PRE-DECISIONAL – SOURCE SELECTION SENSITIVE

BROAD AGENCY ANNOUNCEMENT (BAA)
Chemical and Biological Defense Research & Development Program *BAA14-004*
Solicitation No. HSHQDC-14-R-B0008
Peptide Array Host-based Diagnostics for Detection of Human Exposure to Biological Agents

Department of Homeland Security
Science and Technology (S&T) Directorate

Full Proposals Due: Friday 27 JUNE 2014

For Questions Regarding This Solicitation: Michael.Jones@hq.dhs.gov

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1. GENERAL INFORMATION

1.1. Introduction

This solicitation is a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 to provide for competitive selection of research proposals. A formal Request for Proposals (RFP) will not be issued.

The DHS Chemical & Biological Defense Division issues BAAs to solicit new projects for inclusion into its portfolio of research projects. Areas of interest are described as Technical Focus Areas (TFAs). The number of TFAs and the number of projects selected for funding vary with the level of available funding. One TFA is identified in this BAA. See Section 1.8.3 for a description of the TFA.

1.2. Agency Name

Department of Homeland Security
Science & Technology Directorate
Chemical and Biological Defense Division

DHS S&T CBD – Mail Stop 0201
245 Murray Lane
Washington, DC 20528-0201

1.3. Research Opportunity Title

Peptide Array Host-based Diagnostics for Detection of Human Exposure to Biological Agents

1.4. Program Name

Rapid Diagnostics Development Program (in the Chemical and Biological Defense Division, Science and Technology Directorate, Department of Homeland Security)

1.5. Research Opportunity Number and Title

BAA14-004– Peptide Array Host-based Diagnostics for Detection of Human Exposure to Biological Agents

1.6. Solicitation and Response Approach

The Department of Homeland Security (DHS) Science & Technology (S&T) Directorate will not issue paper copies of this announcement. DHS S&T reserves the right to select for award and fund all, some, or none of the Full Proposals received in response to this solicitation. No funding for direct reimbursement of proposal development costs will be allowed. However, depending on the markings on the proposal, DHS S&T will adhere to

FAR policy on handling source selection information and proprietary proposals. It is the policy of DHS S&T to treat all proposals as sensitive competitive information and to disclose their contents only for the purposes of evaluation. Offerors are to provide unclassified proposals. Documents containing sensitive information that are not suitable for uncontrolled public dissemination should be marked "For Official Use Only" (FOUO). When transmitted electronically, FOUO proposals should be sent with password protection.

Awards may take the form of contracts or other transactions (OTs) agreements. 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. Depending on the nature of the Full Proposals received, the applicable laws and regulations governing the legal vehicle used for award will depend on the legal vehicle chosen by DHS S&T. In this regard, Offerors should propose a preferred vehicle type for DHS S&T to consider for award.

A single-phase proposal selection process will be used for this solicitation, which will consist of the solicitation, receipt, and evaluation of a Full Proposal, limited to 20 pages, excluding the Formal Transmittal Letter, Cover Page, Summary of Costs and Related Information, Table of Contents and resumes/biographical information for proposed performers.

1.7. Response Dates

Full Proposals:

Due: 27 June 2014

1.8. Research Opportunity Description

1.8.1 DHS Chemical and Biological Defense Division Structure and Background

The Homeland Security Act of 2002 (Public Law 107-296) states that DHS S&T will "support basic and applied homeland security research to promote revolutionary changes in technologies; advance the development, testing and evaluation, and deployment of critical homeland security technologies; and accelerate the prototyping and deployment of technologies that would address homeland security vulnerabilities."

Pursuant to this mission, the Chemical and Biological Defense Division (CBD) seeks technologies to prevent and defend against a chemical and biological attack. 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 Science and Technology (S&T) Directorate 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 DHS S&T Directorate, Chemical

and Biological Defense (CBD) Division, supports this effort through its mission to enhance the nation's preparedness against Chemical and Biological Threats.

1.8.2 DHS Chemical and Biological Defense Rapid Diagnostics Program Objectives

The goals of the CBD mission related to the Rapid Diagnostics Program include the development of diagnostic technologies and capabilities for chemical and biological threats. Specific to this BAA, the primary goal of the Rapid Diagnostics Program is to provide a broad-spectrum diagnostic to enable triage in emergency response scenarios to optimize medical actions and decisions. Applications include development of Point-of-Need (PON) diagnostics, laboratory based diagnostics and capabilities to inform and support diagnostics with improved efficacy. To this end, DHS S&T is interested in understanding the utility of array-based technologies that provide potential diagnostics capabilities by leveraging information associated with host immune response markers. Recent developments and accomplishments in exploiting host immune response markers for rapid clinical infectious and chronic disease diagnostics have gained much attention. The novelty of using a single reagent/test to diagnose a broad array of clinical infectious and chronic diseases with minimal sample preparation warrants the need for additional investigation, development, optimization, testing and evaluation for the introduction of a disruptive technology to improve health care and support the Global Health Security initiative. The intent of this solicitation is to leverage prior government and industry investments which have examined quality control processes for array manufacturing, array content, sample handling, assay chemistries and data analysis algorithms to optimize the technology and have enabled the association of blood samples with disease states. Proposals should provide experimental designs that answer key questions to understanding the utility of peptide array technology, which include: 1) the ability to differentiate diseases with high specificity, 2) the ability to capture a disease during early symptomatic stages to support clinical diagnosis, 3) the ability to differentiate acute vs chronic vs previous exposure vs vaccinated individuals, and 4) the ability to obtain reliable and reproducible results by leveraging a defined quality control process during manufacturing and accommodating sample variability.

DHS S&T's vision for this technology includes:

1. Minimal sample preparation.
2. Rapid sample to answer results.
3. Ease of Use.
4. Affordable and sustainable.
5. Test must be highly specific, sensitive and reproducible.
6. Must detect at the early symptomatic stage and differentiate among relevant clinical infectious diseases to support clinical diagnosis with a single test. (must be agent or disease agnostic with respect to reagents required for the test)

1.8.3 Description of Technical Focus Area

TFA-1. Evaluation of commercial or near commercial peptide array host-based diagnostic assays and platforms.

TFA-1 requests the evaluation of commercial or near commercial peptide array host-based diagnostic assays and platforms to facilitate clinical infectious disease surveillance, as well as biodefense-related disease outbreak surveillance, response, and recovery. Additional use cases include continuous infectious disease surveillance, mission related deployment, and mass triage scenarios.

Performers should include the following information in their proposals:

- Peptide Array assay chemistry and how it works
- Assay specificity, sensitivity and reproducibility results and data, if available
- Total cost per test to analyze a patient's sample
- Timeline from start of analysis to results
- Detailed step by step procedure, to include required materials, instruments or equipment, instruments/equipment/reagent associated cost, time associated with each step of the analysis, and method for data analysis, algorithm and interpretation of results
- Is the test kits manufactured under cGMP process? If not, provide plans for implementation or compliance
- Is the test FDA IVD approved? If not, provide plans to ensure that the technology is FDA IVD approved for clinical use and application
- Is the test commercially available? If not, provide plans for commercialization
- Plans and concept for deployment and utilization of this assay
- Justification as to why your proposed approach is well suited to meet DHS S&T's rapid, broad-spectrum clinical diagnostics goals. How is this technology better than other potential technologies or approaches? Discuss the advantages and disadvantages provided by this approach.

Two types of studies are needed to acquire the data necessary to adequately assess utility and efficacy of the peptide array host-based diagnostic assays and platforms for DHS use cases:

1) ***Evaluation studies to examine the suitability of peptide array host-based diagnostics for DHS use cases.*** This phase of development consists of experiments to determine which diseases and applications (if any) are most appropriate. Requirements that may be addressed in this early stage include aspects of disease coverage, identification resolution, disease stage for diagnosis, population coverage and sample types. Each set of experiments proposed should include a statistically relevant number of control and test samples to determine whether or not a resulting cohort of reactive peptides on the array, which are shared among samples that correspond with a known disease, can provide the level of sensitivity, specificity and provide positive predictive value to accurately diagnose the disease and can be used in subsequent experiments to accurately diagnose the disease state in corresponding, well characterized, blinded samples.

2) ***Validation studies to understand robustness and limitations of peptide array host-based diagnostics for specific use cases.*** Experiments conducted in this phase seek to more rigorously demonstrate the applicability and usefulness of the technology for a particular application. Requirements addressed by these types of studies include false positive and negative rates, sustainability, reliability and reproducibility, time to answer and usability.

To respond to this solicitation, detailed plans to accomplish the initial set of technology evaluation studies, described below, should be provided. The following studies should be completed in the order presented and are dependent on each other, i.e. if the first baseline study cannot be accomplished, the performer should not move to the second study. The data generated from these studies is anticipated to provide insight into intended use and applications which then can lead to validation phase studies.

Evaluation Studies

1) **Understanding variability in baseline and disease signals across diverse populations**

Proposed studies should include sample sets from people of different ages (including pediatric and geriatric), gender, races, geographic locations, nationalities, ethnicities, immune health (including immunocompromised), etc. The proposal should include studies to determine whether a broad population-based definition of baseline is possible, or if not, what controls need to be placed on the use of the diagnostic test. Examples of controls include excluding certain sub-populations from receiving the test, or utilizing different baselines for different sub-populations. This study is critical to understanding if a peptide array host-based diagnostic can be used on a diverse population in the aftermath of an event.

2) **Measure individual variability in baseline over time**.

Proposed studies should employ samples from individuals taken at multiple time points to gain an understanding of variation in diagnostic profiles over time. Preferred sample sets should include both short sampling intervals (days) and long sampling intervals (months to years).

3) **Measure variability in disease signal across diverse populations**.

Proposed studies should include evaluation of samples required to understand the variability of the response to disease across diverse populations. Diseases selected for study should include representative types (e.g., bacterial and viral infection) and diseases of interest for clinical use, mission-related deployments and mass triage use.

4) **Measure disease signal for patients with chronic diseases, both with and without acute infections, across a diverse population set.**

Proposed studies should include evaluation of samples corresponding to multiple chronic infections that are common in the population, including, if possible, samples from patients

who have had a past infection with the same pathogen, in order to understand impact of prior or chronic infections on acute disease detection, and how to discriminate between them.

5) **Measure acute disease signal across similar and dissimilar bacterial, viral and fungal infections.**

The proposed studies should evaluate at what level the technology can discriminate between causative pathogens of infectious disease: at the genus, species and/or strain level. The study should include samples from bacterial, viral and fungal infections, with distantly and closely-related bacteria and viruses included. Analysis of the results with the baseline samples will be important to determine the impact of variability across a population on the ability to detect active infections.

6) **Conduct temporal study of targeted disease(s**).

Proposed studies that employ collection of samples to follow disease progression post-exposure should be performed. Where possible, samples from individuals prior to exposure or infection should be compared with those samples taken pre or post-symptomatically and also from chronic and/or convalescent states. If disease specificity can be ascertained by early indicators, then further work should be conducted to determine how specific the result is, which diseases are applicable, and whether signal variability from the target population can be addressed. The proposed study should include the total number of samples that will be collected from individuals at different time points during the course of disease and the number of repeats that will be performed to establish the utility and sensitivity of the test/assay.

Validation Studies

Proposed validation studies for each use cases should be designed to generate data in support of the intended use and application, demonstrating analytical robustness and reproducibility, and measuring relevant analytical and clinical performance metrics. Analytical validation requirements will include determination of normal range and cut-off values, specificity, accuracy, precision, reproducibility, sensitivity and stability. For clinical use, validation requirements will include sensitivity, specificity, positive predictive values and negative predicted values and reproducibility. Sensitivity is demonstrated by the ability of the test to accurately detect exposure/infection by expression of an immune signature diagnostic of that disease state. The assay/test must be capable of detecting a disease course from early symptomatic to late symptomatic stages to support appropriate clinical intervention and mitigation. The proposal should include the total number of samples that will be collected from individuals at different time points during the course of disease and the number of repeats that will be performed to establish the sensitivity of the test/assay. Specificity is demonstrated by the ability of test to differentiate diseases based on an established algorithm developed for results interpretation, and to detect the absence of exposure/infection by expression of an immune signature that is NOT diagnostic of that disease state. The proposal should include evaluation of a variety of clinical samples from patients with diseases associated with near neighbor organisms as well as samples collected

from individuals from different geographic regions, age groups, sexes, and immune statuses, including special populations. The proposal for this study should include a detailed experimental design, including the number of samples that will be subjected to analysis, to include metadata that include the different parameters described above. Positive predicted value (PPV) is demonstrated by the likelihood that an immune signature defined for a disease state will correlate with exposure/infection. Negative predictive value (NPV) is demonstrated by the likelihood that a sample lacking an immune signature defined for a disease state will correlate with the absence of exposure/infection. Reproducibility is demonstrated by the ability of the assays and platforms to yield consistent, reproducible results. This can be achieved via a defined quality control process employed during manufacturing of the test or arrays to ensure the product is consistent from batch to batch during production and should also include an analysis of the serum dilution factor best suited to obtain consistent results, based on the established algorithm for used for interpretation of raw data. Proposals should include a detailed experimental design for the corresponding validation studies, to include a statistically relevant number of control and experimental samples to enable adequate evaluation of sensitivity, specificity and positive or negative predictive values. Reproducibility studies should include testing of a statistically valid number of samples subjected to analysis on different days using various batches of test/arrays produced.

All clinical samples used to establish the proof of concept will be the responsibility of the performer. DHS S&T will not provide any clinical samples or specimens to support the proposals. Performers will be required to forward all data and reports associated with the studies to DHS S&T within 12 months from the inception of the contract.

Blinded Sample Evaluation Study (Option)

Performers and technology that meets the appropriate standards and requirements of the studies described above with supporting data will be down selected to undergo a blinded study conducted by DHS S&T. The ability to discriminate samples from individuals having or lacking an immune signature associated with a disease(s) of interest should be demonstrated. The samples associated with the blinded studies will be arranged for by DHS S&T. The proposal should include the experimental design of a blinded test sample evaluation, which represents a logical extension of the technology evaluation and validation studies demonstrating the utility of the technology for DHS applications, and a cost proposal to cover the work and materials required to evaluate the blinded samples. The study should be designed to differentiate among blood samples from 4 different infectious diseases, and their respective control samples, to be selected by DHS for use in a blinded analysis. The sensitivity and specificity of the approach must be evaluated using samples associated with 4 pathogens of interest, and their respective controls, with statistically relevant sample sizes. The study should be designed based on the following minimum classification criteria: Sensitivity = 97% (91%-99%); Specificity = 95% (92%-97%); Accuracy $\geq$90%; PPV = 86% (79%-91%); NPV = 99% (97%-100%); Performance at 95% confidence. The prior specifications must be met for prevalence $\leq$ 25%.

1.9. Government Representatives

Science and Technology:

Kevin Anderson, Ph.D
Program Manager
Chemical and Biological Defense Research & Development Program
Department of Homeland Security
Science and Technology Directorate
Chemical and Biological Defense Division (Stop 0201)
245 Murray Lane, SW
Washington, DC 20528-0201

Business:

Mr. Michael Jones
Procuring Contracting Officer
Department of Homeland Security
Office of Procurement Operations
Science & Technology Acquisition Division (Stop 0115)
245 Murray Lane, SW
Washington, DC 20528

1.10. Additional Background Information

All final reports and deliverables will be forwarded by the Chemical and Biological Defense Research & Development Program Office to the Chemical Security Analysis Center (CSAC), which maintains a repository of all Chemical and Biological Defense Research & Development Program documents.

2. AWARD INFORMATION

2.1. Available Amount of Funding Expected to be Awarded Through this BAA

Although subject to official fiscal appropriation and availability, it is anticipated that the Chemical and Biological Defense Research & Development Program will have approximately **$4.6 Million** of FY 2014 funds for award under this BAA.

2.2. Limitation of Funds

The Government reserves the right to incrementally fund contracts awarded from this BAA as provided by the FAR 52.232-22, "Limitation of Funds." Contracts or other agreements that obligate funds that are awarded will not have an initial period of performance that exceeds 12 months from the receipt of funding by the performer. However, offerors can propose a base year effort with up to one option year.

2.3. Anticipated Number of Awards

DHS S&T expects to make two or more awards using its FY 2014 funds.

2.4. Anticipated Award Types

Award type is anticipated to be in the form of Cost Reimbursement type contracts. However the Government reserves the right to award Other Transactions (OTs), or interagency agreements (IAAs) to appropriate parties should the situation warrant.

2.5. Anticipated Period of Performance for New Awards

The period of performance for research efforts and studies proposed should either be for a single period not exceeding **one year**, or for multiple years having one base year with up to one option year. If a multi-year project is proposed, something of tangible value must be provided in the first funding year. Funding in the first year cannot be used for planning purposes, with the actual execution of the task to be performed in the subsequent year. Multi-year proposals should make recommendations and present a plan that sets forth the follow-on effort in the subsequent option year. Consideration of the funding of follow-on work in a subsequent year will be contingent upon the value of the product(s) produced by the first-year effort. The period of performance shall commence at the date of award. Proposals that build on current or previous work are encouraged. If Offerors are extending work performed under other DHS projects or projects for other sponsors, the proposal must clearly identify the point of departure and what existing work will be brought forward and what new effort will be performed under this BAA. The final deliverable for an effort should be a final report or a publishable journal article manuscript that can be peer-reviewed, along with standard analytical method(s) and relevant data.

3. ELIGIBILITY INFORMATION

This BAA is open to **ALL** responsible sources.

Offerors may include single entities or teams from academia, private sector organizations, Government laboratories, and Federally Funded Research and Development Centers (FFRDCs), including Department of Energy National Laboratories and Centers.

3.1. Federally Funded Research & Development Centers

FFRDCs, including Department of Energy National Laboratories and Centers, are eligible to respond to this BAA, individually or as a team member of an eligible principal Offeror, so long as they are permitted under a sponsoring agreement between the Government and the specific FFRDC.

3.2. Nonprofit Organizations, Educational Institutions and Small Business Set Aside

The Government encourages nonprofit organizations, educational institutions, small businesses, small minority disadvantaged business (SDB) concerns, Historically Black Colleges and Universities (HBCU), Minority Institutions (MI) (HBCU/MIs), women-owned businesses (WB), and Historically Underutilized Business (HUB) zone enterprises as well as large businesses, academic institutions, and Government laboratories to submit research proposals for consideration and/or to join others in submitting proposals; however, no portion of the BAA will be set-aside for these special entities pursuant to FAR Part 19.502-2, because of the impracticality of reserving discrete or severable areas of research and development in any specific requirement area.

To ensure full consideration in these programs, registration in the https://baa2.st.dhs.gov/ website, described later in this document, requires the appropriate business type selection as well as accurate up-to-date information.

3.3. Organizational Conflict of Interest

Organizational Conflict of Interest issues will be evaluated on a case-by-case basis; as outlined below. Offers who have existing contract(s) to provide scientific, engineering, technical and/or administrative support directly to the DHS S&T will receive particular scrutiny.

(a) Determination. The Government has determined that this effort may result in an actual or potential conflict of interest, or may provide one or more Offerors with the potential to attain an unfair competitive advantage.

(b) If any such conflict of interest is found to exist, the Contracting Officer may (1) disqualify the Offeror, or (2) determine that it is otherwise in the best interest of the United States to contract with the Offeror and include the appropriate provisions to mitigate or avoid such conflict in the contract awarded. After discussion with the Offeror, the Contracting Officer may determine that the actual conflict cannot be avoided, neutralized, mitigated, or otherwise resolved to the satisfaction of the Government, and the Offeror may be found ineligible for award.

(c) Disclosure: The Offeror must represent, as part of its proposal and to the best of its knowledge that: (1) It is not aware of any facts which create any actual or potential organizational conflicts of interest relating to the award of this contract; or (2) It has included information in its proposal, providing all current information bearing on the existence of any actual or potential organizational conflicts of interest, and has included the mitigation plan in accordance with paragraph (d) of this provision.

(d) Mitigation/Waiver. If an Offeror with a potential or actual conflict of interest or unfair competitive advantage believes it can be mitigated, neutralized, or avoided, the Offeror shall submit a mitigation plan to the Contracting Officer for review. Award of a contract where an actual or potential conflict of interest exists shall not occur before Government approval of the mitigation plan.

(e) Other Relevant Information: In addition to the mitigation plan, the Contracting Officer may require further relevant information from the Offeror. The Contracting Officer will use all information submitted by the Offeror, and any other relevant information known to DHS, to determine whether an award to the Offeror may take place, and whether the mitigation plan adequately neutralizes or mitigates the conflict.

(f) Corporation Change. The successful Offeror shall inform the Contracting Officer within thirty (30) calendar days of the effective date of any corporate mergers, acquisitions, and/or divestures that may affect this provision.

(g) Flow-down. The contractor shall insert the substance of this clause in each first tier subcontract that exceeds the simplified acquisition threshold.

4. APPLICATION AND SUBMISSION INFORMATION

4.1. BAA Package Download.

This BAA package may be downloaded in its entirety from the Federal Business Opportunities website http://www.fbo.gov or from https://baa2.st.dhs.gov.

Registration in not required to download the BAA package; however, a registration in https://baa2.st.dhs.gov/ is required to upload a response to the BAA.

4.2. Application and Submission Process

Submissions will not be accepted from organizations that have not registered. Any organization that wishes to participate in this solicitation must register at: https://baa2.st.dhs.gov/.

(a) Submitting a Response to this BAA:

1. To begin the registration process, log on to https://baa2.st.dhs.gov and select *Submissions* link from the side menu. Note users will need their respective company's Tax Identification Number (TIN) or Employee Identification Number (EIN) to complete registration.
2. After logon, click on "Start New Proposal" to initiate a new proposal paper (a completed DHS Chemical and Biological Defense Research & Development Project Proposal Form—See Section 8.2 – Appendix B) registration, and fill in the requisite fields, including selecting the specific Technical Focus Area (TFA) to be addressed by the proposed technology. For additional information download the Submissions Training Guide that can be found from the upper right hand corner of the FAQs.
3. The Full proposal (DHS Chemical and Biological Defense Research & Development Program Project Proposal Forms) must limit the entries for each section of the form to the number of words specified in Section 8.2, Appendix B; any excess words submitted will not be evaluated. Users will receive confirmation of their submission via e-mail.

4. Offerors may register to submit as many Full proposals as desired. Each Full Proposal (DHS Chemical and Biological Defense Research & Development Program Project Proposal Form) submitted must address a primary TFA. If the proposed technology has any relationship to other TFAs over and above the TFA the Full Proposal will be submitted under, then the Full Proposal should address how the proposed technology relates to these additional TFAs.
5. If submitting multiple Full proposals, it is NOT necessary to register multiple times. Registration for multiple Full proposals can be made by using the Start New Proposal button as many times as needed. Submissions will not be accepted from organizations that have not registered. Any organization that wishes to participate in this solicitation must register at: https://baa2.st.dhs.gov

Full Proposals shall be delivered via upload in accordance with instructions provided during registration.

No Classified Full Proposals (or portions of proposals) will be accepted.

The proposal submissions will be protected from unauthorized disclosure in accordance with FAR 15.207, applicable law, and DHS regulations. Offerors are expected to appropriately mark each page of their submission that contains proprietary information.

The DHS BAA website at https://baa2.st.dhs.gov offers electronic access to BAA solicitations, frequently asked questions (FAQs), answers to FAQs, abstracts of previously funded projects, and hyperlinks to other useful information.

For step-by-step instructions for registering your company and submitting your proposal, please refer to the "Registrations and Submissions Training Guide" which can be accessed by clicking the link at the top right corner of the Frequently Asked Questions (FAQs) page.

IMPORTANT: Before submitting a proposal for the first time, you must first register your company and user account in the system. It is recommended that the Business Official or an authorized representative designed by the Business Official be the first person to register for your company. Your company's Taxpayer Identification Number (TIN) is required during registration. (If your company is registered, other new users may register and associated their information with the company's existing record. When registration is completed, users can submit and manage their proposals.

NOTE: User registration is not sufficient for registering the Full Proposal. To register your Full Proposal, you must log on with your credentials. Click the "Start New Proposal" button. When the Start the New Proposal page displays, pick the solicitation and topic, and then enter the title of the full proposal that you are submitting. When you have entered the title, click the "Add Proposal to Activity Worksheet" button. The Proposal Activity worksheet page lists your proposal in the Proposals in progress section of the page. Your Full Proposal is registered at this point. Repeat this step before the Full Proposal registration deadline for every Full Proposal you wish to register.

After you have completed the Coversheets and uploaded your Full Proposal document, you must click on the "Submit Proposal" button to submit the Full Proposal; simply uploading the document is not sufficient.

4.3. Format and Content of Full Proposals

Full Proposals

The due date for receipt of Full Proposals is 4:30 P.M. (Local Eastern Time) on 05 May, 2014. Full Proposals WILL NOT BE ACCEPTED after the published due date.
It is anticipated that negotiations for award will commence on or about 23 May, 2014.
As soon as the final proposal evaluation process is complete, the Offeror will be notified via e-mail of its selection or non-selection for an award. Full Proposals exceeding the page limit will not be evaluated.

Full Proposal Format: Volume 1 - Technical Proposal; and Volume 2 - Cost Proposal

Full proposals will consist of two volumes: a Technical Proposal volume and a Cost Proposal volume.

- Paper Size – 8.5-by-11-inch paper
- Margins – 1 inch
- Spacing – Single- or double-spaced
- Font – Times New Roman, 12 point. Text embedded within graphics or tables in the body of the Project Description Form should be legible and not smaller than 8 point.
- Number of Pages –
    - Volume 1 (Technical Proposal): No more than 20 single-sided pages. Full proposals exceeding the page limit will not be evaluated. The Official Transmittal Letter, as well as the cover page, table of contents and resumes/biographical information about potential performers in the Full Proposal are not subject to the page limitation.
    - Volume 2: (Cost Proposal): No page limitation.
- Copies – A proposal shall consist of one electronic file for the Technical Proposal volume and one electronic volume for Cost proposal volume. Electronic files will be in portable document format (PDF), readable by IBM-compatible PCs. Each file size must be no more than 10 MB.

Full Proposal Content

Volume 1: Technical Proposal

Volume I of the Full Proposal shall be in the form of a Technical Proposal volume. Responsiveness to the order and content of sections listed in Volume I am important to assure thorough and fair evaluation of proposals. Nonconforming proposals may be rejected without review. The Technical Proposal shall cover all of the elements of the Chemical and Biological Research & Development Program's Project Proposal Form that was submitted. In particular, the Technical Proposal must cover the following points in more detail:

- **Official Transmittal Letter:** This is an official transmittal letter with authorizing official signature. For an electronic submission, the letter can be scanned into the electronic proposal. The letter of transmittal shall state whether this proposal has been submitted to another government agency, other than DHS S&T, and if so, which one and when.

- **Cover Page:** This should include the words "Technical Proposal" and the following:

  1) BAA number;
  2) Title of Proposal;
  3) Identity of prime Offeror and complete list of subcontractors, if applicable;
  4) Technical contact (name, address, phone/fax, electronic mail address);
  5) Administrative/business contact (name, address, phone/fax, electronic mail address); and,
  6) Duration of effort (separately identify the basic effort and any options)

- **Table of Contents**

- **Executive Summary:** Summarize the Proposal and the expected benefits of the solution.

- **Proposal:** Describe the proposed work and the associated technical and management issues.

- **Performance Goals:** Describe the overall methodology and how it will meet the Program objectives and the TFA of Section 1.8.3.

- **Detailed Technical Approach:** Describe the proposed technical issues and methodology to address the stated program objectives set forth in the TFA. "Go/No Go" decision points should be identified.

- **Statement of Work (SOW), Schedule, and Milestones:** Provide an integrated display for the proposed research, showing each task with major milestones. Include a proposed schedule for the effort (estimated dates of tasks, milestones and deliverables). Describe how each task will be performed and identify sub-tasks, if

appropriate. Include a section clearly marked as the SOW you propose to undertake. It is anticipated that the proposed SOW will be incorporated as an attachment to the resultant award instrument. To this end, such proposals must include a severable self-standing SOW without any proprietary restrictions, which can be attached to the contract or agreement award.

- **Deliverables:** Provide a brief summary of all deliverables proposed under this effort, including data, and reports consistent with the objectives of the work; along with suggested due dates (calendar days after the effective date of award). This section shall be severable, i.e., it will begin on a new page and the following section shall begin on a new page. It is anticipated that the proposed detailed list and description of all deliverables will be incorporated as an attachment to the resultant award instrument. To this end, such proposals must include a severable self-standing detailed list and description of all deliverables without any proprietary restrictions, which can be attached to the contract or agreement award.

- **Management Plan:** Provide a brief summary of the management plan, including an explicit description of what role each participant or team member will play in the project, and their past experience in technical areas related to this proposal.

- **Facilities:** List the location(s) where the work will be performed, and the facilities to be used. Describe any specialized or unique facilities which directly affect the effort.

- **Government-Furnished Resources:** Provide a brief summary of required information and data which must be provided by the Government to support the proposed work, if any.

- **Cost Summary:** Summarize the projected total costs for each task in the initial period of performance and any proposed option year of the effort, including a summary of subcontracts, man hours, and consumables.

- **Resumes for Key Personnel:** In Appendix A, provide resumes and *curriculum vitae* (CVs) for each of the key personnel. These resumes do not count toward the 20-page limit.

- **Assertion of Data Rights:** Include a summary of any assertions to any technical data or computer software that will be developed or delivered under any resultant award. This includes any assertions to pre-existing results, prototypes, or systems supporting and/or necessary for the use of the research, results, and/or prototype. Any rights asserted in other parts of the proposal that would impact the rights in this section must be cross-referenced. If less than unlimited rights in any data delivered under the resultant award are asserted, the offeror must explain how these rights in the data will affect its ability to deliver research data, subsystems, and toolkits for integration as set forth below. Additionally, the offeror must explain how the program goals are achievable in light of these proprietary and/or restrictive

limitations. If there are no claims of proprietary rights in pre-existing data, this section shall consist of a statement to that effect.

Proposals submitted in response to this solicitation shall identify all technical data or computer software that the Offeror asserts will be furnished to the Government with restrictions on access, use, modification, reproduction, release, performance, display, or disclosure. Offeror's pre-award identification shall be submitted using the following Assertions Table as an attachment to its offer and shall contain the following information:

Assertions Table

For each deliverable listed in the below table, please identify any assertion of restriction on the Government's Use, release or disclosure of technical data or computer software.

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

*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, limited, restricted, or government purpose rights under this or a prior contract, or specially negotiated licenses).

****Corporation, individual, or other person, as appropriate, or enter "none" when all data or software will be submitted without restrictions.
Completed by:

_____ _____

Signature
Printed Name and Title Date

Statement of Assertion. Include the following statement: "The Offeror asserts for itself, or the persons identified below, that the Government's rights to access, use, modify, reproduce, release, perform, display, or disclose only the following technical data or computer software should be restricted:"

Identification of the technical data or computer software to be furnished with restrictions. 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 as specifically as possible (e.g., by referencing specific sections of the proposal or specific technology or components). For computer software or computer software documentation, identify the software or documentation by specific name or module or item number.

Detailed description of the asserted restrictions. For each of the technical data or computer software identified above in paragraph (2), identify the following information:

(i) Asserted rights. Identify the asserted rights for the technical data or computer software.

(ii) Copies of negotiated, commercial, and other non-standard licenses. Offeror shall attach to its offer for each listed item copies of all proposed negotiated license(s), Offeror's standard commercial license(s), and any other asserted restrictions other than Government purpose rights; limited rights; restricted rights; rights under prior government contracts, including SBIR data rights for which the protection period has not expired; or government's minimum rights.

(iii) Specific basis for assertion. Identify the specific basis for the assertion. For example:

(A) Development at private expense, either exclusively or partially. For technical data, development refers to development of the item, component, or process to which the data pertains. For computer software, development refers to the development of the software. Indicate whether development was accomplished exclusively or partially at private expense.

(B) Rights under a prior government contract, including SBIR data rights for which the protection period has not expired.

(C) Standard commercial license customarily provided to the public.

(D) Negotiated license rights.

(iv) Entity asserting restrictions. Identify the corporation, partnership, individual, or other person, as appropriate, asserting the restrictions.

Previously delivered technical data or computer software. The Offeror shall identify the technical data or computer software that are identical or substantially similar to technical data or computer software that the Offeror has produced for, delivered to, or is obligated to deliver to the Government under any contract or subcontract. The Offeror need not identify commercial technical data or computer software delivered subject to a standard commercial license.

Estimated Cost of Development. The estimated cost of development for that technical data or computer software to be delivered with less than Unlimited Rights.

Supplemental information. When requested by the Contracting Officer, the Offeror shall provide sufficient information to enable the Contracting Officer to evaluate the Offeror's assertions. Sufficient information must include, but is not limited to, the following:

(1) The contract number under which the data or software were produced;

(2) The contract number under which, and the name and address of the organization to whom, the data or software were most recently delivered or will be delivered; and

(3) Identification of the expiration date for any limitations on the Government's rights to access, use, modify, reproduce, release, perform, display, or disclose the data or software, when applicable.

The Bayh-Dole Act shall apply for any patentable materials, technologies, or knowledge developed on a contract resulting from this solicitation. The Government reserves nonexclusive, perpetual, royalty-free licensure of any materials developed under a contract resulting from this solicitation.

Ineligibility for award. An Offeror's failure to submit or complete the identifications and assertions required by this provision with its offer may render the offer ineligible for award.

This section must be severable, i.e., it will begin on a new page and the following section shall begin on a new page. It is anticipated that the proposed Assertion of Data Rights will be incorporated as an attachment to the resultant award instrument. To this end, proposals must include a severable self-standing Assertion of Data Rights without any proprietary restrictions, which can be attached to the contract or agreement award.

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- **Other DHS Support:** As an appendix, provide a list of any current or pending awards or proposals with DHS that pertain to CTAs. This section will not count towards the 20-page limit.

VOLUME 2: Cost Proposal

The Cost Proposal shall consist of a cover page and two parts, Part 1 and Part 2. Part 1 will provide a detailed cost breakdown of all costs by cost category and Part 2 will provide a Cost breakdown by task/sub-task using the same task numbers in the Statement of Work. Options must be separately priced.

Cover Page: The use of the SF 1411 is optional. The words "Cost Proposal" should appear on the cover page in addition to the following information:

- BAA number;
- Title of Proposal;
- Identity of prime Offeror and complete list of subcontractors, if applicable;
- Technical contact (name, address, phone/fax, electronic mail address)
- Administrative/business contact (name, address, phone/fax, electronic mail address) and;
- Duration of effort (separately price out the basic effort and any options)

Part 1: Detailed breakdown of all costs by cost category. The Offeror should provide a total estimated price for major demonstrations and other activities associated with the program, including cost sharing, if any. The Offeror should state whether any Independent Research and Development (IR&D) program is or will be dedicated to this effort, or if IR&D is being pursued to benefit related programs as well. Any cost sharing estimates should include the type of cost share, i.e. cash or in-kind. If in-kind is proposed, the Offeror should provide a discussion of how the cost share was valued.

- **Direct Labor** – Individual labor category or person, with associated labor hours and ***unburdened*** direct labor rates;
- **Indirect Costs** – Fringe Benefits, Overhead, G&A, COM, etc. (***Must show base amount and rate***)
- **Travel** – Number of trips, destinations, durations, etc. (Travel estimate should include costs for attendance/presentation at an annual one-day Chemical and Biological Defense Research & Development Program Review that is held in the Washington metropolitan area.)
- **Subcontract** – A cost proposal ***as detailed as the Offeror's cost proposal*** will be required to be submitted by the subcontractor. The subcontractor's cost proposal can be provided in a sealed envelope with the Offeror's cost proposal or will be requested from the subcontractor at a later date;
- **Consultant** – Provide consultant agreement or other document which verifies the proposed loaded daily/hourly rate;

- **Materials**--Materials should be specifically itemized with costs or estimated costs. Where possible, indicate purchasing method, (Competition, engineering estimate, market survey, etc.)
- **Other Directs Costs**, particularly any proposed items of equipment or facilities. Equipment and facilities generally must be furnished by the contractor/recipient. Justifications must be provided when Government funding for such items is sought.
- **Fee/Profit** including fee percentage.

Part 2: Cost breakdown by task/sub-task using the same task numbers in the Statement of Work.

Part 3: Full Proposal (Phase 2) Summary of Costs and Related Information Form (See Section 8.4 – Attachment D of this BAA). Please complete this form and provide it as an attachment to the Cost Proposal. Certified cost and/or pricing data may be required.

The Cost Proposal should be consistent with your proposed SOW. Activities such as demonstrations required to reduce the various technical risks should be identified in the SOW and reflected in the Cost Proposal. The Offeror should provide a total estimated price for the major Research, Development, Test, and Evaluation (RDT&E) activities associated with the program.

For the Cost Proposal, the DHS BAA website system has a web form where the Offeror may enter data regarding the cost proposal. The system does not allow the Full Proposal to be submitted without completing this Cost Proposal web form. Offerors may choose to not enter information in the Cost Proposal web form since the Cost Proposal cover page, Part 1, and Part 2 will be uploaded separately. **However, Offerors will still need to go to the last page of the Cost Proposal web form and hit the confirmation button noting that the Offeror has reviewed the empty web form and is submitting the web form blank.**

4.4. Protection of Information Uploaded to BAA Website:

All data uploaded to https://baa2.st.dhs.gov/ is protected from public view or download. All submissions will be considered proprietary/source selection sensitive and protected accordingly. Documents may only be reviewed by the registrant, authorized Government representatives, and assigned evaluators.

4.5. Significant Dates and Times

DHS S&T plans to review all Full Proposals in accordance with the "Anticipated Schedule of Events" set forth in the table in this section, using the evaluation criteria described in Section 5.1. A Review Panel will evaluate the Full Proposals using the criteria specified under the evaluation criteria set forth in Section 5.1. Following that review, Offerors will be notified whether or not their proposal has been selected for negotiation. It is anticipated that multiple awards may be made under this BAA.

The Government reserves the right to fund none, some, or all of the proposals received. It is the intention upon completion of proposal evaluation to notify Offerors of an initiation of negotiation for awards or rejection of their proposal. Awards will be made based on the evaluation, funds availability, and other programmatic considerations. 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. If requested, there will be a verbal debriefing via teleconference for those proposals that are not selected. The written request to the Contracting Officer must be received within 3 calendar days of notification of non-selection.

Anticipated Schedule of Events*

Anticipated Schedule of Events *		
Event	**Due Date**	**Time (E.T.)**
BAA Posted to Website	**30 MAY 2014**	N/A
Invitations to submit Full Proposals Sent	**03 JUNE 2014**	N/A
Deadline for Submission of Full Proposal Questions	**13 JUNE 2014**	4:30 PM
Full Proposal Website Registration deadline - Full Proposal Due Date	**27 JUNE 2014**	4:30 PM
Notification of Selection for Award Negotiations	**JULY 2014**	N/A
Contract Award	**AUG - SEP 2014**	N/A
Kickoff Meetings	***TBD***	TBD

* These dates are estimates as of the date of this announcement.

4.6. Submission of Late Full Proposals (Project Proposal Forms)

Full Proposals (in Project Proposal Form format) **WILL NOT BE ACCEPTED** after the published due dates.

4.7. Further Assistance Needed for this BAA

The applicable electronic address for all correspondence for this BAA is: Michael.Jones@hq.dhs.gov.

For technical assistance with using the https://baa2.st.dhs.gov/ website, submit questions to the administrators at dhsbaa@reisystems.com, phone (703) 480-7676.

4.8. BAA Contractual and Technical Questions.

All contractual and technical questions regarding this BAA including the published requirements and instructions must be directed to the Contracting Officer at –

Michael.Jones@hq.dhs.gov . The program and technical staff will not acknowledge, forward, or respond to any inquiries received in any other manner concerning this BAA. Contractual questions and answers will be posted periodically under the Frequently Asked Questions (FAQs) section on the www.fbo.gov and https://baa2.st.dhs.gov websites.

5. EVALUATION INFORMATION

5.1. Evaluation Criteria

The evaluation of Full Proposals (in Project Proposal Form format) will be accomplished through an independent technical review using the following criteria, which are listed in descending order of relative importance.

Criterion I: Utility to DHS: Potential of the proposed work for providing technology or solutions that addresses the Technical Focus Areas (TFAs) set forth in Section 1.8.3 of the BAA. Utility to DHS will also be assessed on the criteria used to conduct programmatic analysis reviews of the entire S&T portfolio, of which the Rapid Diagnostics Program is a part.

- **Impact on client mission** (High Impact Potential & High Technical Feasibility)
  - Will the deliverable(s) enhance the nation's preparedness against biological Threats?
  - Will the deliverable significantly improve existing public health and/or disease outbreak surveillance, response, and recovery. Use cases include continuous health surveillance, mission related (military) deployment and mass triage scenarios.?

- **Transitioning of relevant products to the field** (High Relevance & High Transition Likelihood)
  - Is the customer community waiting to implement the deliverable?
  - Will the deliverable(s) be easily transitioned to laboratories or PON to improve continuous health surveillance, mission related (military) deployment and mass triage preparedness?
- **Technical investment positioning the organization for the future** (High Research Leadership & Low Technical Maturity)
  - Is the research positioning the organization and its customers for the future?
- **Clarity of purpose** (High Clarity of Customer Need & High Project Clarity
  - Is the project clear on what it is trying to achieve?
- **Appropriate level of customer involvement** (High level of customer involvement through whole project lifecycle.
  - Is the project lined up with well understood customer requirements?
- **Sufficient innovation to approach the challenges** (High Degree of Innovation & Significant Novel Thinking)
  - Is the project using a new approach or leveraging best practices from projects in other domains)

Criterion II: Sound Technical Approach: Presentation of a sound technical approach to the proposed work that demonstrates reasonableness and responsiveness, as well as, an understanding of the challenges presented by each TFA. Illustration of a unique and clear path to address the challenge(s), e.g. are the sample sets appropriate to evaluate the utility of the technology for each application which the proposal must address.

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. Proposals that utilize industry-academic partnering or utilize industry-Government partnering which enhances the development of novel S&T advances will be given favorable consideration.

Criterion V: Cost Realism: 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 Evaluation panel will be looking for overall best value to the government.

Evaluation of Full Proposals (in Project Proposal Form format) will be based on an assessment of the overall best value to the government based on the aforementioned criteria. There is a possibility that that DHS might choose two lesser ranking proposals over one higher rated proposal for such reasons as breadth of total research program and the need to address certain technical requirements of particular interest. Awards will be made based upon Full Proposal evaluation, funds availability, and other programmatic considerations, including awards to lesser rated proposals where orthogonal or alternative approaches and technologies are deemed to be more technically advantageous.

NOTE: ***DHS S&T reserves the right to select for award and fund all, some, or none of the Full Proposals received in response to this announcement.***

5.2. Evaluation Panel

S&T's policy is to ensure an impartial, equitable, and comprehensive evaluation of all proposals and to select the source (or combination of sources) whose offer is most advantageous to the government. All properly submitted Full Proposals (in Project Proposal Form format) that conform to the BAA requirements will be evaluated by a review panel comprised of Government technical experts drawn from staff within DHS S&T and other Federal agencies. All Government personnel are bound by public law to protect proprietary information. Contractor personnel will be used to handle the submissions administratively only. Contractors will provide administrative support to the

SSEB only. As the activities to be carried out under this BAA do not involve advisory and assistance services (A&AS) contractors evaluating or analyzing proposals, the limitation in FAR 37.203(d) do not apply. Submissions and information received in response to this BAA constitute permission to disclose that information to certified evaluators under these conditions.

6. AWARD ADMINISTRATION INFORMATION

6.1. Comments or Concerns about Solicitation

If Offerors have any comments or concerns about this solicitation, the DHS S&T Contracting Officer can be contacted by mail at:

U. S. Department of Homeland Security
ATTN: Mr. Michael Jones, Contracting Officer
Office of Procurement Operations/S&T Directorate - Stop 210
245 Murray Lane, SW
Washington, DC 20528

7. OTHER INFORMATION

7.1. Government Property, Government Furnished Equipment (GFE) and Facilities

The Government may provide government-furnished equipment (GFE), resources (GFR), information (GFI), or services (GFS) under the terms of each negotiated contract or agreement. GFE, GFR, GFI, or GFS requested by an Offeror must be factored into the Offeror's project cost. Each Offeror must provide a very specific description of any equipment or hardware it needs to acquire to perform the work. This description should indicate whether or not each particular piece of equipment or hardware will be included as part of a deliverable item under the resulting award.

In addition, this description should identify the component, nomenclature, and configuration of the equipment or hardware that it proposes to purchase for this effort. The Government wants to have the contractor purchase the equipment or hardware for deliverable items under its contract. It will evaluate case-by-case the purchase, on a direct reimbursement basis, of special test equipment or other equipment, not included in a deliverable item will be evaluated for allowability on a case-by-case basis. Maximum use of Government integration, test, and experiment facilities is encouraged in each of the Offeror's proposals.

Government research facilities may be available, and should be considered as potential GFE. These facilities and resources are of high value, and some are in constant demand by multiple programs. The use of these facilities and resources will be negotiated as the program unfolds. Offerors should explain which of these facilities they recommend and why.

If any prototype, instrument or device that is produced during the period of performance of a funded project, a sample shall be delivered to DHS S&T CBD before the end of the period of performance for demonstration purposes. More specific information about the provision of a sample(s) will be incorporated in the Statement of Work.

7.2. SAFETY Act

As part of the Homeland Security Act of 2002, Congress enacted the Support Anti-Terrorism by Fostering Effective Technologies Act of 2002 (the "SAFETY Act"). The SAFETY Act puts limitations on the potential liability of firms that develop and provide qualified anti-terrorism technologies. DHS S&T, acting through its Office of SAFETY Act Implementation (OSAI), encourages the development and deployment of anti-terrorism technologies by making available the SAFETY Act's system of "risk management" and "liability management." Offerors submitting proposals in response to this BAA are encouraged to submit SAFETY Act applications for their existing technologies. They are invited to contact OSAI for more information, at 1-866-788-9318 or helpdesk@safetyact.gov. They also can visit OSAI's Web site at www.safetyact.gov.

7.3. Biological Weapons Convention (BWC) Compliance Documentation

Those Offerors whose full proposals are selected for funding, will be provided two forms which will need to be completed and expeditiously returned to the Chemical & Biological Defense Research & Development Program Office. Blank forms will be provided with the letter confirming selection of the proposal. These forms consist of the following:

- BWC Treaty Compliance Project Summary Form
- Biological Weapons Convention (BWC) Checklist

7.4. Export Control Considerations

International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR) may apply to one or more of the topics in this BAA. Foreign nationals must meet the requirements for participation set by those regulations, if required.

7.5. Security Classification

No Classified Project Description Forms or Full Proposals (or portions of proposals) will be accepted.

7.6. Information for Full Proposal (in Project Proposal Form format) Respondents

This BAA seeks to solicit sound scientific studies and techniques to address the DHS Chemical & Biological Defense Research & Development Program objectives set forth in Section 1.8.2. It will not be construed as an obligation on the part of the Government to acquire any products or services. No entitlement to payment of direct or indirect costs or charges by the Government will arise as a result of submission of responses to this BAA and the Government's use of such information. Respondents to this BAA may be

requested to provide additional information based on their submittals. Unnecessarily elaborate responses containing extensive marketing materials are not desired.

7.7. Subcontracting Plan

Successful contract proposals that exceed $650,000.00, submitted by all but small business concerns, will be required to submit a Small Business Subcontracting Plan in accordance with FAR 52.219-9, prior to award.

7.8. Additional Deliverables

Performers should define additional program-specific deliverables as appropriate for the proposed approach. The Government may describe additional deliverables at the time full proposals are requested.

It is desired, whenever possible, that project results be provided in a manuscript format that is publishable in appropriate scientific journals so that peer review can be conducted. If the results of the effort are not appropriate for publication in a journal, they should be provided as a final report.

7.9. Reporting

The following *minimum* deliverables will be required under traditional procurement contracts or other transactions agreements awarded to those Offerors whose Full Proposals are selected for award.

Monthly Project Status Report

Reports of project status will be solicited on a monthly basis from all performers using Chemical Forensic Program "Monthly Project Status Report Forms." A sample of the Monthly Project Status Report Form is provided in Appendix C of this BAA. These reports will be electronically submitted to the Program Manager within fifteen days after the last day of each month. The Monthly Project Status Report Forms provide a standardized format to collect the following information:

Static Information (Information that does not change monthly over the project):

- Project Title
- DHS Project Control #
- Period of Performance
- Principal Investigator's Name, Telephone Number, E-mail and Unclassified/Secure Facsimile Number(s)
- Performer's Financial Contact Name and Telephone Number

Monthly Update Information To Be Provided in Bulleted or Short Narrative Format:

- Activity During the Past Reporting Period (month)
- Progress Achieved Against Deliverable(s) During Reporting Period

- Progress Achieved Against Project Milestones and Tasks During Reporting Period
- Deliverables Submitted This Period
- Milestones Reached/Achieved This Period
- Other Noteworthy Accomplishments (Meetings, Presentations, Publications, etc.)
- Topics of Concern/Slippage (Technical, Schedule and/or Cost)
- Recovery Plan (if needed)
- Explicit Plans for Next Month
- Project Budget Information (Amount Spent During Reporting Period, Cumulative Amount Spent Since Project Inception, and Amount of Funding Remaining)

Performers are requested to provide monthly update information only in those sections of the form that are applicable to the activities performed during the reporting period. If there is no updated information to report in a section, it can be marked "N/A" for Not Applicable, or left blank.

The following deliverables, primarily in contractor format, are anticipated as necessary. However, specific deliverables should be proposed by each Offeror and finalized with the contracting agent:

- Monthly Progress Status Reports (Chemical and Biological Defense Research & Development Program format)
- Presentation Material
- Other Documents or Reports
- Final Report or Journal Manuscript (suitable for publishing and peer review)

7.10. Project Conferences, Meetings and Reviews

The Chemical & Biological Defense Research & Development Program schedules monthly telephone conferences in which all performers are encouraged to participate. Matters of general interest to the performers are provided on agendas that are e-mailed to the performers along with dial-in instructions for access to a toll-free telephone bridge. Those issues that are relevant only to one performer or proprietary in nature are discussed in separate telephone conferences between the performer and the Chemical & Biological Defense Research & Development Program office staff.

Program status reviews may also be held to provide a forum for reviews of the latest results from experiments and any other incremental progress towards the deliverables and major demonstrations. These meetings will be held at various sites throughout the country. For costing purposes, Offerors should assume that one of these one-day meetings will be at or near DHS S&T, Washington D.C., and one other meeting will be held at the contractor's facility or a near-by government facility.

7.11. Certificate of Current Cost or Pricing Data

Successful contract proposals that exceed $700,000.00 may require the submission of a Certificate of Current Cost or Pricing Data in accordance with FAR 15.403-4(b)(2), prior to award.

7.12. Test and Evaluation Facilities

Department of Homeland Security Science & Technology Directorate may make available appropriate test and evaluation facilities to support this program. Offerors should provide any specific requirements needed for test and evaluation of their proposed concept in their Full Proposals.

7.13. Hazardous Materials

Depending on the topic, Offeror may choose to or be required to utilize hazardous materials during the course of the project development effort. If the government provides hazardous samples as part of the developmental and operational testing, information on the samples will be provided to the successful Offerors requiring such samples.

Hazardous material, as used here, includes any material defined as hazardous under the latest version of Federal Standard No. 313 (including revisions adopted during the term of the contract). If the successful Offerors choose to use their own hazardous samples, Offerors must meet the requirements for the identification and material safety as follows:

HAZARDOUS MATERIAL IDENTIFICATION AND MATERIAL SECURITY DATA

(a) "Hazardous material," as used in this clause, includes any material defined as hazardous under the latest version of Federal Standard No. 313 (including revisions adopted during the term of the contract).

(b) The Offeror must list any hazardous material, as defined in paragraph (a) of this clause, to be delivered under this contract. The hazardous material shall be properly identified and include any applicable identification number, such as National Stock Number or Special Item Number. This information shall also be included on the Material Safety Data Sheet submitted under this contract.

Material (*If none, insert "None"*) Identification No.

_____ _____
_____ _____
_____ _____

(c) This list must be updated during performance of the contract whenever the Contractor determines that any other material to be delivered under this contract is hazardous.

(d) The apparently successful Offeror agrees to submit, for each item as required prior to award, a Material Safety Data Sheet, meeting the requirements of 29 CFR 1910.1200(g) and the latest version of Federal Standard No. 313, for all hazardous material identified in paragraph (b) of this clause. Data shall be submitted in accordance with Federal Standard No. 313, whether or not the apparently successful Offeror is the actual manufacturer of these items. Failure to submit the Material Safety Data Sheet prior to award may result in the apparently successful Offeror being considered nonresponsible and ineligible for award.

(e) If, after award, there is a change in the composition of the item(s) or a revision to Federal Standard No. 313, which renders incomplete or inaccurate the data submitted under paragraph (d) of this clause, the Contractor shall promptly notify the Contracting Officer and resubmit the data.

(f) Neither the requirements of this clause nor any act or failure to act by the Government shall relieve the Contractor of any responsibility or liability for the safety of Government, Contractor, or subcontractor personnel or property.

(g) Nothing contained in this clause shall relieve the Contractor from complying with applicable Federal, State, and local laws, codes, ordinances, and regulations (including the obtaining of licenses and permits) in connection with hazardous material.

(h) The Government's rights in data furnished under this contract with respect to hazardous material are as follows:

(1) To use, duplicate and disclose any data to which this clause is applicable. The purposes of this right are to—

(i) Apprise personnel of the hazards to which they may be exposed in using, handling, packaging, transporting, or disposing of hazardous materials;

(ii) Obtain medical treatment for those affected by the material; and

(iii) Have others use, duplicate, and disclose the data for the Government for these purposes.

(2) To use, duplicate, and disclose data furnished under this clause, in accordance with paragraph (h) (1) of this clause, in precedence over any other clause of this contract providing for rights in data.

(3) The Government is not precluded from using similar or identical data acquired from other sources.

(i) Except as provided in paragraph (i)(2), the Contractor shall prepare and submit a sufficient number of Material Safety Data Sheets (MSDS's), meeting the requirements of 29 CFR 1910.1200(g) and the latest version of Federal Standard No. 313, for all hazardous materials identified in paragraph (b) of this clause.

(1) For items shipped to consignees, the Contractor shall include a copy of the MSDS's with the packing list or other suitable shipping document which accompanies each shipment. Alternatively, the Contractor is permitted to transmit MSDS's to consignees in

advance of receipt of shipments by consignees, if authorized in writing by the Contracting Officer.
(2) For items shipped to consignees identified by mailing address as agency depots, distribution centers or customer supply centers, the Contractor shall provide one copy of the MSDS's in or on each shipping container. If affixed to the outside of each container, the MSDS's must be placed in a weather resistant envelope.

8. APPENDICES

8.1. Appendix A – List of Acronyms

8.2. Appendix B - Sample DHS Chemical & Biological Defense Division Program "Monthly Project Status Reporting Form"

8.4 Appendix C – Sample DHS Chemical and Biological Defense Division "Monthly Project Status Reporting Form"

8.1 - APPENDIX A – List of Acronyms

BAA	Broad Agency Announcement
BWC	Biological Weapons Convention
CBD	Chemical and Biological Defense Division
DHS	Department of Homeland Security
DOE	Department of Energy
FAQs	Frequently Asked Questions
FAR	Federal Acquisition Regulations
FedBizOps	Federal Business Opportunities (www.fbo.gov)
FOUO	For Official Use Only
FFRDC	Federally Funded Research and Development Center
G&A	General and Administrative
GFE	Government-Furnished Equipment
GFI	Government-Furnished Information
GFR	Government-Furnished Resources
GFS	Government-Furnished Services
HBCU	Historically Black Colleges and Universities
HSPD	Homeland Security Presidential Directive
HUB	Historically Underutilized Businesses
IAA	Interagency Agreement
IR&D	Independent Research and Development
MI	Minority Institutions
OSAI	Office of SAFETY Act Implementation (DHS)
OTs	Other Transactions
PDF	Portable Document Format
PL	Public Law
PPF	Project Proposal Form (Chemical and Biological Defense Research & Development Program Form used in place of narrative on website)
RFP	Request for Proposal
RDT&E	Research, Development, Test and Evaluation
S&T	Science and Technology
SAFETY Act	Support Anti-Terrorism by Fostering Effective Technologies Act 20
SDB	Small Disadvantaged Businesses
TFA	Technical Focus Area

8.2 – Appendix B - Sample "DHS Chemical & Biological Defense Division Project Proposal Form" Format

CHEMICAL & BIOLOGICAL DEFENSE DIVISION
FY 2014 PROJECT PROPOSAL FORM

Name of Project
Project Name XXX
TFA# or TFA#s Being Addressed in This Proposal
TFA# or N/A
Name(s) and Contact Information of Performers
Name: XXX Mailing Address: XXX Telephone: XXX Fax: XXX Secure Fax: XXX Email: XXX Secure Email : XXX
Name and Contact Information of Financial Contact
Name: XXX Mailing Address: XXX Telephone: XXX Fax: XXX Email: XXX
Requirement Addressed (500 words or less) (Reference Technology Focus Area[s])
XXX
Summary of Technical Approach & Project Activity (2,500 words or less)
XXX
Justification & Potential Benefits/Outcomes of Project (750 words or less)
XXX
Relationship to Other Proposals Being Submitted in Response to This BAA, if Any (300 words or less)
XXX
List of Tasks and Schedule During First Year (From Contract Award Date) (1,000 words or less)
Task 1: Task Name XXX (Contract Award Date to X month) Task 2: Task Name XXX (Month X to X month) … Task N: Task Name XXX (Month X to X month) (Note: POP not to exceed 12 months)
Approximate Cost of Each Task/Total Project Cost During First Year
Task 1 Cost: $ XXX Task 2 Cost: $ XXX …. Task N Cost: $ XXX **Total Cost: $** XXX
Description of Deliverable(s) and Schedule of Delivery During First Year
Deliverable 1: Deliverable Name XXX (Contract Award Date + X months) Deliverable 2: Deliverable Name XXX (Contract Award Date + X months) … Deliverable N: Deliverable Name XXX (Contract Award Date + X months)
Proposed Follow-on Tasks in Option Years (If Multi-Year Project) (1,000 words or less)
Option Year #1 Tasks: Task Name(s) XXX Option Year #2 Tasks: Task Name(s) XXX Option Year #3 Tasks: Task Name(s) XXX

Estimated Costs for Work in Follow-On Years (If Multi-Year Project)
Total Cost for Option Year #1 Tasks: $ XXX Total Cost for Option Year #2 Tasks: $ XXX Total Cost for Option Year #3 Tasks: $ XXX
Go / No Go Decision Point(s) for Project Completion &/or Follow-On Work (150 words or less)
Project Completion and/or Follow-on Decision Point(s): (*Criteria at completion of particular Task or Deliverable* (Contract Award Date + X months)
Related Experience/Qualifications of Performer(s)/Laboratory (500 words or less)
XXX
References/Related Research (500 words or less)
XXX
Comments (500 words or less)
XXX

8.3. – Appendix C- Sample DHS Chemical and Biological Defense Division "Monthly Project Status Reporting Form"

DHS CHEMICAL AND BIOLOGICAL DEFENSE DIVISION
FY 2014 MONTHLY PROJECT STATUS REPORT FORM
PERFORMER: XXX
MONTHLY PROJECT STATUS REPORT # x
For: xxx 201X (Month/Yr.)
Date Submitted: xxx ,201X
(Must be submitted to DHS PM by 15th of following month)

Deliverable: Immunosignature (IS) Studies	
Project Title: Project Name XXX	
Purchase Request/IAA No.: XXX	**Period of Performance: Contract Award Date (C.A.D.) [xx/xx/201X] + X Months = xx/xx/201X**
Principal Investigator (PI): XXX	**PI Telephone No.: XXX**
PI Email: XXX	**PI Facsimile No.: XXX**
Financial Contact: XXX	**Financial Contact Telephone No.: XXX**
DHS Program Manager: XXX	**DHS PM Telephone No.: XXX**
DHS PM Email: XXX	**DHS PM Facsimile No.: XXX**

(Instructions: Provide bullets, short narrative and/or budget information updates in regular (non-Bold) red font at areas marked with "xxx," where applicable. If nothing relevant to report occurred during reporting period, leave "xxx" on form. Use Bold red font if a noteworthy technical accomplishment is being reported that is appropriate for bringing to the attention of DHS and other federal senior managers [e.g. White House]. Completed forms should be provided as attachments to an e-mail to XXX and XXX by the 15th of the following month.

Activity During Past Month: xxx

Progress Achieved Against Deliverables: (C.A.D. = Contract Award Date)
Deliverable 1: Deliverable Name XXX (C.A.D. + X Mo. = xx/xx/20 xx) xxx
Deliverable 2: Deliverable Name XXX (C.A.D. + X Mo. = xx/xx/20 xx) xxx
Deliverable n: Deliverable Name XXX (C.A.D. + X Mo. = xx/xx/20 xx) xxx

Progress Achieved Against Project/Milestones/Tasks This Reporting Period:
Task 1: Task Name XXX (C.A.D. + X Mo. = xx/xx/20 xx) xxx
Task 1.1: xxx
Task 1.2: xxx
Task 2: Task Name XXX (C.A.D. + X Mo. = xx/xx/20 xx) xxx
Task 2.1: xxx
Task 2.2: xxx
Task 2.n: xxx
Task 3: Task Name XXX (C.A.D. + X Mo. = xx/xx/20 xx) xxx
Task 3.1: xxx
Task 3.2: xxx
Task 3.n: xxx

Deliverables Submitted This Period: xxx

Milestones Reached/Achieved This Period: xxx

Other Noteworthy Accomplishments (Meetings, Presentations, Publications, etc.): xxx

Topics of Concern/Slippage: xxx
- **Technical - xxx**

- **Cost - xxx**
- **Schedule – xxx**

Recovery Plan (if needed): xxx

Explicit Plans for Next Month:
Task # _: xxx
Task # _: xxx

Project Budget Information:

Total FY 2014 Funding Available:	**$XXX**
Spent this Month:	**xxx**
Cumulative Amount Spent since Inception of Project:	**xxx**
Amount of Funding Remaining:	**xxx**