing these isolates and studying their underlying mechanisms of resistance and virulence has reached a critical threshold. These organisms are not select agents, nor are their possession or sharing restricted. A proactive approach to this problem needs to be

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taken rather than reacting to intentional releases or outbreaks that shut down hospitals, kill a significant proportion of those infected, and cause panic throughout the U.S.

4.1.2. Description Technical Topic Areas

An orthogonal approach should be pursued that would rapidly provide genotypic and phenotypic results, e.g., combining TaqMan PCR with lateral flow immunoassays, would be an acceptable methodology to provide rapid detection assays that would be sensitive, specific, and provide actionable information. Using TaqMan PCR alone will not confirm the expression of the resistance markers, but only that the gene(s) are present. In order to confirm the phenotypic activity (e.g., resistance to carbapenems or other drugs) an orthogonal approach must be used. While not all mutations leading to colistin resistance have been identified, the end result of these mutations (e.g., altered LPS) is known.

Points to be considered for prospective offerors in responding to this announcement pertaining to the nature of the targets include: TaqMan PCR alone will not be very useful for the detection of colistin resistance, which in many cases is related to mutations in regulatory genes that govern LPS structure/modification that result in resistance to polymyxins (e.g., colistin). Complicating this task is that in the analysis of a complex sample, it will be difficult to determine which organism is actually carrying the gene. For example, preferably, TaqMan-PCR could be used for the detection of NDM-1, etc., genes, followed by a lateral flow assay for the detection of the enzyme and detection of altered LPS, thus providing both genotypic and phenotypic results.

It is recommended that the prospective offeror shall first obtain a sufficient number of resistant isolates to provide a statistically sound number of genomic sequences to inform on targets amenable to PCR amplification and detection. Perform high resolution sequence analysis of the isolates in order to develop a comprehensive database of SNPs, repeats, and other discernable and reliable targets for TaqMan PCR detection. Create and then validate TaqMan-based amplification assays. Once the assays have been developed, an initial target strain panel will be utilized to evaluate the prototype assays for further development and validation. The development of a rapid, specific and sensitive lateral flow immunological assay(s) using monoclonal antibodies that recognize and bind the altered component(s) and enzymes would complete the methods needed to detect phenotypic resistance. The prospective offeror will work with Government guidance to validate the final 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. Proposals should 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 should be included in the proposal. Refer to Section 5.4 of the OBAA for the required format and content of full proposals.

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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 Evaluation Criteria Section 11 of this notice will be given **equal** weight in determining final award recommendation decision. 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 Government 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 (1) award using its FY 2017 funds
6. **Anticipated Ceiling:** Although subject to official fiscal appropriation and availability, it is anticipated that approximately \$500,000 of Fiscal Year (FY) 2017 funds will be available for any resultant awards under this OBAA Call. **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 18 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 subofferor 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 2017 is when the Government anticipates making any resultant contract awards under this Call for those proposal(s) 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.

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10. Full Proposal Instructions: Prospective offerors shall submit their Full Proposals in accordance with OBAA 14-003, Section 5.2 – Application and Submission Process.

Proposals must be submitted to the DHS S&T BAA Portal at
<https://baa2.st.dhs.gov/portal/BAA/>

Proposals must not be submitted to the OBAA FBO link nor should they be submitted directly to the DHS Contracting Officer. Please carefully follow all instructions shown in Section 5.2, Application and Submission Process.

11. Evaluation Criteria: The evaluation of Full Proposals will be accomplished through an independent Government 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 work or 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 related to this area.

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- The proposed 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 technical requirements associated with the specialized development and genetic analysis of bacterial agents involved in this effort.
- The offeror has an established collaboration(s) in place to obtain and supply the necessary bacterial strains demonstrated to possess the required phenotypic traits needed for this project. This will include foreign and domestic isolates.
- The 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.

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 **January 17, 2017 3:00 PM EST** in the following format:

Question #	Reference	Offeror Question
1	General (if there is no specific document reference)	

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2	(Example) OBAA 14-003, page 15, Section 5.2, first paragraph, second sentence	
3	(Example) OBAA 14-003/Call 0018, page 2, Section 9, first sentence	

Please include “Questions for OBAA 14-003/ Call 0018” 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.