DEFENSE THREAT REDUCTION AGENCY
BROAD AGENCY ANNOUNCEMENT
HDTRA1-14-24-FRCWMD-BAA
Amendment 12
December 2019

Research and Development Directorate (RD)
Enabling Capabilities Department (RD-EC)

Fundamental Research to Counter Weapons of Mass Destruction (C-WMD)

Original Posting Date: March 2015

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OVERVIEW INFORMATION

Agency Name:

Defense Threat Reduction Agency (DTRA)
Research and Development (RD) Directorate
Enabling Capabilities Department (EC)
8725 John J. Kingman Road, MS 6201
Fort Belvoir, VA 22060-6201

Funding Opportunity Title: Fundamental Research to Counter Weapons of Mass Destruction (FRCWMD) Broad Agency Announcement (BAA)

Announcement Type: This is an amended announcement of this funding opportunity. This BAA is in effect from March 2015 through September 2024. It is anticipated that a majority of the actions funded from this announcement will be in the form of grants; however, other instruments such as contracts, cooperative agreements (CAs) or other transactions agreements (OTAs) may also be awarded from this announcement. Submissions for this BAA may occur in two ways: 1) in response to the published topics detailed in Attachment 1 or 2) to a general thrust area as described in Section 1.5.

In general, all topic-specific and general thrust area submissions require pre-coordination in accordance with the guidelines in Section 1.5 and Section 4.2.1. DTRA reserves the right to waive the pre-coordination requirement for topics on a case-by-case basis; and will state the waiver applies within the individual topic description. If a pre-application white paper is received without prior coordination, DTRA may not review it. From the date of the disposition email the applicant has 63 days to submit the pre-application white paper. If the submission is not feasible within this 63-day window, the abstract must be coordinated again to ensure the interest in the white paper remains.

The evaluation of all submissions will be conducted in two phases. Phase I is for receipt and evaluation of pre-application white papers in direct response to a published topic or by invitation based on the assessment of the idea by the Technical POC. Phase II is for receipt and evaluation of invited proposal applications. Invitation to the Phase II, invited proposal submission, will be based on the evaluation results of the Phase I pre-application white paper.

Funding Opportunity Number: HDTRA1-14-24-FRCWMD-BAA

Catalog of Federal Domestic Assistance (CFDA) Number: 12.351

Dates: This BAA is open continuously from March 2015 through September 2024. Published topics will include instructions on any topic-specific opening and closing dates as well as any topic-specific limitations on award types, dollar values, and eligibility. Submissions to a general thrust area may occur at any time this BAA is in effect. Applicants should take care to note requirements for pre-coordination of an abstract.

ADDITIONAL OVERVIEW CONTENT

Research, educational program, or other effort proposals are sought from accredited degree-granting colleges and universities. Research, educational program, or other effort proposals are also sought from industrial, commercial (including small businesses), and not-for-profit research entities. DTRA strongly encourages and may give preference to pre-application white papers and proposals that demonstrate a significant contribution (significant is defined as a minimum of

30% of total value) by one (1) or more universities.

All submissions (pre-application white papers and invited proposals) must be made in accordance with the submission instructions in this BAA through www.grants.gov using the application packages linked with this BAA (under the "Package" tab) on www.grants.gov. Applicants are responsible for ensuring compliant and final submission of their pre-application white papers and proposal applications. Any submission that does not conform to the requirements outlined in the BAA and in the invitation for proposal may not be reviewed or considered further at the discretion of DTRA.

Pre-application white papers may be evaluated any time after receipt. Invitations for full proposal submission may occur any time after the pre-application white paper evaluation and will be limited to available program funds.

Efforts may be proposed for up to five (5) years. Awards may be for a base period of one (1) year with four (4) additional years as possible options, a base period of two (2) years with three (3) additional years as possible options, or a base period of three (3) years with two (2) additional years as possible options. Applicants should take care to propose the most logical mix of base and option years for the scope of work. Further, the base period should yield a logical completion point for the work. In cases where option years are proposed, decisions regarding exercising those options will be based on the evaluation of the work accomplished in the base period. Pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable; however, the Government reserves the right to invite option years for awards that originally only included a base period.

Grants may range from small dollar value (e.g., $25K) up to $1M annually (total, including both direct and indirect costs) depending on the nature and the scope of work. Payments on grants will be made in advance, subject to the conditions described in 2 CFR 200.305. Funding amounts for contracts, CAs, and other procurement instruments will be considered on a case-by-case basis. Thirty (30)-60 individual awards are anticipated each year.

Any assistance instrument awarded under this announcement will be governed by the award terms and conditions, which conform to DoD's implementation of OMB circulars applicable to financial assistance. This includes DoD implementation of OMB guidance in 2 CFR part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

1. FUNDING OPPORTUNITY DESCRIPTION

1.1. DTRA safeguards America and its allies from weapons of mass destruction (WMD) and provides capabilities to reduce, eliminate, and counter the threat and effects from chemical, biological, radiological, nuclear, and high yield explosives. DTRA seeks to identify, adopt, and adapt emerging, existing and revolutionary sciences that may demonstrate high payoff potential to Counter-WMD (C-WMD) threats, including improvised threats. This BAA is an extramural endeavor that combines the fundamental research, educational program, or other effort needs appropriate for basic or applied research funding of DTRA and other DoD interests.

This announcement solicits ideas and topic-based pre-application white papers for long-term challenges that offer a significant contribution: to the current body of knowledge, to the understanding of phenomena and observable facts, to significantly advance revolutionary technology, to new concepts for technology application, or that may have impact on future C-WMD threat reduction, expertise, or capabilities.

A portion of this effort is expected to be devoted to awards for science, technology, engineering and mathematics education programs with a C-WMD focus; such as, but not limited to postdoctoral fellowships, stipends, degrees, visiting scientist programs, student exchange programs, and development of accredited C-WMD curricula.

1.2. Fundamental research means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

Contracted Fundamental Research includes research performed under grants, contracts (awards), or OTAs that are (a) funded by budget Category 6.1 (Basic Research), whether performed by universities or industry or (b) funded by budget Category 6.2 (Applied Research) performed on-campus at a university. Fundamental research provides for science and technology (S&T) research and early applied development. It seeks to lower performance risk to a manageable level and facilitate transition and funding to capability end-state programs.

1.3. Technology Readiness Levels (TRLs) provide a systematic metric/measurement system that supports assessments of the maturity of a particular technology and the consistent comparison of maturity between different types of technology. Fundamental research may be defined within the first four (4) TRLs.

1.4. This BAA seeks optimum approaches to meet DTRA fundamental research objectives. The Government encourages pre-application white papers and proposals that span a wide spectrum of research to expand fundamental scientific knowledge in response to specific topics and to the more general thrust areas. The Government reserves the right to award any combination of approaches which offer the best overall value to the Government and to oversee any and all processes and approaches once ongoing.

1.5. Thrust Areas 1-7 are described below. When a specific set of topics has been identified, these detailed needs will be described in Attachment 1 along with any topic-specific submission instructions, deadlines, anticipated award structure, and funding requirements. Otherwise, pre-application white papers and proposals may be written against one of the general thrust area descriptions.

DTRA may not review any pre-application white papers without prior coordination of the idea with the appropriate thrust area- e-mail address (Section 7). Applicants should note that there is extremely limited funding available for many of the thrust areas; Thrust Areas 1-5 are not currently accepting abstracts for pre-coordination. Pre-application white papers will only be accepted from the coordinated abstracts under limited circumstances.

1.5.1. **Thrust Area 1—*Science of WMD Sensing and Recognition:*** The science of WMD sensing and recognition investigates the fundamental understanding of materials that demonstrate measurable changes when stimulated by radiation or particles from WMD in the environment. This involves the exploration and exploitation of interactions between materials and various electromagnetic phenomena, molecules, nuclear radiation, and particles. Furthermore, these interactions and the specific form of recognition they offer are used for the subsequent generation of information, providing knowledge of the presence, identity, and quantity of material or energy in the environment that may be significant. The goal of this thrust area's portfolio is to advance the following capabilities: location, identification and characterization of radiological-nuclear (RN) materials; detection of RN materials at significant stand-off distances; and the reduction of the technical nuclear forensics timeline. Thrust Area 1 is currently not interested in research focusing on the sensing of explosives or the detection of Improvised Explosive Devices (IEDs). **Thrust Area 1 is NOT currently accepting abstracts for pre-coordination.**

1.5.2. **Thrust Area 2—*Network Sciences:*** The fundamental science of network sciences includes advancing knowledge of complex disparate but interdependent networks critical to military operations where WMD-related robustness, resiliency, recovery of, and informational and operational utility is required. It includes response, resilience, and recovery of interdependent, multi-layered physical networks after exposure from electromagnetic pulse and other nuclear weapons effects, rapid discovery and analyzing low-observable WMD-related information from large, disparate WMD-related data sets from multiple types of networks, and to develop theories and representations for low observable WMD-related radical ideation from social networks. **Thrust Area 2 is NOT currently accepting abstracts for pre-coordination.**

1.5.3. **Thrust Area 3—*Science for Protection:*** Fundamental science for protection involves advancing knowledge in physical, biological, and engineering sciences to protect personnel, sensitive electronic systems, and structural infrastructure from the effects of weapons of mass destruction. Protection includes both passive and active defense against threats. Approaches include advanced highly-ordered materials and nanomaterials to hardening infrastructure and facilities against blast, nuclear events, or other CBRNE effects; exploring new methods to experimentally and computationally simulate the effects of a nuclear event; investigations of the interaction of radiation with sensitive electronics and systems as well as development of novel materials and methods that are robust against radiation effects; novel methods to protect personnel from the physical, radiological, and nuclear effects of WMDs; and the study of biological systems, including intact structures, metabolic products, or discrete components and pathways, as applied to protection of U.S. Forces during operations in areas actually or potentially contaminated by radiation. For protection of personnel the areas of interest include development of radiation countermeasures to prevent biological damage associated with exposure to ionizing radiation and development of novel biologically-based or -produced detection systems for wide area surveillance to determine the nature, extent, and distribution of contamination. **Thrust Area 3 is NOT currently accepting abstracts for pre-coordination.**

1.5.4. **Thrust Area 4—*Science to Defeat WMD:*** Fundamental science for significantly improving energetic materials for use against WMD facilities and systems with minimal collateral effects from post-blast WMD release, for deeper penetration to deny the adversary sanctuary of WMD, and for predictable modeling of counter-WMD munitions and simulation of in-theater scenarios with accurate lethality calculations. **Thrust Area 4 is NOT currently accepting abstracts for pre-coordination.**

1.5.5. **Thrust Area 5—*Science to Secure WMDs:*** Fundamental science to support securing WMD includes: revolutionary means to safely handle, transport, control access, or eliminate WMD components and weapons; new physical or other methods to monitor compliance to support future agreements or treaties; and, exploring phenomena and means that facilitate reduction of nuclear or non-nuclear WMD proliferation pathways. This includes focus on: science principles to assist tagging, tracking, location to secure WMD; novel means to mark and read objects in order to secure inventories; remote or unattended monitoring to understand the nature of objects (e.g., is it nuclear, biological, chemical or conventional?); monitoring to detect intrusion, diversion or substitution, tampering, and other adverse activity; and, understanding of both physical and life science environmental signatures as witnesses of WMD-related activity. The ability to secure WMD may impact either verification of treaties, or control of WMD outside treaty regimes. **Thrust Area 5 is NOT currently accepting abstracts for pre-coordination.**

1.5.6. **Thrust Area 6—*Cooperative Counter WMD Research with Global Partners:*** Cooperative fundamental research to reduce the global threat of WMD in collaboration with a broad range of global research partners. This thrust area involves exploratory basic and applied research that will address opportunities to reduce, eliminate, and counter WMD across the Chemical, Biological, Radiological, Nuclear, and High Explosive (CBRNE) spectrum. Efforts in this area will develop strong international relationships which will foster a smooth transition of program ownership to the partnering country. The goal is to improve international collaboration to detect, characterize, and report WMD, and to advance partner nation sustainment through a culture of long-term cooperation and scientific responsibility for such programs. Multi-disciplinary, multinational research in science, technology, engineering, and mathematics development will be conducted to promote transparency through quality research publications and continual dialogue between scientists/engineers and young researchers.

The Cooperative Biological Engagement Program (CBEP), a component of the DoD Cooperative Threat Reduction (CTR) Program, recognizes the danger to U.S. and global health security posed by the risk of outbreaks of dangerous infectious diseases, whether natural or manmade. Consistent with the national and departmental strategies, CBEP strives to address this risk by promoting best practices in biological safety and security, improving partner country capability to safely and rapidly detect and report dangerous diseases, and establish and enhance international research partnerships that focus on informing the disease surveillance network. The desired end state for CBEP engagements is the development of sustainable partner country capabilities to:

- Employ responsible bio-risk management best practices and principles,
- Conduct a modern and effective disease surveillance mission,
- Independently sustain engagement with, and effectively compete for funding within, the international scientific community,

- Comply with World Health Organization (WHO) International Health Regulations (IHR) and World Organization for Animal Health (OIE)/U.N. Food and Agriculture Organization (FAO) reporting guidelines, and
- Promote the One Health Concept.

The goals and objectives of CBEP international research partnerships are to:

- Goal 1: Support Biosurveillance, Biosafety and Biosecurity (BS&S) Capability Building Efforts
    - Objective 1: Inform and enhance operational biosurveillance strategies and implementation through improved understanding of endemic disease burden and pathogen biology.
    - Objective 2: Institutionalize responsible biorisk management best practices with partner country scientists.
- Goal 2: Engage Partner Country Scientists in Hypothesis-Driven Research
    - Objective 1: Support local, national, and regional priorities for understanding and mitigating human and animal disease risk (e.g., small, focused projects within individual countries linked by broad, integrating projects that include regional partners).
    - Objective 2: Improve international collaborations to survey, detect, characterize, and report disease.
- Goal 3: Promote One Health Initiative
    - Objective 1: Emphasize the nexus of human health, animal health, and the environment, and seek to further understand the mechanisms and factors involved in disease transmission.
    - Objective 2: Advance partner country sustainment of global health security initiatives.
- Goal 4: Foster an International Culture of Responsible and Ethical Conduct in Biological Research
    - Objective 1: Transition to a culture of responsibility and ethical conduct in biological research through thoughtful experimental design and good laboratory practices that result in high-quality data, and active participation in professional societies and the peer-review process.
    - Objective 2: Train partner country researchers to think critically in the pursuit of ethical research and to be competitive in soliciting funding from the international scientific community.

Ultimately, the techniques, procedures, and approaches must be sustainable for the partner country and linked with appropriate training in order to promote global health security, reinforce norms of safe and responsible conduct, obtain timely and accurate insight on current and emerging infectious disease risks, and transform the international dialogue on biological threats.

CBEP research projects are not determined by or limited to specific biological agents, but must be plausibly linked to pathogens of security concern and aimed at measurably supporting threat reduction objectives that:

- Enhance partner country's/region's capability to identify, consolidate, and secure collections of pathogens and diseases of security concern in order to prevent the sale, theft, diversion, or accidental release of such pathogens and diseases.
- Enhance partner country's/region's capability to rapidly and accurately survey, detect, diagnose, and report biological terrorism and outbreaks of pathogens and diseases of security concern in accordance with international reporting requirements.

Region-specific areas of interest are described in CBEP Regional Science Plans. Examples of general CBEP research areas of interest include: Epidemiology (e.g. studies measuring disease prevalence and incidence), Pathogen Biology, Pathogen Characterization, Assay Adaptation and Optimization, Microbial Ecology within a Public Health Context, and Preventative Strategies and Countermeasures. For clarification, medical countermeasure development (i.e., development of diagnostic tools, vaccines, therapeutics) is supported by many other U.S. Government or international agencies and is generally not supported by CBEP; however, research projects may inform medical countermeasure development and support validation and verification testing (e.g., as part of proficiency testing, pilot studies/testing, or exercises, etc.). Additionally, CBEP does ***not*** generally support research with common disease agents such as HIV/AIDS, malaria, and tuberculosis where other U.S. agencies have dedicated missions to do so; however, the program may choose to capitalize on opportunities to leverage research on these diseases to further CBEP goals, for example by testing samples collected under the auspices of other programs. CBEP also **will not** support research which poses risks to the overall threat reduction mission of CBEP, Dual-Use Research of Concern, or related activities (i.e., *in vivo* pathogenicity studies, virulence studies, animal passaging, etc.).

CBEP is interested in collaborative research engagements with foreign partners in any one of the following regions: Countries of the Former Soviet Union (FSU) (specifically, Armenia, Azerbaijan, Georgia, Kazakhstan, and Ukraine), Africa (including, but not limited to, Kenya, Tanzania Uganda, South Africa), Southeast Asia (including, but not limited to, Cambodia, Indonesia, Laos, Malaysia, Philippines, Thailand), and Middle Eastern /South Asian countries (including, but not limited to, Afghanistan, Iraq, India and Pakistan). CBEP encourages proposers to develop projects in conjunction with foreign institutions in CBEP-engaged countries.

1.5.7. **Thrust Area 7—*Fundamental Science for Chemical and Biological Defense:*** Fundamental science for chemical and biological (CB) defense includes science and technology research that advances knowledge in physical and life sciences to defend and counter chemical and biological WMD that could be used against our Nation's warfighters. Fundamental research efforts enable capabilities such as development of improved detection devices for traditional and nontraditional chemical agents; development of diagnostics for existing and emerging infectious disease threats; increasing knowledge and improved capabilities for development of new or improved medical and material countermeasures to CB threats for both pre- and post-exposure scenarios; enhanced personal protection against, modeling of, prevention of, or decontamination of CB threats; and providing effective elimination strategies via non-kinetic approaches for threat agent destruction, neutralization and/or sequestration.

1.6. This BAA, in addition to any amendments issued in conjunction with this BAA, will be posted to the Grant Opportunities Website (www.grants.gov), the Federal Business Opportunities Website (www.fbo.gov), and the DTRA website (www.dtra.mil). The DTRA website is not the

official sites; applicants are responsible for monitoring both www.fbo.gov and www.grants.gov. Posted amendments supersede all previous versions of the BAA. Note that topics will be listed in Attachment 1 and will be added/closed with Amendments to this BAA.

1.7. All administrative coordination and communication between applicants and the Government will be conducted using the e-mail address associated with this BAA, specified in Section 7. DTRA will not release employee personal contact information.

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2. AWARD INFORMATION

2.1. Award Types. The full range of flexible procurement instruments available to DTRA are possible results from this announcement, including but not limited to contracts, grants, CAs, and OTAs; however, grants will likely be the predominant procurement instrument. Each of the applicable procurement instruments offer different advantages, liabilities and responsibilities for applicants and the Government.

Applicants must specify in their submittal their recommended approach (e.g. contract, grant, CA, or OTA); however, the Government reserves the right to negotiate and award the types of procurement instruments determined most appropriate under the circumstances. If warranted, portions of resulting awards may be segregated into pre-priced options.

Except for OTAs, the Government actions under this BAA shall adhere to the requirements of the Federal Acquisition Regulation (FAR), Defense Federal Acquisition Regulation Supplement (DFARS) and/or DoD Grant and Agreement Regulations (DoDGARS), as appropriate for the type of instrument. DoDGARs can be accessed online at http://www.ecfr.gov/cgi-bin/text-idx?SID=e5d686f6760f3274b3368f36723fbb7e&mc=true&tpl=/ecfrbrowse/Title32/32CIsubchapC.tpl . See also 32 Code of Federal Regulations (CFR) 22, which can be accessed online at http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=32%3A1.1.1.3.16 . Any assistance instrument awarded under this announcement will be governed by the award terms and conditions, which conform to DoD's implementation of OMB circulars applicable to financial assistance.

On average, DTRA expects to award 30-60 individual awards each year. The predominance of awards will be grants. Payments on grants will be made in advance, subject to the conditions described in 2 CFR 200.305.

2.2. Scope of Awards. Awards may range from focused, exploratory projects with a high risk approach in innovative research in subjects with potential for high impact to C-WMD science to comprehensive programs of innovative research in an interdisciplinary area with potential for high impact.

Awards may have multiple Co-Principal Investigators (Co-PIs) and subawards. Authors of pre-application white papers and proposals should detail the contribution of all Co-PIs and any subawards to the C-WMD scientific impact.

Preference will be given to projects where undergraduate and/or graduate students, and/or postgraduate students are supported by the awards. Details regarding the participation of the students and the value of the research to the students as part of the pre-application white paper and full proposal are expected. Additional guidance regarding student and/or postgraduate student participation may be provided in the published topics or in communications with the

applicant to include the coordination of the abstract or in the debrief summary of the pre-application white paper. Any specific guidance provided in a topic or to an applicant supersedes the information provided herein.

2.3. Subawards. Subawards (subgrants and/or subcontracts) are permitted. Subawards may be used to carry out a portion of the research or efforts. Awards may have multiple subawards. Awards will be made by a single award, e.g., grant or contract, to the lead organization. All subawards are the responsibility of the award recipient; exceptions will not be made.

For submissions made to Thrust Area 6 and associated topics, there is no limitation on subawards. DTRA will review and consider the proposed subawards for all pre-application white papers and proposals on a case-by-case basis. The prime awardee will be responsible for transferring funds to the subawardee. Applicants are reminded that priority is given to projects with the main locus of activity in the region-of-interest, so budgets should be allocated accordingly. Preference will be given to proposals where the subaward component to the region-of-interest partner(s) represents more than half of the award value (as measured in U.S. dollars).

2.4. Award Values. Grants resulting from submissions to Thrust Areas 1-7, including topics associated with these thrust areas, may range from small dollar value (e.g., $25K) up to $1M annually (total, including both direct and indirect costs) depending on the nature and the scope of work. Contracts, CAs, and OTAs will be considered on a case-by-case basis. All awards are subject to the availability of funds. Additional guidance regarding award values may be provided in the published topics or in communications with the applicant to include the coordination of the abstract or in the debrief summary of the pre-application white paper. Any specific guidance provided in a topic or to an applicant supersedes the information provided herein. Funding for participation in this program is highly competitive and the cost of proposed research should strictly be maintained as detailed herein or as indicated in the invitation instructions.

2.5. Period of Performance and Award Structure. Efforts for Thrust Areas 1-7, including topics associated with these thrust areas, may be proposed for up to five (5) years. Awards may be for a base period of one (1) year with four (4) additional years as possible options, a base period of two (2) years with three (3) additional years as possible options, or a base period of three (3) years with two (2) additional years as possible options. Additional guidance regarding award structure may be provided in the published topics or in communications with the applicant to include the coordination of the abstract or in the debrief summary of the pre-application white paper. Any specific guidance provided in a topic or to an applicant supersedes the information provided herein.

Applicants should take care to propose the most logical mix of base and option years for the scope of work. Further, the base period should yield a logical completion point for the work. In cases where option years are proposed, decisions regarding exercising those options will be based on the evaluation of the work accomplished in the base period.

DTRA is flexible on the award structure unless otherwise specified in the published topics or in communications with the applicant to include the coordination of the abstract or in the debrief summary of the pre-application white paper. Applicants should take care to clearly label the tasks and anticipated outcomes for the base and option years in the pre-application white papers and the proposals. Pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable; however, the Government

reserves the right to invite option years for awards that were originally awarded with only a base period.

2.6. The Government Accountability Office, in its report GAO-16-14, WOMEN IN STEM RESEARCH: Better Data and Information Sharing Could Improve Oversight of Federal Grant-making and Title IX Compliance, December 3, 2015, recommended that the DoD collect certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics disciplines. To enable this assessment, DTRA will include with each Phase II application package the Research and Related Senior/Key Person Profile (Expanded) form and the Research and Related Personal Data form.

2.7. The Government does not anticipate the need to provide any hardware or software to execute the proposed research. However, DTRA will review and consider any hardware/software requests for all pre-application white papers and proposals on a case-by-case basis.

2.8. The Government reserves the right to fund all, some, or none of the proposals submitted; may elect to fund only part of any or all proposals; and may incrementally fund any or all awards under this BAA. The Government also reserves the right to request applicants make any changes necessary to submitted full proposals to increase the feasibility of making the proposal fundable. Applicants may decline to participate in any revisions to application packages requested by DTRA.

2.9. The Government may offer funding for any full proposals or portions of proposals at any time during the lifetime of this BAA.

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3. ELIGIBILITY INFORMATION

3.1. Pre-application white papers and proposals submitted for this BAA will be considered from the following U.S. and Foreign Institutions as follows:

- Accredited degree-granting colleges, universities, and academic institutions.
- Industrial and commercial entities, including small businesses.
- Not-for-profit entities with a portfolio predominantly in research and foreign government laboratories. Proof of 501(c)(3) status from the Internal Revenue Service may be required. For foreign-based establishments entirely based outside the U.S. and/or its territories, proof of not-for-profit status may be required. Foreign based government laboratory equivalents include those residing in the Ministry of Defense, Ministry of Health, Ministry of Agriculture, Ministry of Education and Science and Food Safety Agencies.

DTRA strongly encourages and may give preference to pre-application white papers and proposals that demonstrate a significant contribution (significant is defined as a minimum of 30% of total value) by one (1) or more universities. Applicants should note that university participation may be mandatory for some published topics. Additional guidance regarding university participation may be provided in the published topics or in communications with the applicant to include the coordination of the abstract or in the debrief summary of the pre-application white paper. Any specific guidance provided in a topic or to an applicant supersedes

the information provided herein.

The following entities may not participate as prime awardees nor furnish Principal Investigators (PIs) in awards made under this BAA but may act as collaborators, including as Co-PIs, and/or subawardees:

- Federal Academic organizations (e.g., Naval Postgraduate School).
- Federal laboratories (including DoD and Department of Energy (DOE)).
- U.S. Government agencies.
- DoD-sponsored Federally Funded Research and Development Centers (FFRDCs) specified in the Defense Federal Acquisition Regulation Supplement (DFARS) 235.017-1 (http://farsite.hill.af.mil/VFDFARA.HTM) and click on 'DFARS Part 35'.
- DOE-sponsored FFRDCs.

Note: Federal laboratories (including DoD and DOE) and FFRDCs are eligible to submit abstracts (when required), pre-application white papers, and proposals in response to the Government Call issued by the DTRA Chief Scientist and Innovations Department. However, a FFRDC (other than the DoD FFRDCs specified in DFARS 235.017-1) must have authorization from its sponsoring agency in accordance with FAR 35.017-1. Eligibility requirements under the Call are subject to change. See http://www.dtrasubmission.net and after logging in, follow the link to the 'FY12-17 Fundamental Research to Counter Weapons of Mass Destruction (C-WMD) Government Call'.

3.2. Cost Sharing or Matching. In general, cost sharing or matching is not required for applications to this announcement. However, DTRA reserves the right to require cost sharing or matching on a case-by-case basis. Such instances will be specifically detailed in the published topics or in communications with the applicant to include the coordination of the abstract or in the debrief summary of the pre-application white paper.

3.3. Other. DTRA uses the System for Award Management (SAM) to exclude recipients ineligible to receive Federal awards. SAM can be accessed online at http://sam.gov (Reference 2 CFR 1125).

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4. APPLICATION AND SUBMISSION INFORMATION

4.1. Address to Request Application Package. This announcement contains all information required to submit a pre-application white paper and invited proposal.

4.1.1. The required application packages for the pre-application white papers and for the invited proposals are posted with this announcement. Note that each thrust area (as outlined in Section 1.6) and each topic (as outlined in Attachment 1) has a unique application package posted with this BAA. The application package corresponding to both: a.) the thrust area or topic of interest and b.) the phase, should be used for submission of pre-application white papers and invited full proposals.

4.1.2. The application packages posted to www.grants.gov consist of the forms as detailed in Table 2.

Form Name	Phase I Pre-Application White Paper	Phase II Invited Proposal
SF-424 (R&R) Application for Federal Assistance Form	Required	Required
RR Budget Form	N/A	Required
R&R Subaward Budget Attachment(s) Form(s)	N/A	If Applicable
Research & Related Senior/Key Person Profile Form (Expanded)	N/A	Required
RR Personal Data	N/A	Required
Research & Related Other Project Information	N/A	Required
Disclosure of Lobbying Activities (SF-LLL)	N/A	If Applicable
Attachments Form	N/A	Required

Table 2: Forms. The instructions for completing each of these forms may be found online at the following web link: http://www.grants.gov/web/grants/form-instructions.html.

4.2. Content and Form of Application Submission. Submissions for this BAA will be conducted in two phases. Phase I is for receipt of pre-application white papers. Phase II is for receipt of invited proposal applications. Invitation to the Phase II proposal submission will be based on the evaluation results of the Phase I pre-application white paper.

4.2.1. The predominance of efforts, including all submissions to the thrust areas and some submissions to topics posted in Attachment 1, as noted within the topic, **must be** coordinated with the relevant technical point of contact (POC) for the appropriate thrust area prior to submission of a pre-application white paper; an e-mail for the DTRA technical POCs for Thrust Areas 1-7 are provided in Section 7. Applicants should note that Thrust Areas 1-5 are not currently accepting abstracts for pre-coordination. Coordination of research ideas and efforts must be accomplished via these email addresses, except in cases where a topic specifically states that pre-coordination is not required, and includes submission of an abstract (recommend less than 250 words) of the proposed project/effort or a paragraph description of the proposed project/effort to the email address in Section 7 and a reply email from the relevant email address in Section 7 with the disposition to the applicant. Pre-coordination may not be accomplished with email addresses other than those listed in Section 7. DTRA will not review white papers without prior coordination. Please note that attachments to e-mails may not be reviewed.

Applicants should note that there is extremely limited funding available for the general thrust areas. Pre-application white papers will only be accepted from the coordinated abstracts under very limited circumstances.

Topics may be posted in Attachment 1 of this announcement that may not require pre-coordination of an abstract. Please review the topics carefully.

4.2.2. Pre-application white papers and invited proposals **must be** submitted electronically using www.grants.gov and the corresponding application packages linked with this BAA on www.grants.gov (under the "Packages" tab). All applications, including all supporting

documents, must be submitted in the English language.

Applicants are responsible for ensuring compliant and final submission of their Phase I pre-application white paper and Phase II invited proposal application. Note that this also applies to applicants using third party systems to submit application packages and attachments. Any submission that does not conform to the requirements outlined in the BAA and in the invitation for proposal may not be reviewed or considered further at the discretion of DTRA.

4.2.3. DTRA will not review any of the following:

- Pre-application white papers that are not pre-coordinated as required
- Pre-application white papers and proposals that are not submitted in the English language.
- Pre-application white papers that are submitted to topics that have been previously closed via an amendment to the BAA.
- Application packages and proposals for Phase II submissions that were not invited.

Exceptions WILL NOT be made under any circumstances.

4.2.4. Phase I Pre-Application White Paper Submission and Content. Each pre-application white paper must address only one thrust area or topic. Each pre-application white paper must use the corresponding thrust area or topic application package.

Each Phase I application package contains the following forms:

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	Up to four (4) page white paper	Enter the appropriate information in data fields

Table 3: Phase I Pre-Application White Paper Package Chart.

Each Phase I application package contains the SF 424 (R&R) Application for Federal Assistance. To be considered a complete package, an up to four (4) page white paper is required to be uploaded as an attachment to the SF 424 (R&R).

DTRA-specific instructions for completing the SF 424 (R&R) Application for Federal Assistance are below, general application instructions can be found on www.grants.gov:

- Block 1 – Type of Submission. Applicants should indicate the Phase I submission is a "Pre-Application."
- Block 2.1 – Applicant Identifier. Not applicable.
- Block 3 – Date Received by State. Not applicable.
- Block 3.1 – State Application Identifier. Not applicable.
- Block 5 – Applicant Information. You must provide a Business Office Point of Contact (BPOC) with an e-mail address.
- Block 19 – Authorized Representative. The "signature of AOR" is not an actual signature and is automatically completed upon submission of the electronic application package. Hard copies or email attachments of applications will not be accepted.
- Block 20 – Pre-application. Must be used to attach an up to four (4) page white paper. The

white paper itself should provide sufficient information on the research being proposed (e.g., the hypothesis, theories, concepts, approaches, data measurements and analysis, etc.) to allow for an assessment by a technical expert.

Any pages submitted for the white paper that exceed the limit of four pages will not be read or evaluated. A page is defined as 8 ½ x 11 inches, single-spaced, with one-inch margins in type not smaller than 12 point Times New Roman font. The white paper must be provided in portrait layout.

At minimum, the white paper should address the following:

- A project abstract, which should be concise (less than 250 words), provide a summary of the proposed work, and demonstrate relevance to the topic being addressed. The abstract should not contain any proprietary data or markings.
- Potential scientific impact to provide greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts, including how the research contributes to the C-WMD science needs outlined in the thrust area or topic.
- The impact of the research on C-WMD science must be clearly delineated.
- Cost estimate by year and total dollars required to accomplish the research as presented in the white paper (no details or breakout of costs is required).
- Potential team and management plan, including details on student involvement.
- Multidisciplinary white papers should carefully detail each of the institutions/departments involved and the contribution that will be made by each of the investigators.
- Do NOT include corporate or personnel qualifications, past experience, or any supplemental information with the white paper. References may be included within the 4-page limit at the discretion of the applicant; however, extensive references are not required.
- Thrust Area 6 pre-application white papers must also include a description of the extent and duration of the relationship/collaboration between the universities/institutes/entities and/or scientists.
- The thrust area or the topic should be included as a header on the white paper attachment and referenced in the text of the white paper.

4.2.5. Phase I Pre-Application White Paper Re-Submission and Content. On a limited basis a second pre-application white paper may be submitted without pre-coordination of an abstract. These re-submissions will be based on the review of the original pre-application white paper and will be allowed when changes to the project scope, technical approach, and/or cost are envisioned for any potential full proposals. Revised pre-application white papers must conform to the standards for the pre-application white papers detailed in Section 4.2.4.

All submissions should be made with the appropriate Phase I application package which contains the following form:

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	Up to four (4) page white paper	Enter the appropriate information in data fields

Table 4: Phase I Pre-Application White Paper Package Chart.

Each Phase I application package contains the SF 424 (R&R) Application for Federal Assistance. To be considered a complete package, an up to four (4) page white paper is required to be uploaded as an attachment to the SF 424 (R&R).

The DTRA-specific instructions for completing the SF 424 (R&R) Application for Federal Assistance are the same as for the original pre-application white paper submission except for the following:

- Block 1 – Type of Submission. Applicants should indicate the Phase I re-submission is a "Changed/Corrected Application."
- Block 4c – Previous Grants.gov Tracking ID. Enter the Phase I Grant ID for the original submission.

At minimum, the revised white paper should address the issues and questions detailed in the debrief summary.

4.2.6. Phase II - Invited Proposal Submission and Content. Each proposal must address only the thrust area or topic for which it was invited. The application package corresponding to the thrust area or topic of interest should be used for submission of invited full proposals.

Each Phase II application package contains the following forms and attachments:

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	*N/A*	Enter the appropriate information in data fields
RR Budget Form	Budget Justification for entire performance period	Attach to Section K in budget period one
RR Sub-award Budget Attachment(s) Form (*if applicable*)	Individual sub-award budgets	Attach a separate budget with justification for each sub-award
Research & Related Senior/Key Person Profile Form	PI Biographical Sketch	Attach to Biographical Sketch field
	PI Current/Pending Support	Attach to Current & Pending Support field
	Key Personnel Biographical Sketches	Attach to Biographical Sketch field for each senior/key person
	Key Personnel Current/Pending Support	Attach to Current & Pending Support field for each senior/key person
RR Personal Data Form	*N/A*	Enter the appropriate information in data fields
Research & Related Other Project Information Form	Publically Releasable Proposal Summary/ Abstract	Attach to Block 7 Project Summary/ Abstract
	Project Narrative/Technical Proposal	Attach to Block 8 Project Narrative
Disclosure of Lobbying Activities (SF-LLL) *(if applicable)*	*N/A*	Enter the appropriate information
Attachments Form	Attachment 1 – SOW	Upload as Attachment 1
	Attachment 2 – Quad Chart	Upload as Attachment 2
	Attachment 3 – Supporting Documentation (Thrust Area 6 submissions only)	Upload as Attachment 3

Table 5: Phase II Proposal Package Forms and Attachments.

DTRA reserves the right to consider incomplete application packages and required attachments and to request any missing information via email. Should the applicant fail to provide all the requested information either as part of the www.grants.gov submission or in response to email requests from DTRA, at their discretion, DTRA may not consider the proposal further.

SF 424 (R&R) Application for Federal Assistance: DTRA-specific instructions for completing the SF 424 (R&R) are below. General application instructions can be found on www.grants.gov:

Block 1 – Type of Submission. Applicants should indicate the Phase II submission is an "Application."

Block 2.1 – Applicant Identifier. Not applicable.

Block 3 – Date Received by State. Not applicable.

Block 3.1 – State Application Identifier. Not applicable.

Block 4b – Agency Routing Identifier. Enter the corresponding Phase I Grant ID. If

resubmissions were involved, enter the Grant ID for the last submission.

Block 5 – Applicant Information. You must provide a Business Office Point of Contact (BPOC) with an e-mail address.

Block 19 – Authorized Representative. The "signature of AOR" is not an actual signature and is automatically completed upon submission of the electronic application package.

RR Budget Form: The Research and Related Budget Form provided as part of the application package for the Phase II submission should be filled out in its entirety for each project year proposed. Applicants are responsible for ensuring appropriate, approved rates are used in their budget forms. When notified of selection applicants will be requested to provide their current rate agreement and the rate agreement of their subcontractor(s), if applicable. Applicants should note that in accordance with 32 CFR 22.205(b), grants shall not provide for the payment of fee or profit to the recipient.

Applicants should plan and budget for travel to accommodate the two meetings outlined below:

- National Conferences/Workshops/Symposia: Applicants are strongly encouraged to attend a nationally recognized conference, workshop, or symposium in the field of research each calendar year (1 at minimum). Research should be presented as soon as adequate data are available to support posters and presentations. Conferences/workshops/symposia should be attended by the PI and students supporting the research, as appropriate.
- Annual Technical Review: Applicants should plan to attend an annual technical program review meeting. For planning purposes the review will be for five days and will be held in Northern Virginia.

Budget Justification: Applicants are required to submit a budget justification. The budget justification should be prepared as outlined in the instructions for the Research and Related Budget and uploaded as an attachment to Section K "Budget Justification" of the Research and Related Budget Form. The budget justification does not have a page limit, but should include sufficiently detailed information for meaningful evaluation. In addition, the budget justification must specifically address subaward costs and type to include the portion of work to be subawarded with a supporting rationale. The budget justification should include a discussion of how the subawardee(s) cost was determined to be fair and reasonable.

RR Subaward Budget Attachment(s) Form (if applicable): Detailed cost estimates are required for each proposed subaward. The cost estimate for the subawards should include sufficiently detailed information for meaningful evaluation, including labor rates and indirect cost rates.

Research and Related Senior/Key Person Profile Form (Expanded): The Research and Related Senior/Key Person Profile Form (Expanded) should be completed in its entirety for each of the PIs and Co-PIs on the project. The inclusion of additional personnel is at the discretion of the PI. The Degree Type and Degree Year fields will be used by DoD as the source for career information to assess the success rates of women. In addition to the required fields on the form, applicants should complete these two fields for all individuals that are identified as senior or key persons. For Thrust Area 6 submissions, the PI (and Co-PIs) in the region-of-interest should be included as key personnel.

A biographical sketch is required for each PI and Co-PI on the project. DTRA does not have a preference for the format of the biographical sketch; however, it should be limited to 1 page per

person. The biographical sketch should be uploaded as an attachment to the corresponding field on the Research and Related Senior/Key Person Profile Form.

Additionally, a statement of current and pending support must be provided for each of the key personnel (e.g., PI and Co-PI) on the project. This statement must include the following items and requires disclosure of all grants and contracts through which each of the key personnel is currently receiving or may potentially receive financial support:

- A list of all current projects the individual is working on, in addition to any future support the individual has applied to receive, regardless of the source.
- Title and objectives of the other research projects.
- The percentage per year to be devoted to the other projects.
- The total amount of support the individual is receiving in connection to each of the other research projects or will receive if other proposals are awarded.
- Name and address of the agencies and/or other parties supporting the other research projects.
- Period of performance for the other research projects.

RR Personal Data Form: This form will be used by DoD as the source of demographic information, such as gender, race, ethnicity, and disability information for the PI and Co-PI(s). Each application must include this form with the name fields of the PI and any Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. The demographic information, if provided, will be used for statistical purposes only and will not be made available to merit reviewers. Applicants who do not wish to provide some or all of the information should check or select the "Do not wish to provide" option.

Research and Related Other Project Information Form:

Block 7 – Project Summary/Abstract. To fulfill the requirements of Section 8123 of the Defense Appropriations Act, which states: "The Secretary of Defense shall post grant awards on a public Web site in a searchable format," DTRA will collect and post via the Defense Technical Information Center (DTIC) basic information about all awards made under this BAA. The information posted will include the abstract submitted to Block 7 of this form.

The uploaded project abstract should be less than one page and provide a summary of the proposed work and demonstrate relevance to the topic being addressed. Most importantly, the abstract **must be** written such that the general public may easily understand the potential scientific contribution and the impact of the research. The header of this uploaded document must contain the following statement:

> *"This publically releasable abstract is provided to DTRA for use in fulfillment of Section 8123 of the Defense Appropriations Act and future versions of the same."*

The abstract absolutely must not contain any proprietary data or markings.

Block 8 – Project Narrative (Technical Proposal). The uploaded technical proposal must not exceed 20 pages (including references). If the proposal exceeds 20 pages, only the first 20 pages will be reviewed. A page is defined as 8 ½ x 11 inches, single-spaced, with one-inch margins in type not smaller than 12 point Times New Roman font. The technical proposal must be provided

in portrait layout.

The project narrative (technical proposal) must include the following components:

- ***Abstract.*** Should be a technical project abstract that is distinct from the Project Summary/Abstract that is attached to Block 7.
- ***Scope.***
- ***Objective.*** A clear and concise objective of the proposed project.
- ***Background.*** Provide the necessary technical and scientific background to support the scientific and/or technical merit of the proposed project.
- ***Programmatics.*** Describe your organization's management plan for the proposed project; list supporting and collaborating centers, and the roles/responsibilities of each identified academic and/or industrial subcontractor supporting the project. Authors of multidisciplinary proposals must take great care to clearly outline the impact to C-WMD science that is to be gained from the investment and justify the scientific contribution from each investigator.

  Thrust Area 6 narratives must also describe of the extent and duration of the relationship/collaboration between the universities/institutes/entities and/or scientists. Teams with pre-existing collaborative research relationships and those which propose to establish new collaborations will be considered, provided teams can supply documentation to demonstrate that an operational framework exists to support the proposed work. Please see Attachment 3 below for information on the submission of this documentation.
- ***Relevance.*** Describe the relevance of the proposed project in terms of advancing the state of the science and the anticipated scientific impact on capabilities to potentially reduce, eliminate, counter, provide greater knowledge or understanding of the threat, and mitigate the effects of WMD fundamental aspects of phenomena and of observable facts.
- ***Credentials.*** Describe the PI's qualifications and the organization's qualifications to perform the proposed work. Summarize the credentials of the primary performing center, and supporting academic and industrial partners to perform the work. Describe specific examples of equipment and/or facilities available to perform the proposed work. Focus on information directly relevant to the proposed work.
- ***Work to be Performed.*** Provide details of the work to be performed by task and subtask. Tasks must be grouped by project year; base and option years should be clearly labeled. Additional details that are required include the following:
  - ***Sample Repository.*** Thrust Area 6 narratives must also clearly identify how the applicant plans to maintain samples collected during the proposed research effort, along with relevant metadata, for at least 12 months after the project end date. Note that annual sample repository information must be submitted using a DTRA-specified format that will be made available to awardees.
  - ***Protection of Human Subjects.*** For full discussion, see Section 6.2.2. If the proposed research does involve human subjects or materials, applicants are asked to: a) justify the use of human subjects, b) outline the human use, and c) include the source of the human subjects or materials involved in the research. Applicants shall submit written evidence, to include a provisional protocol number and Institutional Review Board (IRB) point of

contact information, that a human use protocol has been submitted to, and is pending approval by, a qualified IRB. Further information may be required if the proposal is successful.

- ***Animal Use.*** For full discussion, see Section 6.2.3. If the proposed research involves animal use, applicants are asked to justify the use of animals. Any proposals involving animal studies or animal work must include detailed information on the animal protocols to be used and verify the location where the studies will be conducted. Animal studies are subject to review and approval for safety and adherence to regulations. Applicants shall submit with the full proposal package written evidence, to include a provisional protocol number and Institutional Animal Care and Use Committee (IACUC) point of contact information, that a vertebrate animal use protocol has been submitted to, and is pending approval by, a qualified IACUC. Further information may be required if the proposal is successful.

- ***Performance Schedule.*** Provide a table of tasks and sub-tasks and the duration of performance of each in a Gantt or other suitably formatted chart.
- ***References.*** List any relevant documents referenced.

Disclosure of Lobbying Activities (SF-LLL) Form: The Disclosure of Lobbying Activities Standard Form-LLL, if applicable, should be completed.

Attachments Form: The attachments form should be used to include the following three items with the application:

Attachment 1 – SOW. The SOW does not have a page limit, but should be approximately 3-5 pages in length for incorporation into an award document. The SOW should not contain any proprietary data or markings. Pages should be numbered and the initial page should have a date (document date) shown under the title (the title of the SOW should match that of the proposal).

The proposed SOW must accurately describe the research to be performed. The proposed SOW must also contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the SOW inflexible. The SOW format/guidance is as follows:

- ***Objective:*** Brief overview of the specialty area. Describe why the research is being pursued and what knowledge is being sought.
- ***Scope:*** Include a statement of what the SOW covers including the research area to be investigated, objectives/goals, and major milestones and schedule for the effort.
- ***Background:*** The applicant must identify appropriate documents, including publications that are applicable to the research to be performed. This section includes any information, explanations, or constraints that are necessary in order to understand the hypothesis and scientific impact on capabilities needed to reduce, eliminate, and counter the threat, and also mitigate the effects of WMD. It may also include previously performed relevant research and preliminary data.
- ***Tasks/Scientific Goals:*** This section contains the detailed description of tasks which represent the research to be performed that are contractually binding. Thus, this portion of the SOW should be developed in an orderly progression and presented in sufficient detail to

establish the methodology and feasibility of accomplishing the overall program goals. The work effort should be segregated by performance period for all tasks to be performed and anticipated milestones realized in that year (e.g., Year 1, Year 2, etc., should be detailed separately). Identify the major tasks in separately numbered sub-paragraphs. Each major task should delineate, by subtask, the research to be performed by year and number each task using the decimal system (e.g., 4.1, 4.1.1, 4.1.1.1, 4.2, etc.). The sequence of performance of tasks and achievement of milestones must be presented by project year and task in the same sequence as in the Project Narrative/Technical Proposal. The SOW must contain every task to be accomplished to include a detailed schedule.

- The tasks must be definite, realistic, and clearly stated. Use "the awardee shall" whenever the work statement expresses a provision that is binding. Use "should" or "may" whenever it is necessary to express a declaration of purpose. Use active voice in describing work to be performed. Do not use acronyms or abbreviations without spelling out acronyms and abbreviations at the first use; place the abbreviation in parenthesis immediately following a spelled-out phrase. If presentations/meetings are identified in your schedule, include the following statement in your SOW: "Conduct presentations/meetings at times and places specified in the grant schedule."
- ***Deliverables:*** Thrust Area 6 **requires** several additional items be included in the SOW. These items are as follows:
    - Submission of annual sample repository information using a DTRA-specified format.
    - Access to all samples collected and data generated during the course of the project, up to and including at least 12 months after the project end date.

Attachment 2 – Quad Chart. The quad chart must be presented on one (1) page. The quad chart must not contain any proprietary data or markings. The quad chart must be provided in landscape layout. The quad chart should be uploaded as "Attachment 2" of the Attachments Form.

Attachment 3 – Supporting Documentation. For Thrust Area 6 proposals ONLY. Thrust Area 6 narratives must also describe an operational framework to support the proposed work. This includes, but is not limited to the following: the extent and duration of the relationship/collaboration between the universities/institutes/entities and/or scientists. Teams with pre-existing collaborative research relationships and those which propose to establish new collaborations will be considered, provided teams can supply documentation to demonstrate that an operational framework exists to support the proposed work. Each of the following should be concatenated into a single document, in the order specified:

- Specific identification of foreign Principal Investigators (PIs) and number of/job title for other members of the foreign research team.
- Detailed description of the relationship between the proposed research project and current research efforts at the foreign institution.
- Description of facilities and any other evidence of suitability of foreign collaborators and sites. In the event that the foreign research component will involve human or other vertebrate animal use, appropriate facilities compliance and certifications documents must be provided. Refer to Section 6.2.2 and Section 6.2.3 for specific information on required

approvals and documentation.

- Foreign PI letter of collaboration describing, at minimum, the suitability of the proposed work with respect to ongoing research efforts at the foreign institution, merit of the proposed collaboration, and the expected mutual benefits.

Protocol Risk Assessment Tool (PRAT). For Thrust Area 6 proposals ONLY. Applicants will be provided a copy of the PRAT file following their invitation to submit a Phase II full proposal and complete it in its entirety for **each** foreign institution participating in the project. Additional instructions for completing the PRAT may be found within the file. The completed PRAT file(s) should be emailed as a Portable Document File (PDF) format to HDTRA1-FRCWMD-A@mail.mil within two (2) weeks of the full proposal submission. **DO NOT** attempt to attach the PRAT(s) to the www.grants.gov submission.

4.2.7. Phase II - Additional Information Requests by DTRA. A revised proposal may be requested based on the review of the original proposal. Revised proposals will be requested when changes to the project scope, technical approach, and/or cost are required before the proposal could be further considered for an award. Applicants whose proposals are of interest to DTRA may be contacted to provide additional information or to make requested revisions prior to the final decision on funding. This request for further information may include revised budgets or budget explanations, revised SOWs, and other information, as applicable, to the proposed award. Additional instructions may be provided in the request for a revised proposal. Applicants who are not responsive to Government requests for information in a timely manner, defined as meeting Government deadlines established and communicated with the request and not making satisfactory updates as requested, may be removed from award consideration. Applicants may also be removed from award consideration if the applicant and the Government fail to negotiate mutually agreeable terms within a reasonable period of time.

Re-submissions should be made with the appropriate Phase II application package for the thrust area or topic of interest and should be completed in accordance with the instructions provided in the notification email.

The DTRA-specific instructions for completing a proposal re-submission are the same as for the original submission, except the SF 424 (R&R) Application for Federal Assistance should be marked as follows:

- Block 1 – Type of Submission. Applicants should indicate the Phase II submission is a "Changed/Corrected Application."
- Block 4b – Agency Routing Identifier. Enter the corresponding Phase I Grant ID.
- Block 4c – Previous Grants.gov Tracking ID. Enter the Phase II Grant ID for the original Phase II submission.

4.2.8. File Format. Documents should be uploaded as a Portable Document File (PDF) format. Perform a virus check before uploading any files to www.grants.gov as part of your application package. If a virus is detected, it may cause rejection of the file.

Do not lock or encrypt any files you upload to www.grants.gov as part of your application package. Movie and sound file attachments will not be accepted.

4.2.9. All submissions must be completely UNRESTRICTED and UNCLASSIFIED;

submissions must not contain For Official Use Only (FOUO) or Official Use Only (OUO) information or be marked as such.

4.2.10. Confirmed Proposal Expiration Date. Applicants requesting contracts must provide written confirmation that holds the proposal, to include proposed costs, firm for 180 days after the submission due date, as included in the invitation to submit a full proposal. This information must be included in the text of the technical proposal.

4.2.11. Withdrawal of Proposals. Proposals may be withdrawn by written notice received at any time before award. Withdrawals are effective upon receipt of notice by the Grants/Contracting Officer via the administrative e-mail address listed in Section 7.

4.3. Submission Dates and Times.

Coordination of abstracts may be accomplished at any time that this BAA is in effect, unless otherwise stated as part of a specific topic. Once an applicant has been notified that a pre-application white paper is welcomed, the white paper should be submitted within 60 days. If the white paper is not submitted within 60 days, DTRA reserves the right to require the applicant to re-initiate the process with another abstract coordination.

Pre-application white papers may be submitted anytime that this BAA is in effect (as long as it occurs within the 60 day window following pre-coordination of the abstract), unless otherwise stated as part of a specific topic. Pre-application white papers may be evaluated at any time after submission and invitations for full proposal submission may occur any time after pre-application white paper evaluation. Note that proposal invitations may be limited to available program funds.

The due date for the Phase II invited proposal submissions will be provided in the letter of invitation. The applicant will not be allowed less than 45 days to prepare a full proposal submission; there is no penalty for early submissions. An extension for submission of the Phase II proposal submission may be requested by emailing the administrative email address in Section 7 prior to the deadline for the proposal submission. Full proposals may be evaluated at any time after submission.

Applicants are responsible for submitting all materials to www.grants.gov. When sending electronic files, the applicant should allow for potential delays in file transfer from the originator's computer server to the www.grants.gov website/computer server, as well as the delay associated with the www.grants.gov validation of applications, which may be up to 48 hours. Applicants are encouraged to submit their proposals early to avoid issues with file transfers, rejection of applications by www.grants.gov, and delays due to high website demand.

Acceptable evidence to establish the time of receipt at the Government office includes documentary and electronic evidence of receipt maintained by DTRA. Applicants should also print, and maintain for their records, the electronic receipt following submission of a proposal to www.grants.gov.

Applicants should note that DTRA uses a system that pulls applications from www.grants.gov en masse, but this system does not mark applications as "retrieved" on www.grants.gov. As a result, when applicants check the status on www.grants.gov the applications will always look like they have not been retrieved by DTRA. Should you require confirmation of receipt by the Agency, you may request such via the administrative email address provided in Section 7. Note that such requests will generally be treated with low priority by the Agency.

Please note 15 U.S.C. 260a establishes daylight saving time as the standard time during the daylight saving period.

If the application package and required attachments are submitted to www.grants.gov after the exact time and date specified in this announcement or in any written communications provided by DTRA, the application may be considered "late" and may not be reviewed.

If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be submitted to www.grants.gov by the exact time specified by DTRA correspondence, the time specified for receipt of applications will be deemed to be extended to the same time of day specified in the BAA or in the letter of invitation on the first work day on which normal Government processes resume.

4.4. Intergovernmental Review. Not Applicable.

4.5. Other Submission Requirements.

4.5.1. Registration with www.grants.gov. Applicants should note that each organization must complete a one-time registration in order to submit its pre-application white paper(s) and full proposal(s) through www.grants.gov. Please see the following web link on information about registering with www.grants.gov: http://www07.grants.gov/applicants/applicants.jsp. If your organization is already registered in www.grants.gov, no further action should be required.

The registration process may take up to **four (4) weeks** to complete depending on your organization and requires multiple steps, some of which are detailed below.

- Identifying the Data Universal Number Systems (DUNS) number or registering for one with Dun & Bradstreet at http://fedgov.dnb.com/webform/displayHomePage.do if your organization does not have a DUNS number.
- Registering with the System for Award Management (SAM) by calling the SAM Assistance Center at 1-866-606-8220, or you may register online at www.sam.gov. You will NOT be able to complete your SAM registration until SAM has confirmed your Employer Identification Number (EIN) or Taxpayer Identification Number (TIN) with the Internal Revenue Service (IRS).

4.5.2. Compliance with Appendix A to 32 CFR 28. All awards require certifications of compliance with Appendix A to 32 CFR 28 regarding lobbying. Proposers are certifying compliance with this regulation by submitting the invited proposal. It is not necessary to include the certification text with your invited proposal. If applicable, proposers should submit the Disclosure of Lobbying Activities (SF-LLL) Form in accordance with Section 4.2.6.

4.5.3. Marking Guidance for Pre-Application White Paper and Invited Proposal and Disclosure of Proprietary Information other than to the Government. The pre-application white papers and invited proposals submitted in response to this BAA may contain technical and other data that the applicant does not want disclosed to the public or used by the Government for any purpose other than application evaluation. Public release of information in any pre-application white paper and invited proposal submitted will be subject to existing statutory and regulatory requirements.

If proprietary information which constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting national security, is provided by an applicant in a pre-application white paper and/or invited proposal, it will be treated in

confidence, to the extent permitted by law, provided that the following legend is included on the front page of the pre-application white paper and/or invited proposal:

"For any purpose other than to evaluate the pre-application white paper and/or proposal, this data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part, provided that if an award is made to the applicant as a result of or in connection with the submission of this data, the Government shall have the right to duplicate, use or disclose the data to the extent provided in the agreement. This restriction does not limit the right of the Government to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction is contained in page(s) _____ of this pre-application white paper and/or proposal."

Any other legend may be unacceptable to the Government and may constitute grounds for removing the pre-application white paper and/or invited proposal from further consideration without assuming any liability for inadvertent disclosure.

The Government will limit dissemination of properly marked information to within official channels. In addition, the pages indicated as restricted must be marked with the following legend:

> *"Use or disclosure of the pre-application white paper and/or proposal data on lines specifically identified by asterisk (*) are subject to the restriction on the front page of this pre-application white paper and/or proposal."*

The Government assumes no liability for disclosure or use of unmarked data and may use or disclose such data for any purpose.

In the event that properly marked data contained in a pre-application white paper and/or invited proposal submitted in response to this BAA is requested pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, the applicant will be advised of such request and prior to such release of information, will be requested to expeditiously submit to DTRA a detailed listing of all information in the pre-application white paper and/or invited proposal which the applicant believes to be exempt from disclosure under the Act. Such action and cooperation on the part of the applicant will ensure that any information released by DTRA pursuant to the Act is properly identified.

By submission of a pre-application white paper and/or invited proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. DTRA will obtain a non-disclosure agreement from the evaluator that proprietary information in the pre-application white paper and/or invited proposal will only be used for evaluation purposes and will not be further disclosed or utilized.

4.6. Applicants that Propose Use of Contracts or OTAs.

4.6.1. Recommended Procurement Instrument and Pricing Arrangement. Applicants that propose use of contracts or OTAs must provide a summary of their recommended procurement instrument and pricing arrangement as part of the Phase II proposal. However, the Government reserves the right to negotiate and award the types of instruments determined most appropriate under the circumstances. It is anticipated that most instruments will be grants.

4.6.2. Representations and Certifications. Representations and Certifications must be completed at the time of Phase II submission. The applicant must complete the annual

representations and certifications electronically via the System for Award Management (SAM) website at https://www.sam.gov/portal/SAM/#1#1. After reviewing their information, the applicant verifies by submission of the application that the representations and certifications currently posted electronically have been entered or updated within the last 12 months.

4.6.3. Organization Conflict of Interest Advisory. Certain post-employment restrictions on former federal officers and employees may exist, including special Government employees (including but not limited to 18 U.S.C § 207, the Procurement Integrity Act, 41 U.S.C. § 2101 *et.seq*). If a prospective applicant believes that a conflict of interest exists, the situation should be raised to the DTRA Contract/Grant Officer before time and effort are expended in preparing a proposal. All applicants and proposed sub-contractors must therefore affirmatively state whether they are providing scientific, engineering and technical assistance (SETA), advisory and assistance services (A&AS) or similar support, through an active contract or subcontract, to any DoD technical office to include, but not limited to, the Joint Program Executive Office (JPEO), the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD-NCB), or the Office of the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs (OSA (CBD&CDP)). This information must be included in Technical Proposal of the Phase II full submission. All affirmations must state which office(s) the applicant(s) supports, and identify the prime contract number. Affirmations must be furnished at the time of Phase II full proposal submission. All facts relevant to the existence or potential existence of organizational conflicts of interest, including but not limited to those arising out of activities with the above-referenced organizations, must be disclosed. The disclosure must include a description of the action the applicant has taken or proposes to take to avoid, neutralize, or mitigate such conflict.

4.6.4. Contracts with Subcontracts. Any applicant, other than small businesses, submitting a proposal that exceeds $650,000.00 must submit a subcontracting plan in accordance with FAR 19.704(a) (1) and (2). This information must be included in Technical Proposal of the Phase II full submission. The plan format is outlined in FAR 19.704. Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. § 637(d)), it is the policy of the Government to enable small business and small disadvantaged business concerns to be considered fairly as subcontractors to contractors performing work or rendering services as prime contractors or subcontractors under Government contracts, and to assure that prime contractors and subcontractors carry out this policy.

4.6.5. Limitations on OTAs. Applicants are advised that an Other Transaction for Research Agreement (10 U.S. Code § 2371) or an Other Transaction for Prototype Agreement (10 U.S. Code § 2371b) will only be awarded if the use of a standard contract or CA is not feasible or appropriate. Applicants are advised that an OTA may only be awarded if there is:

a. At least one nontraditional defense contractor participating to a significant extent in the prototype project, or

b. All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors; or

c. At least one-third of the total cost of the prototype project is to be paid out of funds provided by the parties to the transaction other than the Federal Government. The cost share should generally consist of labor, materials, equipment, and facilities costs (including allocable indirect costs).

d. Exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a procurement contract.

e. Although use of one of these options is required to use an Other Transaction for Prototype agreement as the procurement vehicle, no single option is encouraged or desired over the others.

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

a. "Nontraditional defense contractor" means an entity that is not currently performing or has not performed, for at least the one-year period preceding this solicitation, any of the following for the Department of Defense: any contract or subcontract that is subject to full coverage under the cost accounting standards prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 USCS §§ 1501 et seq.) and the regulations implementing such section; or any other contract in excess of $500,000 under which the contractor is required to submit certified cost or pricing data under section 2306a of this title (10 USCS § 2306a).b. "Small business" means a small business concern as defined under Section 3 of the Small Business Act (15 U.S.C. § 632).

"Participating to a significant extent in the prototype project" means that the nontraditional defense contractor or small business is supplying a new key technology or product, is accomplishing a significant amount of the effort wherein the role played is more than a nominal or token role in the research effort, or in some other way plays a significant part in causing a material reduction in the cost or schedule of the effort or an increase in performance of the prototype in question. NOTE: Applicants are cautioned that if they are classified as a traditional defense contractor, and propose the use of an Other Transaction for Prototype Agreement, the Government will require submittal of both a cost proposal under the guidelines of the FAR/DFARS, and a cost proposal under the proposed Other Transaction for Prototype Agreement, so that an evaluation may be made with respect to the cost tradeoffs applicable under both situations. The Government reserves the right to negotiate either a FAR based procurement contract, or Other Transaction for Prototype Agreement as it deems is warranted under the circumstances.

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5. APPLICATION REVIEW INFORMATION

5.1. Evaluation Criteria. The four evaluation criteria to be used for responses received to this BAA are as follows:

1. Scientific and Technical Merit. The objective of this criterion is to assess the extent to which the applicant presents ideas that are innovative and/or unique with the potential for high payoff in the science area and details a comprehensive technical approach based on sound scientific principles. Innovation will be judged contextually against the white

paper's/proposal's scope, goals, and setting. To the extent possible, the technical risks, including those of biosafety and security, to accomplish the research or project should be identified with appropriate mitigation/management details.

For Thrust Area 6 white papers/proposals, innovation will also be considered with respect to partner country capabilities.

2. Value to Mission Goals. The objective of this criterion is to assess the extent to which the applicant demonstrates an understanding of the C-WMD research or mission challenges and the contribution to the C-WMD research or mission needs of that thrust area/topic. White papers/proposals must detail research or a project that is responsive to the thrust area/topic as presented in this solicitation. This criterion also addresses the benefit of the proposed effort on enabling knowledge, technology, or capabilities over current methods and/or practices and on the transition potential that is appropriate to the proposed effort. Applicants must also demonstrate an impact of the proposed effort on the institution's ability to perform research relevant to reducing the global WMD threat; and/or to train, through the proposed effort, students and/or partner scientists in science, technology, engineering and/or mathematics.

   Thrust Area 6 white papers/proposals must demonstrate an understanding of the CBEP priorities and mission. As such, the degree to which the proposed collaborations may lead to long-term partner country self-sufficiency and sustainment of the jointly developed capabilities will be considered.

3. Capability of the Personnel and Facilities to Perform the Proposed Effort. The objective of this criterion is to assess the extent to which the applicant's team has the requisite expertise, skills and resources necessary to perform the proposed program. This includes an assessment of the team's management construct, key personnel, facilities and past technical experience in conducting similar efforts of the proposed scope. Applicants must demonstrate that their team has the necessary background and experience to perform this project. Facilities should be detailed with discussion of any unique capabilities pertinent to the research. Subcontractors may include Government facilities or Agencies; however the unique expertise or specialized facilities provided through their inclusion must be clearly presented and the validity of the proposer-Governmental relationship must be clearly documented.

4. Cost Realism Evaluation. The objective of this criterion is to establish that the proposed costs are reasonable, realistic, and justified for the technical approach offered and to assess the applicant's practical understanding of the scope of the proposed effort.

5.2. Review and Selection Process. The pre-application white paper and proposal selection process will be conducted based upon a technical review as described in the DoDGARs (32 CFR 22.315(c)) and includes the use of non-Government peer-reviewers.

Each pre-application white paper and invited proposal submitted to a general TA will be reviewed on a rolling basis; topic-based submissions will be reviewed as a batch following receipt deadlines. All applications will be reviewed based on the merit and relevance of the specific pre-application white paper/proposal as it relates to the DTRA program, rather than against other pre-application white papers/proposals for research in the same general area.

Pre-application white paper (Phase I) evaluation will be based on the two (2) equally weighted criteria of (1) Technical/Scientific Merit and (2) Value to Mission Goals. The criteria will be scored as Outstanding (O), Good (G), Acceptable (A), Marginal (M) or Unacceptable (U). Any

criterion scored as "Unacceptable (U)" will render the pre-application white paper "Not Selectable," and the pre-application white paper will not be considered further.

The full proposal evaluation will be based on the four criteria listed above. Of these, the first two (2) criteria of (1) Technical/Scientific Merit and (2) Value to Mission Goals are equally weighted and more important than the third criterion of (3) Capability of the Personnel and Facilities to Perform the Proposed Effort. These first three criteria will be scored Outstanding (O), Good (G), Acceptable (A), Marginal (M) or Unacceptable (U). The fourth criterion of Cost Realism will be scored as either Acceptable (A) or Unacceptable (U). Any criterion scored as "Unacceptable (U)" will render the proposal "Not Selectable," and the proposal will not be considered further.

Other factors that may be considered are duplication with other research, program balance, past performance and budget limitations. Prior to award, the Government reserves the right to perform a review of past performance. Sources that may be used for past performance review may include the Past Performance Information Retrieval System (PPIRS) and the Federal Awardee Performance and Integrity Information System (FAPIIS). The Government will also evaluate the impact of any proposed limitations to the use of intellectual property (e.g. asserted technical data/computer software restrictions or patents) during the selection and/or negotiation process, and may request additional information from the applicant, as may be necessary, to evaluate the applicant's assertions. Accordingly, proposals may be selected for funding which are not reviewed as highly as others, which are of higher risk and/or which may be of a higher cost.

The Government reserves the right to select all, some, or none of the proposals, or any part of any proposal received in response to this BAA and to make awards without discussions with applicants; however, the Government reserves the right to conduct discussions if determined necessary.

5.3. DTRA anticipates that the total Federal share of awards made under this announcement will be greater than the simplified acquisition threshold over the period of performance (see §200.88 Simplified Acquisition Threshold). Therefore, in accordance with Appendix I to 2 CFR Part 200, Section E.3, this section serves to inform applicant:

i. That DTRA, prior to making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold, is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently Federal Awardee Performance and Integrity Information System (FAPIIS)) (see 41 U.S.C. 2313);

ii. That an applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM;

iii. That DTRA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in §200.205 Federal awarding agency review of risk posed by applicants.

iv. For awards that exceed $500,000 over the period of performance, DTRA will employ the additional post-award reporting requirements reflected in Appendix XII—Award Term and Condition for Recipient Integrity and Performance Matters of 2 CFR 200.

5.4. Technical and Administrative Support by Non-Government Personnel. It is the intent of DTRA to use both Government and non-Government personnel to assist with the review and administration of submittals for this BAA. All pre-application white papers and invited proposals may be reviewed by subject matter experts, including, but not limited to, peer reviewers from across the academic and industrial community, as applicable to the research proposed.

Further, participation in this BAA requires DTRA support contractors to have access to pre-application white paper and invited proposal information including information that may be considered proprietary or otherwise marked with restrictive legends. Existing DTRA contractors include but may not be limited to the following: Cherokee Nation Strategic Programs (contract specialist support), Engility Corporation (a company under Science Applications International Corporation) (Advisory & Assistance Services) and their subcontractors, Quanterion Solutions Inc., Kforce Government Solutions Inc., Kent, Campa, and Kate Inc., CACI, , SBG Technology Solutions and their subcontractors, and Terremark Worldwide Inc. Each contract contains organizational conflict of interest provisions and/or includes contractual requirements for non-disclosure of proprietary contractor information or data/software marked with restrictive legends. The applicant, by submitting a white paper or proposal, is deemed to have consented to the disclosure of its information to the aforementioned contractors under the conditions and limitations described herein.

All individuals—including subject matter experts and support contractors—having access to any proprietary data must certify that they will not disclose any information pertaining to this BAA including any submittal, the identity of any submitters, or any other information relevant to this BAA. All applicants to this BAA consent to the disclosure of their information under these conditions.

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6. AWARD ADMINISTRATION INFORMATION

6.1. Award Notices. Applicants will be notified regarding the status of their applications (invitation/non-invitation for full proposals, re-submission of white papers, selection/non-selection for award, etc.) via e-mail to the BPOC listed in Block 5 of the SF-424 and the PI listed in Block 14 of the SF-424 provided at the time of submission. A debrief summary will be provided as part of all notification e-mails.

A notice of selection should not be construed as an obligation on the part of the Government; only duly authorized procurement personnel may commit resources, this will be done by issuing a grant or contract document to the selected applicant. Also, this notification must not be used as a basis for accruing costs to the Government prior to award. Selected applicants are not authorized to begin work, as any award is subject to successful negotiations (if determined necessary by DTRA) between the DTRA contracting division and the selected organization, and to the availability of funds.

All notifications will be made from notification@dtrasubmission.net. **E-mails to this e-mail**

address will not be answered or forwarded.

Applicants must be aware that it is their responsibility to ensure: (1) correct e-mail addresses are provided at the time of submission, (2) this e-mail notification reaches the intended recipient(s), and (3) the e-mail is not blocked by the use of 'spam blocker' software or other means that the recipient's Internet Service Provider may have implemented as a means to block the receipt of certain e-mail messages.

If for any reason there is a delivery failure of these e-mail notices, DTRA will not further attempt to contact the applicants.

6.2. Administrative and National Policy Requirements. All awards require certifications of compliance with national policy requirements. Statutes and Government-wide regulations require some certifications to be submitted at the time of proposal submission. See Section 4.5.2 and Section 4.6.2 for the certification(s) required at the time of submission.

This BAA focuses on fundamental research in a DoD contractual context, which was defined in Section 1.2 of this BAA. Per DoD policy[1], "…products of fundamental research are to remain unrestricted to the maximum extent possible." Furthermore, "The DoD will place no other restrictions on the conduct or reporting of unclassified fundamental research, except as otherwise required by statue [sic], regulation, or Executive Order." As such, fundamental research is normally exempt from controls under the International Traffic in Arms Regulation (ITAR) (22 CFR Parts 120-130) and/or the Department of Commerce regarding the Export Administration Regulations (15 CFR Parts 730-774), but the DoD rule recognizes that there are "rare" situations where export-controlled information or technology may be used in fundamental research that may require a license(s) or restrictions on products.

6.2.1. Export Control Notification. Applicants are responsible for ensuring compliance with any export control laws and regulations that may be applicable to the export of and foreign access to their proposed research. Applicants may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CFR Parts 120-130) and/or the Department of Commerce regarding the Export Administration Regulations (15 CFR Parts 730-774). Please note that the prime awardee is responsible for monitoring ITAR compliance of all subawardees.

6.2.2. Protection of Human Subjects. If the proposed research involves human subjects or materials, applicants are asked to: a) justify the use of human subjects, b) outline the human use, and c) include the source of the human subjects or materials involved in the research. As a condition precedent to receipt of DTRA funding, applicants must ensure that the basic rights and welfare of human subjects are protected. Applicants shall submit with the full proposal package written evidence, to include a provisional protocol number and Institutional Review Board (IRB) point of contact information, that a human use protocol has been submitted to, and is pending approval by, a qualified IRB. Further information may be required if the proposal is successful.

All research under any award made under this BAA involving human subjects must be conducted in accordance with 32 CFR 219, 10 U.S.C. § 980, and DoD Instruction 3216.02, and, as applicable, 21 CFR parts 11, 50, 56, Good Clinical Practice, the ICH, as well as other

[1] Under Secretary of Defense for Acquisition, Technology and Logistics Memorandum, SUBJECT: Contracted Fundamental Research, dated 26 Jun 2008

applicable federal and state regulations. Awardees must be cognizant of and abide by the additional restrictions and limitations imposed on the DoD regarding research involving human subjects, specifically as regards vulnerable populations (32 CFR 219 modifications to subparts B-D of 45 CFR 46), recruitment of military research subjects (32 CFR 219), and surrogate consent (10 U.S.C. § 980).

DTRA Directive 3216.01 of June 9, 2010, modified March 18, 2015, established the DTRA Human Subjects Protection Program, set forth the policies, defined the applicable terms, and delineated the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing human subject research. The regulations mandate that all DoD activities, components, and agencies protect the rights and welfare of human subjects of study in DoD supported research, development, test and evaluation, and related activities hereafter referred to as "research." The requirement to comply with the regulations applies to new starts and to continuing research.

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

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

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

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

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

Research projects lasting more than one year require IRB review at least annually, or more frequently as required by the responsible IRB. The contractor or subcontractor must provide

documentation of continued IRB review of protocols for ROB review and approval in accordance with the Contract Data Requirements List. Research changes must be reviewed by the IRB and ROB in advance unless necessary to eliminate apparent and immediate hazards to the subject(s).

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

6.2.3. Animal Use. If the proposed research involves the use of live nonhuman vertebrate animals, applicants are required to justify the use of animals by providing detailed information on the proposed animal use, to include the proposed species and number of animals planned, along with the location(s) where the animal study(ies) is planned. Additional information will be required if the proposal is selected for award subject to successful negotiations. The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (ORP), must review and approve all animal use prior to the start of working with animals. Therefore, Principle Investigators will be required to complete and submit the animal use appendix titled "Research Involving Animals", after award of the procurement instrument, which is available on the ACURO website (http://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro). Allow 2 to 4 months for regulatory review and approval processes for animal studies. Applicants are to build this review time into their project schedules.

DoD Instruction 3216.01, dated September 13, 2010, provides policy and requirements for the use of animals in DoD-funded research based on Army Regulation (AR) 40-33. The DoD definition of animal is any live nonhuman vertebrate. All proposals that involve the use of animals must be in compliance with DoD Instruction 3216.01 and AR 40-33. DTRA requires that research using animals not begin or continue until the ACURO has reviewed and approved the proposed animal use. For animals, the provisions include rules on animal acquisition, transport, care, handling, and use in: (i) 9 CFR parts 1-4, Department of Agriculture rules that implement the Laboratory Animal Welfare Action of 1966 (U.S.C. 2131-2156); and (ii) the "Guide for the Care and Use of Laboratory Animals," National Institutes of Health Publication No. 86-23.

6.2.4. Biological Defense Research Program (BDRP) Requirements: BioSurety and Select Agent Use.

Proposals must specify what Select Agent work will be conducted at the applicant's facility and what Select Agent work will be performed in other facilities. Proposals also must provide the source of the Select Agent(s), any appropriate registration information for the facilities, and specify the Laboratory Bio-safety Level. All Select Agent work is subject to verification of information and certifications. Further information may be required if the proposal is successful.

For those institutions in which PI's are conducting research with Bio-safety Levels 3 and 4 material, a Facility Safety Plan must be prepared and made available during the project award phase in accordance with 32 CFR 626.18. For grants awarded to foreign institutions, you must follow either local or U.S. laws (as stated above) depending on which laws provide stronger

protection. (DTRA requires that research using Select Agents not begin or continue until DTRA has reviewed and approved the proposed agent use. See URL: https://www.gpo.gov/fdsys/pkg/CFR-2002-title32-vol3/pdf/CFR-2002-title32-vol3-sec626-18.pdf for a copy of 32 CFR 626.18, Biological Defense Safety Program.)

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

6.2.5. Dual-Use Potential. In accordance with National Science Advisory Board for Biosecurity (NSABB) recommendations, DTRA will not support research that, based on current understanding, can reasonably be anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Research involving select agents and toxins is within scope of the DTRA mission; however, the use of select agents and toxins in certain experimental categories is considered "dual-use research of concern" (DURC) according to U.S. policy. (http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf) Proposals that contain DURC will not be funded. Dual-use potential will be assessed based on application of the following criteria:

- Use of select agents or toxins. This factor evaluates whether the proposed research involves use of one or more select agents or toxins [as identified by the Select Agent Program under Federal Law (7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73)] which pose significant risk of deliberate misuse with potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence.
- Scope of proposed experiments. This factor evaluates whether the proposed research involves experiments that will produce, aim to produce, or is reasonably anticipated to produce: (a) Enhanced harmful consequences of the agent or toxin; (b) Disruption of immunity or effectiveness of an immunization against the agent or toxin without clinical or agricultural justification; (c) Conferred resistance by the agent or toxin to clinically or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin, or facilitated ability to evade detection methodologies; (d) Increased stability, transmissibility, or dissemination ability of the agent or toxin; (e) Altered host range or tropism of the agent or toxin; (f) Enhanced susceptibility of a host population to the agent or toxin; or (g) Eradicated or extinct select agents or toxins.

6.2.6. Military Recruiting. This is to notify potential applicants that each award under this announcement to an institution of higher education, with exception of any grants awarded to institutions of higher education entirely located outside the United States and/or its territories, must include the following term and condition: "As a condition for receipt of funds available to DoD under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 CFR 216) that has a policy of denying, and that it is not an institution of higher education that effectively prevents, the Secretary of Defense from obtaining the following for military recruiting purposes: (A) entry to campuses or access to students on campuses; or (B) access to directory information pertaining to students. If the recipient is determined, using procedures in 32 CFR 216 to be such an institution of higher education during the period of

performance of this agreement, and therefore to be in breach of this clause, the Government will cease all payments of DoD funds under this agreement and all other DoD grants and CAs, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of award." 32 CFR 216 may be accessed electronically at http://www.ecfr.gov/cgi-bin/text-idx?SID=ee45add5e352854b7089ce420c7fd0a6&mc=true&tpl=/ecfrbrowse/Title32/32cfr216_main_02.tpl . If your institution has been identified under the procedures established by the Secretary of Defense to implement Section 558 of Public Law 103-337, then: (1) no funds available to DoD may be provided to your institution through any grant, including any existing grant; and (2) your institution is not eligible to receive a grant in response to this BAA. This is to notify potential applicants that each award under this announcement to an institution of higher education, with exception of any grants awarded to institutions of higher education entirely located outside the United States and/or its territories, must include the following clause: 32 CFR 22.520 (DoDGARS 22.520), Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education.

6.2.7. Combating Trafficking in Persons. The recipient agrees to comply with the trafficking in persons requirement in Section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 U.S.C. 7104(g)).

6.2.8. Reporting Subawards and Executive Compensation. The recipient agrees to ensure they have the necessary processes and systems in place to comply with the reporting requirements of the Transparency Act, as defined at 2 CFR 170.320, unless they meet the exception under 2 CFR 170.110(b).

6.2.9. Representation Regarding the Prohibition on Using Funds under Grants and Cooperative Agreements with Entities that Require Certain Internal Confidentiality Agreements. By submission of its proposal or application, the applicant represents that it does not require any of its employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, or subrecipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. Note that: (1) the basis for this representation is a prohibition in section 743 of the Financial Services and General Government Appropriations Act, 2015 (Division E of the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113-235) and any successor provision of law on making funds available through grants and cooperative agreements to entities with certain internal confidentiality agreements or statements; and (2) section 743 states that it does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

6.3. Reporting. General requirements are provided below; however, each awardee should check the award agreement and its contract data requirements list (CDRLs) and/or terms and conditions to determine the requirements for that specific award.

6.3.1. Annual Reports. Annual Reports will be due no later than 1 July of each year. Awards effective after 31 January will not require an Annual Report until 1 July of the following year. The Annual Report is *not* a cumulative report.

6.3.2. Final Technical Reports. A comprehensive final technical report is required prior to the

end of an effort, due on the date specified in CDRLs and/or the terms and conditions of the award document. The purpose of the Final Report is to document the results of the effort. The Final Report *is* a cumulative report.

The final report will always be sent to the Defense Technical Information Center (DTIC) and reports may be available to the public through the National Technical Information Service (NTIS).

6.3.3. Financial Reports. Federal Financial Reports (SF-425) are due no later than 1 July of each year. Grants effective after 31 January will not require a Federal Financial Report until 1 July of the following year.

6.3.4. Foreign Travel Reports. Within thirty (30) days after returning to the United States from foreign travel, the PI may be required to submit an acceptable trip report summarizing the highlights of the trip. For grants, contracts, or OTAs awarded to institutions entirely located outside the United States and/or its territories, this is not required.

6.4. After-the-Award Requirements for *Grants*. Closeout, subsequent adjustments, continuing responsibilities, and collection of amounts due are subject to requirements found in 32 CFR 32.71 – 73 (Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations) and 32 CFR 34.61 – 63 (For-Profit Organizations).

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7. AGENCY CONTACTS

Administrative Correspondence and Questions	HDTRA1-FRCWMD-A@mail.mil
Thrust Area 1: *Science of WMD Sensing and Recognition*	HDTRA1-FRCWMD-TA1@mail.mil
Thrust Area 2: *Network Sciences*	HDTRA1-FRCWMD-TA2@mail.mil
Thrust Area 3: *Science for Protection*	HDTRA1-FRCWMD-TA3@mail.mil
Thrust Area 4: *Science to Defeat WMD*	HDTRA1-FRCWMD-TA4@mail.mil
Thrust Area 5: *Science to Secure WMD*	HDTRA1-FRCWMD-TA5@mail.mil
Thrust Area 6: *Cooperative Counter WMD Research with Global Partners*	HDTRA1-FRCWMD-TA6@mail.mil
Thrust Area 7: *Fundamental Science for Chemical and Biological Defense*	HDTRA1-FRCWMD-TA7@mail.mil

Table 6: Agency Contacts.

7.1. Questions regarding administrative content of this BAA must be addressed to the administrative e-mail address listed above.

7.2. Questions regarding technical content of this BAA must be referred to the thrust area email listed above.

DTRA will not release employee personal contact information.

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8. OTHER INFORMATION

Topics from previous periods may or may not be repeated. DTRA will not provide additional information regarding the posting of future topics, including dates for posting, the potential for a topic to be repeated in out years, the potential for similar topics to be posted, and/or topic details in advance of issuance of an amended BAA.

ATTACHMENT 1: SPECIFIC TOPICS

Thrust Areas 1, 2, 3, 4, 5, have no specific topics at this time and are closed for abstract pre-coordination.

Thrust Area 6 has no specific topics at this time.

Thrust Area 7 has five (5) topics —Topics J1-J5—detailed below. Submissions to the general thrust area descriptions for this thrust area in accordance with the requirements detailed in this BAA are also welcome.

Great care must be taken to use the appropriate application package on www.grants.gov, as the package selection dictates how each submission will be reviewed:

- If NOT submitting to one of the specific topic numbers detailed below, use one of the **Thrust Area N NO TOPIC** application packages
- If you ARE submitting to one of the specific topic numbers detailed below, use the applicable **Basic Research-Thrust Area 7-Topic J1 to J5** application package

*****BASIC RESEARCH TOPICS J1-J5*****

In accordance with Section 4.2.1, the requirement for abstract pre-coordination is waived for Topics J1-J5; these topics do NOT require pre-coordination of an abstract prior to the submission of pre-application white papers. All other pre-coordination requirements remain in effect.

The pre-application white paper deadline for Topics J1-J5 is 4 March 2020. **PRE-APPLICATION WHITE PAPERS FOR THESE TOPICS MUST BE SUBMITTED BY 11:59 PM (MIDNIGHT) EST ON 4 March 2020.** White papers submitted to Topics J1-J5 may not be considered if they are received after this deadline.

Topics J1-J5 are interested in research projects that span from those that focus on exploratory aspects of a unique problem or approaches to those that involve a comprehensive program with interdisciplinary areas. Consistent across all proposals should be the focus on innovative research with the potential for high impact to C-WMD science.

DTRA anticipates that the predominance of awards made under Topics JI-J5 will be grants. Pre-application white papers and proposals submitted to Topics J1-J5 must have a single lead organization and single submission for the pre-application white paper and the invited proposal. Awards will be made by a single award to the lead institution. Sub-awards, including all grants and/or contracts, are the responsibility of the award recipient; exceptions will not be made.

Thrust Area 7, Topic J1: The Dark Side of Photocatalysis: Destruction of Chemical Warfare Agents Around the Clock

Award Amounts for this topic are anticipated to be up to $500,000 per year (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full

proposal invitation.

The preferred award structure for this topic is a base period of three (3) years with up to two (2) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of five (5) years will not be considered.

Background: A variety of inorganic-based materials have demonstrated efficacy toward neutralizing chemical warfare agents (CWAs) in ambient conditions through catalytic mechanisms that may support future warfighter protection applications (i.e., for potential use with protective suit-based technologies). Some of these materials include photocatalysts that react with CWAs via a plasmonic or photocatalytic mechanism utilizing non-precious metals; however they generally do not continue to photocatalytically react with CWAs after the stimuli (sunlight, etc.) are removed in light independent/dark reactions.

Recently there has been a paradigm shift in the field towards developing photocatalytic materials to perform photocatalytic reactions under both light and dark conditions, otherwise known as "day–night" photocatalysis, or "round-the-clock" photocatalytic reaction. This area of photocatalysis has not been explored for application to CWA destruction through continued photocatalytic reactions upon cessation of light stimuli.

This topic seeks to develop a fundamental understanding of inorganic photocatalytic materials and mechanisms that use sunlight or other readily available stimuli to photocatalytically degrade CWAs. This topic also seeks to absorb and store photocatalytic species for use in light independent reactions over time or if a threat becomes present in the dark. Storage of the photocatalytic species can take the form of nanophotovoltaics, electrons, photons, or reactive species (as examples) to maintain the ability to destroy CWA (or simulant) for 1h (threshold) and up to 12 h (objective), after the stimuli are removed. This topic does not seek to continuously destroy the agents for 1 to 12 hrs but needs to have the ability to react if a threat becomes present after stimuli have been removed. This project also seeks to potentially develop tools/techniques to investigate and confirm the storage capacity and release of the reaction potential to continue to degrade CWAs or simulants after the stimuli are removed.

While the ultimate intention is to integrate these materials into suit-based technologies that decontaminate when exposed to low levels of CWA vapor, the basic research should be focused solely on the "dark"/light independent photocatalytic storage and degradation of CWAs.

Impact: The research explored in this topic seeks to develop a fundamental understanding of photocatalytic materials and mechanisms that promote extended destruction of CWAs after the cessation of photocatalytic stimuli for light independent reactions. This could be integrated into suit technology and degrade agents and other toxic materials in the dark in order to either

regenerate the suit or minimize risk in during decontamination procedures and suit removal.

Objective: Pre-application white papers and proposals should describe the development and demonstration of the potential to continue or initiate CWA destruction reactions after the stimuli (e.g., sunlight) are removed in light independent reactions. Applicants should keep in mind the stimulus must be operationally relevant for warfighters and available in the field.

Applicants should propose photocatalytic materials that will be able to have adequate activity to meet metrics including:

- Prior to stimuli (before light activation)–
    - Minimally photocatalytically active to CWA simulant destruction
- With stimuli (light dependent reactions) –
    - Activity to destroy CWA simulant at 1mg/cm2 within 24 hours
        - Simulant must emulate activity of CWA and not degrade in varying environmental conditions w/o photocatalytic destruction
    - Utilization of natural sunlight or other stimuli readily available to warfighters in the field
    - Photoactivated CWA destruction kinetics must be at least an order of magnitude more than that of the ground state
- Post stimuli removal (light independent reactions) –
    - Demonstration that 50% of photocatalytic activity of stimulated photocatalytic state remains for at least an hour (threshold) and up to 12 hours (objective) after the stimuli are removed
        - Maintain ability to destroy CWA (or simulants) for 1 or 12 hours but not necessarily continuously react with agents or simulants
        - This dark reaction can continue if a threat is present or become initiated if a threat becomes present in the dark.
        - Demonstration of threshold metrics (above) within base period (3 years from award) or prove significant progress towards those goals
    - Require no external resources for reaction to initiate or continue in the dark
        - No batteries or power sources
        - No additional materials/chemicals required (water, hydrogen peroxide, etc.) to be added to initiate or continue reaction
- Live traditional warfare agent testing should be considered but should not be included as part of this effort or proposed work. If successful, this effort will transition into existing projects conducting live agent testing.

Ultimately, these materials should be cost-realistic, utilize non-precious metals, and deployment in varying environmental conditions should be considered.

Research areas may include, but are not limited to:

- Determination (theoretical and experimental) of photocatalytic materials that work in ambient conditions, using wavelengths available with natural sunlight, that are capable of storing the catalytic capability over time to allow for reactions to continue for 1 to 12 hrs after the stimuli is removed for destruction of CWAs or simulants
    - Experimental synthesis and characterization of the materials and measurements at

the laboratory scale with chemical warfare agent simulants
- Applicants are encouraged to submit non-precious metal photocatalyst systems that will work using natural sunlight or other means available to warfighters in the field as stimuli to generate active species.
- Applicants are encouraged to evaluate chemistries including the potential for photoacatalytic species storage (photon, electron, reactive oxygen, etc.) and obtaining energy for catalytic degradation of CWAs (or simulants) after stimuli have been removed.
- Applicants should propose determination of conditions (e.g., light, temperature, relative humidity), preferably ambient conditions, that optimize or limit the neutralization chemistry after stimuli are removed
- Applicants should propose evaluation of CWA simulants with these catalytic materials (required) that reacts similarly to agents in a natural environment.

It is anticipated that this topic will require teams of researchers with different expertise in modeling, synthesis and characterization of these materials. A justification of the budget will need to be provided to supplement the costs proposed for this effort.

Pre-application white papers and proposals should focus on a fundamental understanding of development, demonstration, and quantification of "dark" photocatalytic species storage and reaction without stimuli with traditional chemical warfare agents/simulants for potential use with warfighter suit technologies and decontamination procedures.

References:

1. T. Cai, Y. Liu, L. Wang, W. Dong, G. Zeng. Recent Advances in Round-the-Clock Photocatalytic System: Mechanisms, Characterization Techniques and Applications. J. Photochem. and Photobio. C: Photochemistry Reviews, 2019, 29, 58-75.
2. M. Logan. Design, Synthesis, Stability and Photocatalytic Studies of Sustainable Metal Organic Frameworks. University of Central Florida Doctoral Dissertation, 2018.
3. D. Giannakoudakis, J. Colón-Ortiz, J. Landersb, S. Murali, M. Florent, A. Neimark, T. Bandosz. Polyoxometalate hybrid catalyst for detection and photodecomposition of mustard gas surrogate vapors. Applied Surface Science, 2019, 467-468, 428-438.
4. Y. Wang, N. Ma, K. Cao, W. Zhang, J. Chen, D. Wang, Z. Gao, Fang Xu, K. Jiang, Dapeng Wu. Single-crystal-like ZnO mesoporous spheres derived from metal organic framework delivering high electron mobility for enhanced energy conversion and storage performances. Electrochimica Acta 2019 305, 474e483.
5. V. Wing-hei Lau, D. Klose, H. Kasap, F. Podjaski, M-C. Pigni, E. Reisner, G. Jeschke, and B. Lotsch. Dark Photocatalysis: Storage of Solar Energy in Carbon Nitride for Time-Delayed Hydrogen Generation. Angaw. Chem. Int. Ed. 2017, 56, 510-514.
6. M. Sirkar, C-C. Nguyen, M-H. Vu, T-O. Do. Materials and Mechanisms of Photo-Assisted Chemical Reactions under Light and Dark Conditions: Can Day–Night Photocatalysis Be Achieved? ChemSusChem 2018, 11, 809-820.

<u>Thrust Area 7, Topic J2: Stand-Off Physiological Monitoring for CB Exposure Detection</u>

Award Amounts for this topic are anticipated to be up to $400,000 per year through the base

period phase to establish proof of concept and, if successful, up to $800,000 per year thereafter (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full proposal invitation.

The preferred award structure for this topic is a base period of one (1) year with up to two (2) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of three (3) years will not be considered.

Note: For this topic, awardees will be required to grant the US Government a licensing agreement to all software and or hardware in perpetuity for all Chemical and Biological Defense Program (CBDP) uses.

Background: Efforts to rapidly detect and intercept biological exposures to the warfighter are revolutionizing methods of early integrated warning, and interest has been turning to non-invasive biomarker analysis for swift indication of exposure. Physiological data can provide vital information about the health status of a warfighter, and research has evidenced that certain biomarkers can provide warning to a biological exposure. Existing science and technology (S&T) investments have worked to develop predictive algorithms based on physiological signals such as heart rate wave forms, oxygen saturation, and blood pressure, obtained from commercial-off the shelf (COTS) devices. Challenges with this approach is that collection of physiological data is dependent on device wearing compliance, device operability, battery life, streamlined brand and type of device, and interference with performance to the mission. Exploration of remote and contactless vital sign monitoring and analysis for application in warfighter chemical and biological threat exposure alerting provides an advantageous approach to this problem by eliminating the need for cumbersome and impractical donning of wearable devices. Existing capabilities in this space include stand-off gait analysis, facial recognition, and short-range laser vibrometry to detect surface movement caused by heartbeat have advanced technology in remote detection. However, CBDP investments have determined a range of biometrics beyond just heartbeat are necessary for high-fidelity decision support. Furthermore, to be of greater use to the DoD, remote detection needs have a further longitudinal reach, whereby the next step is to explore a capability to develop long-range monitoring on multiple vital signs.

Relevance: The DoD has a unique set of challenges within the CBDP for developing early integrated warning tools and capabilities, for which remote sensing of physiological signals can address and help to inform more rapid decision making. Remote detection would provide the DoD with non-invasive data collection methodologies to determine anomalous vital signs in the warfighter. This can be coupled with developing physiological data algorithms predictive of biological agent exposure prior to symptom onset, and allow for rapid awareness without the need for wearable devices. This will reduce cost on necessary technology to arm the warfighter with, reliability of data as there is no risk of electrodes slipping off or misfit of technology, along with other real challenges with technology in the field. To this end, this topic seeks to solicit

groups working in the field of remote detection of physiological signals to help determine if stand-off technology is advanced enough to help enhance capabilities for predictive decision support to inform medical countermeasure solutions to the DoD.

Objective: As a proof of concept, the initial work will be directed towards the development of a stand-off physiological detection infrastructure to monitor signals evidenced to provide 48 hour advance notice that personnel may begin exhibiting symptoms of illness due to a biological exposure. While the DoD has been developing short range identification of heartbeat through stand-off laser technology, the Joint Science and Technology Office (JSTO) S&T efforts have analyzed critical vital sign feature sets to be more highly indicative of exposure at a high fidelity, where heart rate cannot be relied on alone. Basic understanding of methods for detecting features like oxygen saturation, heart rate variability, and blood pressure through similar methods of remote heartbeat detection is a novel area of research that can inform predictive algorithms of infection in warfighters prior to onset of symptoms.

This topic seeks to answer the following fundamental research questions on whether critical vital signs can be remotely detected and analyzed at a distance of value to the military, and at a fidelity equal to that of wearable devices:

- Is there a feasible approach to remotely detecting vital signs on a warfighter?
- To what degree of can these vital signs be relied upon? (Fidelity of information)
- How does remote sensing data collection sensitivity compare to that of commercial-off-the-shelf (COTS) devices?
- What is the farthest range that these signals can be detected without significant loss of confidence in accuracy?
- How closely can remote detection of physiological signals be paired with those signal sets determined to be most predictive of biological exposure prior to symptom onset without loss of accuracy?
- How can AI/ML be leveraged to increase the speed and confidence of predictive algorithms of exposure?

While not required, it should be recognized that the CBDP has made investments in the development of pre-symptomatic illness predictive algorithms based on big data sets and has access to a potential learning set of data that could aid in the development of a useful algorithm. For this reason, there may be some benefits to partnering with groups that have been involved in the design of antibodies against pathogens of interest to the DoD. Further guidance on potential partnerships/collaborations to be provided with each full proposal invitation.

The end state for the base year of this work will be a validated data collection set of physiological data from remote sensing techniques of either vital signs other than heartbeat, or at a distance greater than 200 meters. Subsequent follow on years if exercised will provide greater fidelity of datasets, increased number of vital signs able to be detected remotely, and / or remote detection at a greater distance. The end goal of this effort is for sensing capabilities to be integrated into an algorithm predictive of exposure to a biological agent prior to symptom onset.

Impact: If successful, the work will support the RD-CB program through improved integrated early warning systems to provide actionable high-fidelity information to support decision making

on implementing rapid medical countermeasures for biological exposures. The foundational research will provide the DoD CBDP with a platform to expand upon novel and enhanced detection and warning systems.

References:

1. Bonner, M. A., & Wilson, G. F. (2002). Heart rate measures of flight test and evaluation. The International Journal of Aviation Psychology, 12(1), 63-77.
2. Hambling, David. "The Pentagon Has a Laser That Can Identify People from a Distance-by Their Heartbeat." MIT Technology Review, MIT Technology Review, 27 June 2019, www.technologyreview.com/s/613891/the-pentagon-has-a-laser-that-can-identify-people-from-a-distanceby-their-heartbeat/.
3. Hassan, M A, et al. "Novel Health Monitoring Method Using an RGB Camera." Biomedical Optics Express, Optical Society of America, 4 Oct. 2017, www.ncbi.nlm.nih.gov/pmc/articles/PMC5695935/.
4. "SOMBA." Charles River Analytics, 30 Oct. 2017, www.cra.com/work/case-studies/somba.
5. Bryant, Meg. "NYP Partners with Philips to Offer Remote Patient Monitoring." Healthcare Dive, 25 Jan. 2019, www.healthcaredive.com/news/nyp-partners-with-philips-to-offer-remote-patient-monitoring/546831/.
6. "Evaluation of a Machine Learning Algorithm for up to 48-Hour Advance Prediction of Sepsis Using Six Vital Signs." Computers in Biology and Medicine, Pergamon, 24 Apr. 2019, www.sciencedirect.com/science/article/pii/S0010482519301350.

Thrust Area 7, Topic J3: Machine Learning for Hazard Prediction

Award Amounts for this topic are anticipated to be up to $2500,000 per year through the base period phase to establish proof of concept and, if successful, up to $250,000 per year thereafter (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full proposal invitation.

The preferred award structure for this topic is a base period of one (1) year with up to two (2) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of three (3) years will not be considered.

Note: For this topic, awardees will be required to grant the US Government a licensing agreement to all software and or hardware in perpetuity for all Chemical and Biological Defense Program (CBDP) uses.

Background: Hazard prediction modeling and simulation provides the warfighter with vital decision support for contamination avoidance. Due to the fast-acting and destructive nature of chemical and biological (CB) agents, situational awareness tools need to provide equally fast and

trustworthy results. However, current methods for hazard prediction utilize complex physics based models that require lengthy computing times. Improvements in machine/deep learning (ML/DL) and artificial intelligence (AI) coupled with the decreasing cost of computer power have been leveraged to increase the speed, complexity, and capability of data analytics, allowing the deployment of fast and accurate ML/DL models on end-user devices in disconnected environments. Additionally, ML/DL methods have been successful in approximating physics based models and computational fluid dynamics in broad applications including modeling heart mechanics and ship hydrodynamics and may prove to be better than traditional methods of hazard prediction due to the ability to intake disparate sources and make informed prediction with minimal or missing data input. This topic will explore the feasibility and course of action for deploying ML/DL methods for hazard prediction.
Relevance: The CBDP is pursuing solutions for bringing high fidelity hazard prediction to the tactical edge. In disconnected and potentially CB contaminated environments, reachback is not an available option and when timeliness is a factor it is desirable to have decision support tools in the field for contamination avoidance. In addition, the warfighter may not have the full array of data inputs necessary for typical physics based models, e.g. humidity, and ML/DL may be better able to make predictions with approximated values.

Objective: The effort aims to answer the following fundamental questions:

- How can ML/DL be used to increase the speed of hazard prediction without sacrificing fidelity of output?
- What ML/DL methods are best for hazard prediction?
- How do ML/DL model outputs compare to traditional methods?
- How many model runs are needed to provide an adequate training set?
    - Is it prudent to train on runs of traditional models (e.g. the Hazard Prediction Assessment Capability (HPAC) or the Joint Effects Model (JEM)) or is it best to train on field trial data to avoid bias?
- Are physics-based ML/DL methods more accurate than other methods?
- How does environmental and geographic variability effect results?
- Is it possible to validate the process and how the decision was made (white box vs. black box ML)?
- How many parameters are needed—which variables add value and which are confounders?
- Can this approach provide building-aware hazard prediction? What terrain inputs are necessary? What can be pre-loaded? How does this added capability affect run-time?
- What inputs can be automated (e.g. weather and agent/dose from sensors)?
    - Is the model able to update in real-time based on changing wind patterns?

The end state for this work will be a validated algorithm capable of providing rapid, high fidelity CB hazard prediction that surpasses current capabilities in features, speed, and automation.

Impact: If successful, the work will support the CBDP in laying the groundwork for developing future hazard prediction capabilities utilizing ML/DL, therefore providing the warfighter with

real-time decision support for contamination avoidance and risk mitigation.

References:

1. Valeriy Gavrishchaka, Olga Senyukova, and Mark Koepke (2019) Synergy of physics-based reasoning and machine learning in biomedical applications: towards unlimited deep learning with limited data, Advances in Physics: X, 4:1, DOI: 10.1080/23746149.2019.1582361
2. Tesche et al. (2018) Coronary CT Angiography-derived Fractional Flow Reserve: Machine Learning Algorithm versus Computational Fluid Dynamics Modeling, Radiological Society of North America: Vol. 288, No. 1, DOI: 10.1148/radiol.2018171291
3. Dabiri et al. (2019) Prediction of Left Ventricular Mechanics Using Machine Learning, Frontiers in Physics: 06 September 2019, DOI: 10.3389/fphy.2019.00117
4. Gabriel D. Weymouth and Dick KP Yue (2013) Physics-based learning models for ship hydrodynamics, Journal of Ship Research: 57.1, Pgs. 1-12.

Thrust Area 7, Topic J4: Cellular and Genetic Regulatory Mechanisms Critical to Normal Cell Function After CWA Exposure

"Award Amounts for this topic are anticipated to be up to $500,000 per year through the base period phase to establish proof of concept and, if successful, up to $800,000 per year thereafter (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full proposal invitation.

The preferred award structure for this topic is a base period of two (2) years with up to three (3) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of five (5) years will not be considered.

Background: Exposure to nerve-acting chemical weapon agents unleashes a cascade of molecular and biochemical processes that culminate in the acute and long term effects of these WMDs. Current medical countermeasures (MCMs) consist of small molecules that act to mitigate acute symptoms and restore function. These MCMs have limited efficacy owing to difficulties crossing the blood brain barrier and a short time in which to act; furthermore they are effective against only a restricted set of known nerve agents.

The S&T strategy for the CBDP calls for anticipating and preventing surprise in the area of chemical defense. For this reason, it is critical to investigate how emerging insights into cellular and molecular regulatory mechanisms can be used to further understand the nerve agent toxidrome, and to start developing these mechanisms as technologies with future MCM

applications.

The modern genomic sequencing era, and other high throughput approaches to biology since then, have revealed a wide range of subcellular and intercellular mechanisms for control of cell function. These include regulatory and other non-coding RNAs, novel gene expression control mechanisms, and exosomes which can transmit nucleic acid, protein, and metabolite effectors between cells at a distance. At the same time, technologies for transient gene delivery and expression are being established and refined. These innovations have the potential to significantly contribute to our understanding and control of the effects of CWA exposure. Eventual applications for chemical MCMs could include the management of intracellular or systemic signaling networks, intracellular gene expression and function, and the genetic delivery of MCMs.

The goal of this effort is to exploit emerging molecular biotechnology and insights into cell biology regulatory processes to advance our understanding of the toxicity of nerve agent exposure, reveal novel molecular targets for intervention, and develop methods to exploit subcellular and intercellular mechanisms for control of cell function.
Impact: This program will expand our understanding of the molecular pathophysiology of nerve agents. It can be anticipated to identify new targets for medical intervention, and to generate advances over existing technology in the manipulation and control of cellular and molecular regulatory networks.

The discovery of methods to exploit signaling mechanisms including noncoding RNAs and exosomes lays the groundwork for platform biotechnology to rapidly address any effector step in signaling pathways, without the need to identify relevant pharmacologic small molecules. Furthermore, advancements in understanding of gene regulation processes can be broadly applied to countermeasure applications across the whole spectrum of chemical and biological threats.

Objective: The objective of this topic is to apply emerging insights into cellular and genetic regulation to the problem of understanding and controlling the effects of nerve agents.
Examples of appropriate proposals include:

- Using innovative applications of emerging cellular and molecular regulatory mechanisms to characterize the effects of nerve agents at the cellular and subcellular level
- Developing and testing novel ways of modulating endogenous cell function in the context of nerve agent toxicity
- Developing and demonstrating transient expression of exogenous genes to control the pathological effects of nerve agent exposure

Successful proposals will exploit cutting-edge cellular and molecular tools and emerging insights into biological function to achieve beneficial insights into understanding and controlling the pathophysiology of nerve agents. Innovative selection of effectors and targets, as well as strategies for intervention, based on mechanistic insights is desired. Pre-application white papers and proposals which focus on inflammation mechanisms or on direct receptors for nerve agents

will not be considered.

Thrust Area 7, Topic J5: Machine Learning for Chemical and Biological Defense

Overview: The CBDP is exploring the feasibility of leveraging machine learning (ML) approaches in increasing the speed, complexity, and performance for rapid response to advancing medical countermeasures, diagnostic assays, and infectious biological agent predictive analytic tools for the Warfighter. This overall topic is separated into four discreet sub-areas (A-D) as detailed below. Several of these sub-areas utilize a multi-disciplinary approach that includes ML to solve a problem of interest to CBDP. Each pre-application white paper and proposal should address one (1) sub-area only. Applicants may submit multiple pre-application white papers and proposals; there is no limit on the number of sub-areas an applicant may submit to. Applicants must clearly identify the sub-area being addressed in the title of the application.

Objective: As a proof of concept, this effort aims to answer/address the following fundamental questions/capability gaps in understanding on how ML methods may be used to aide in discovery of CB medical countermeasures and diagnostic assays, and predictive tools for emerging infectious biological pathogens of relevance to CBDP:

- Are ML methods more accurate than other traditional methods for developing rapid response capabilities?
- Which ML algorithms increase the speed of predictions without sacrificing accuracy and relevance of output?
- Is there one ML approach (e.g., supervised or unsupervised) that outperforms others?
    - If so, which? How is it measured? What are the use cases?
- What learning strategies can be used to prevent model over/under fit?
    - Are these strategies generalizable to all chemical or biological agents respectively? If yes, what are the assumptions? If no, what are the limitations?
- What metrics are most effective at quantifiably measuring and characterizing different ML approaches?
- Can we define a standardized format for data collection and pre-processing including metadata for training, validation, and testing of ML algorithms in this space?
- How many model runs are needed to provide an adequate training set?
- How many experimental samples do you need to collect to generate data for deep learning?
- Is there a "gold standard" criteria by which we can assess/evaluate results from ML to establish casual inference?
- What is the best method to validate and evaluate the ML algorithms and increase transparency into feature selection and output parameters (white box vs. black box ML)?
- How many input parameters are sufficient to inform accurate model predictions? Which ones?
    - Which data sets/variables add predictive value and which are confounders?
- Can certain input parameters be pre-loaded? If so, which ones? How does this added

capability affect run-time?
- What inputs can be automated versus those that require manual inputs?
- What strategies can used to sample our way from “fat data” to “big data”?

Thrust Area 7, Topic J5-A: Machine Learning for Infectious Biological Agent Forecasting

Award Amounts for this topic are anticipated to be up to $250,000 per year (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full proposal invitation.

The preferred award structure for this topic is a base period of one (1) year with up to two (2) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of three (3) years will not be considered.

Note: For this topic, awardees will be required to grant the US Government a licensing agreement to all software and or hardware in perpetuity for all Chemical and Biological Defense Program (CBDP) uses.

Background: The deliberate release and spread of an infectious biological agent poses an operational threat to Warfighter readiness and lethality. This risk is heightened in the age of synthetic biology where genetic modification or engineering of a biological pathogen may increase its virulence, pathogenicity, or transmission potential potentially resulting in increased numbers of casualties and fatalities on the battlefield. Decision support and analysis tools can be used to predict the risk and spread of infectious agents in space and time and estimate the expected numbers of casualties and fatalities resulting from an incidental release enabling commanders to effectively prepare for, and respond to, biological agent threats and maintain force readiness and lethality.

In order to provide timely and actionable information to the Warfighter, decision support tools must provide accurate estimates of the numbers of casualties and fatalities resulting from the release and spread of an infectious biological agent in near real time. However, current predictive models rely on complex mathematical and statistics based approaches that are both manually intensive to develop and computationally expensive to implement. Machine learning/deep learning (ML/DL) approaches have been successfully applied to predict the morbidity and mortality of naturally occurring infectious disease epidemics for which there is an abundance of high fidelity biosurveillance data such as influenza1 or vector borne diseases (e.g., malaria and West Nile).2 These approaches may also perform better than traditional statistical based methods when applied to predict infectious biological agents with little available robust biosurveillance data due to the inherent ability of machine learning to learn and discover predictive patterns in complex systems and translate these features into accurate predictions on novel datasets.3 Yet, there is limited published information on the utility of applying ML/DL to

predicting the infectious disease dynamics for biological agents whose epidemic dynamics are too complex or unknown.

Relevance: The CBDP is exploring the feasibility of leveraging ML approaches in increasing the speed, complexity, and performance of infectious biological agent predictive analytic tools for the Warfighter. Additionally, this topic is exploring the accuracy of predictions compared to traditional statistical methods for infectious biological agent predictions.
Objective: As a proof of concept, this effort aims to answer/address the fundamental questions/ capability gaps outlined in the general Objective Section above in understanding how ML methods can be used to predict risk from novel or emerging infectious biological pathogens of relevance to CBDP, to include the strategies can be used to update disease predictions to account for changing infectious disease dynamics throughout the course of an outbreak.
Impact: If successful, the end state for this work will support the CBDP by providing an evidence base supporting the development a validated ML algorithm capable of providing rapid, high fidelity disease prediction for infectious biological agents that outperforms current mathematical or statistical based approaches for predicting risk in features, speed, and automation.

References:

1. Ray, E.L. and Reich, N.G. (2018) Prediction of infectious disease epidemics via weighted density ensembles. PLoS Computational Biology 14(2). February 20, 2018.
2. Erraguntla, M., Zapletal, J., and Lawley, M. (2017) Framework for Infectious Disease Analysis: A comprehensive and integrative multi-modeling approach to disease prediction and management. Health Informatics Journal. December 27, 2017.
3. Camacho, D.M., Collins, K.M., Powers, R.K., Costello, J.C., and Collins, J.J. (2018) Next-Generation Machine Learning for Biological Networks. Cell 173, June 14, 2018.

Thrust Area 7, Topic J5-B: Assay Target Screening: Discovery of Common Binding Surfaces to Expedite Assay Development

Award Amounts for this topic are anticipated to be up to $500,000 per year through the base period phase to establish proof of concept and, if successful, up to $1,000,000 per year thereafter (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full proposal invitation.

The preferred award structure for this topic is a base period of one (1) year with up to two (2) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of three (3) years will not be considered. Efforts for phage-based assays will not be considered. Efforts using chemically synthesized or *in silico* peptides will be considered. Awardees will be required to grant the US Government a licensing agreement to all software and or hardware in perpetuity for all Chemical

and Biological Defense Program (CBDP) uses.

Note: For this topic, awardees will be required to grant the US Government a licensing agreement to all software and or hardware in perpetuity for all Chemical and Biological Defense Program (CBDP) uses.

Background: Recent advances in synthetic biopolymer development and the development of synthetic molecules that mimic antibody function offer the opportunity for the DoD to address several deficiencies in antibody-based assay development and other strategies that involve pathogen detection through molecular recognition and binding.

The discovery of affinity reagents for specific biomolecules is a long-standing goal in chemical biology and biomedical research, as they enable development of new drugs, diagnostics and assays to protect life from biological threats. Peptides or other synthetically developed molecules are suitable agents to achieve this goal by binding biopolymers and are usually discovered by screening randomized combinatorial libraries against the target of interest. Chemically synthesized or in silico designed peptide/polymer libraries can provide access to non-natural or modified building blocks that yield variants with enhanced affinity and stability.

Determining peptide or polymer-based synthetic library binding affinities requires screening aptamer, peptoid or similar libraries against the expressed bacterial proteome. Typically this screening process requires approximately 6 months to complete for one bacterial strain. The discovery of binding molecules could be accomplished more efficiently if multiple strains could be screened using in silico methods incorporating machine learning simultaneously.

Relevance: Determining peptide-based synthetic library binding affinities requires screening aptamer, peptoid or similar libraries against the expressed bacterial proteome. The binding pairs identified through these screens can be used to develop new therapeutics, diagnostic assays, detection capabilities, etc. Typically this screening process requires approximately 6 months to complete for one bacterial strain. The discovery of binding molecules could be accomplished more efficiently if multiple strains could be screened simultaneously. The described approach offers a more cost-effective, more rapid approach to the identification of molecular targets through a deep, parallel screening approach.
Not only will the time required for a binder to be identified be reduced, the information gained allows for the characterization of the structure of the synthetic molecule binding space and could reveal links between primary structure and biological recognition. Furthermore, identifying bound peptides and linking them to metabolic pathways could aid understanding common metabolic pathways.

Objective: As proof of principle, a synthetic library of approximately 1012 unique molecules will be developed and used to sequentially screen five distinct (i.e. Strain) peptide libraries from each of three pathogens of interest. The anticipated result of this highly complex screen will be neighborhoods, or clusters, of peptides with structural similarities; the beginnings of a database of peptides, grouped by structural similarities, which can aid with the selection of target/binder

pairs for an uncharacterized pathogen.

Second, as a proof of concept, this effort will then aim to answer/address the fundamental questions/ capability gaps outlined in the general Objective Section above in understanding how ML methods can be used to support rapid screening of uncharacterized pathogens, to include the following:

- Could AI/ML approaches provide rapid responses with high accuracy when compared to traditional screening approaches?
    - How is this measured?
- How are batch effects accounted for?

Impact: Detection, diagnostics, therapeutics and decontamination will benefit from rapid prediction of binding targets that the described database would provide. The screening approach described here is unprecedented, given its very high throughput and parallelism. This novel database-driven predictive modeling tool could be considered a new capability for rapid response.

References:

1. Kheirabadi, M., Çelebi-Ölçüm, N., Parker, M. F. L., Zhao, Q., Kiss, G., Houk, K. N., and Schafmeister, C. E., JACS 134, (2012): 18345–18353. doi:10.1021/ja3069648
2. Hiss, Jan A., E. Gawehn and G. Schneider. 2016. Deep learning in drug discovery. Mol. Inform. 35, 1 (Jan. 2016), 3–14. https://doi.org/10.1002/minf. 201501008
3. Northrup, J. D., G. Mancini, C. R. Purcell, and C. E. Schafmeister (2017): Development of Spiroligomer−Peptoid Hybrids. J. Organ. Chem. 2017 82 (24), 13020-13033 DOI: 10.1021/acs.joc.7b01956
4. Torres-Saez, R, F. L. Camacho and R. Ramos-Pollan. 2017. Assessing the behavior of machine learning methods to predict the activity of antimicrobial peptides. Rev. Fac. Ing. 26, 44 (2017), 167–180. https://doi.org/10.19053/01211129.v26.n44.2017.5834
5. Engkvist O., J. Bajorath, T. Blaschke, M. Olivecrona and H. Chen. 2017. Application of generative autoencoder in de novo molecular design. Mol. Inform. 37, 1–2 (Jan. 2017). https://doi.org/10.1002/minf. 201700123

Thrust Area 7, Topic J5-C: Validation of Artificial Intelligence (AI) for the Discovery of Chemical Medical Countermeasures: Comparison of Virtual and Ultra High-Throughput Screening (uHTS) of a Small Molecule Library

Award Amounts for this topic are anticipated to be up to $500,000 per year through the base period phase to establish proof of concept and, if successful, up to $900,000 per year thereafter (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full proposal invitation.

The preferred award structure for this topic is a base period of one (1) year with up to three (3) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period

and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of four (4) years will not be considered.

Note: For this topic, awardees will be required to grant the US Government a licensing agreement to all software and or hardware in perpetuity for all Chemical and Biological Defense Program (CBDP) uses.

Background: Artificial Intelligence (AI)/Machine Learning (ML) as a tool for development of small molecule chemical MCMs.

In order to identify potential prophylactic or therapeutic treatments for injury or insult due to CWA exposure, chemical libraries are often screened. A robust chemical library serves as a preliminary foundation of existing compounds from which to initially elucidate and identify potential hit candidates that could be down-selected for further screening and studies. CBDP has current efforts in which a library of ~385,000 small molecules are being assayed in Ultra High-Throughput Screening (uHTS) for their potential as next-generation nerve agent MCMs (CB10777). The results of those assays are supporting data-mining efforts (CB10858) to enhance evaluation and tiered downselection of candidates from that vast library.

In this topic, we wish to leverage the significant real-world insights into the properties of that molecular library gained from the uHTS, to test an AI/ML approach to virtually screening the same library. The development and execution of such a large virtual screen, and its congruence and divergence compared to authentic experimental results, is a rare opportunity to test both the virtual screening and the actual screening. On one hand, the virtual method must deliver results that hold true when actually tested. On the other hand, the human judgment calls involved in evaluating such a large data set make interpretation of these experimental results vulnerable to subjective errors. To perform these screens in parallel will test the performance of both and potentially deliver better results than either alone.

Relevance: The CBDP is exploring the feasibility of leveraging ML approaches in increasing the speed, complexity, and performance in the identification and assessment of viable lead compounds for chemical medical countermeasure development. Funding an effort to develop ML algorithms to predict optimized targets in parallel with a funded uHTS screening effort would facilitate the evaluation and utility of these technologies in the chemical MCM space.

Objective: As a proof of concept, the initial work will be directed towards understanding how AI/ML approaches can be applied to design, identify, and assess novel chemical compounds. While the application of AI/ML approaches to rational drug discovery is not novel, the CBDP has the opportunity to directly evaluate the potential for AI/ML to expedite the discovery of small molecules targeting AChE and perform validation and comparative analytics of AI/ML predictions with products of a virtual screen with an uHTS with a reduced timeline and cost. This effort aims to answer some of the fundamental gaps in understanding:

- Are AI/ML methods more accurate than other traditional high throughput screens of small molecule libraries?
- Do the outcomes of AI/ML methods suggest ways to improve current experimental

approaches to chemical MCM discovery?
- Does the combination of AI/ML approaches and conventional uHTS perform better than either strategy alone?
- Can we define a standardized format for data collection and pre-processing including metadata for training, validation, and testing of ML algorithms in this space?
- How many input parameters are sufficient to inform accurate model predictions? Which ones?

Impact: If successful, the end state for this work will support the RD-CBS through improved pathways for designing, identifying, and assessing novel chemical compounds, and screening existing libraries for drug development of chemical compounds with a reduced timeline and cost. It would also support RD-CBI in laying the groundwork for the potential to develop a more encompassing AI drug discovery platform that could be applied across the spectrum of DoD medical areas within the CBDP.

References:

1. Fleming, N (2018) How artificial intelligence is changing drug discovery. Nature 557, S55-S57 May 30, 2018.
2. Mak, K.K. et al. (2019) Artificial intelligence in drug development: present status and future prospects. Drug Discovery Today 24(3) March, 2019.
3. Chen, H., Engkvist, O., Wang, Y., Olivecrona, M., and Blaschke, T. (2018). The rise of deep learning in drug discovery. Drug Discovery Today 23(6), June 2018.

Thrust Area 7, Topic J5-D: Discovery and Development of Medical Countermeasures using Artificial Intelligence (AI) and Machine Learning (ML)

Award Amounts for this topic are anticipated to be up to $700,000 per year through the base period phase to establish proof of concept and, if successful, up to $700,000 per year thereafter (total dollar value = direct and indirect costs). In all cases, the proposed award value should be clearly substantiated by the scope of the effort. Further guidance on scope and cost may be provided in each full proposal invitation.

The preferred award structure for this topic is a base period of one (1) year with up to two (2) additional years as possible options. However, pre-application white papers and proposals that outline scope and effort for only the base period and do not propose options are also acceptable. Pre-application white papers and proposals that outline scope and effort for different base period and option combinations may also be considered; however, note that pre-application white papers and proposals that outline scope and effort that exceed a total of three (3) years will not be considered.

Note: For this topic, awardees will be required to grant the US Government a licensing agreement to all software and or hardware in perpetuity for all Chemical and Biological Defense Program (CBDP) uses.

Background: Identifying and developing medical countermeasures for an infectious biological agent is long, arduous, and expensive. It can take 10-15 years and hundreds of millions of

dollars. The risk is even higher for genetically modified or engineered biological threats. Once a target for a biological infectious disease is identified, assay development and high-throughput screening occurs to identify potential chemical compounds. The screen libraries can contain millions of potential compounds. Testing of identified compounds against the biological targets results in tens of thousands potential candidates. These results are narrowed down to hundreds and eventually to a lead candidate through silico modeling. The small molecule is then tested for pharmacokinetics, absorption, distribution, metabolism, and excretion (ADME) in an appropriate animal model along with safety and efficacy.

If a candidate is proven in the animal model, the candidate moves on to Phase I Clinical trials in healthy humans to determine safety, ADME, and side effects. Seventy percent of compounds move on to Phase II trials. Phase II Clinical trials focus on efficacy in patients with the disease to demonstrate proof of concept including dosage and dosing regimen. On average only 33% of candidates move on from Phase II trials. Phase III trials focuses on confirming the efficacy in a large patient populations. Twenty-five percent of candidates successfully pass the Phase III Clinical trial.

The large number of compounds that have to be screened for one disease target combined with the safety and efficacy studies that produces high failure rates result in a process that is extremely risky and expensive. Combined with the continue rise of antibiotic resistance, medical countermeasures are slow to be delivered to the warfighter.

Genetic algorithms have been used to design natural product peptides for use as antibiotics. Data sets are being used by ML to study biological networks and systems and provide the framework for discovery of bioactive compounds with pre-determined pharmacokinetics and pharmacodynamics. AI was recently used to design a flu vaccine that is now in Phase I Clinical trials in the U.S. All of these advancements require the use of datasets to train and test the AI and ML.

Relevance: The CBDP wants to develop medical countermeasures and predict safety, toxicity, and efficacy using ML and AI. Using ML and AI will decrease the amount of time required to screen, identify, and test potential medical countermeasures. Additionally, being able to identify safety and efficacy problems should reduce the number of failures and reduce cost in the long term.

Objective: Develop AI and ML assisted platform to design and predict drug safety, toxicity, and efficacy for pathogens of interest to DTRA. Efforts should address data set generation methodology (if required).

Impact: An AI and ML platform used to identify bioactive compounds to combat biological diseases and/or predict safety and efficacy will reduce time and resources needed to field medical countermeasures to the warfighter.

References:

1. Porto, W.F., Irazazabal, L., Alves E.S., Ribeiro, S.M., Matos, C.O, Pires A.S., Fensterseifer, I.C., Miranda, V.J., Haney, E.F., Humblot, V., Torres, M.D., Hancock,

R.E., Liao, L.M., Lardram, A., Lu, T.K., de la Funete-Nunez, C. and Franco, O. (2018) In silico optimization of a guava antimicrobial peptide enables combinatorial exploration for peptide design, Nature Communications 9, April 16, 2018.
2. Camacho, D.M., Collins, K.M., Powers, R.K., Costello, J.C., and Collins, J.J. (2018) Next-Generation Machine Learning for Biological Networks. Cell 173, June 14, 2018.
3. Hiss, Jan A., E. Gawehn and G. Schneider. 2016. Deep learning in drug discovery. Mol. Inform. 35, 1 (Jan. 2016), 3–14.
4. Masige, H. Australian Researchers Have Just Released The World's First AI-Developed Vaccine. Business Insider, July 13, 2019.

ATTACHMENT 2: INTELLECTUAL PROPERTY

(Applies to FAR Contracts & OTAs)

Applicants must describe any limitations on the use of any intellectual property (patents, inventions, trade secrets, copyrights, trademarks, technical data or computer software) that will impact the offeror's performance of the contract or impact the Government's subsequent use of any deliverable under the contract. In particular, the applicant must describe the intellectual property in sufficient detail and describe the limitations on its use (potential patent licenses required by the Government, data assertions of the offeror or any subcontractor, etc.) and describe how the Government can accomplish the stated objectives of this BAA with the limitations described or proposed by the offeror.

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

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

Be advised that no patent, patent application, or invention disclosure will be accepted if identified in the Data Rights Assertion list. **The list of patents, patent applications, and inventions of this section must be a separate list from the Data Rights Assertion list.**

Government rights in any technology that might be invented or reduced to practice under the contract are addressed in the patent rights clause to be included in the contract.

Data Rights. Applications submitted in response to this BAA shall identify, to the extent known at the time an offer is submitted to the Government, the technical , the technical data, or computer software that the Offeror, its subcontractors or suppliers, or potential subcontractors or suppliers assert should be furnished to the Government with restrictions on use, release, or disclosure, in accordance with DFARS 252.227-7017, Identification and Assertion of Use, Release or Disclosure Restrictions, and DFARS 252.227-7028, Technical Data or Computer Software Previously Delivered to the Government. The applicant's assertions, including the assertions of its subcontractors or suppliers, or potential subcontractors or suppliers, shall be submitted in the following format, dated and signed by an official authorized to contractually obligate the applicant. If the applicant will deliver all technical data and computer software to the Government without restrictions, enter "NONE" in this table under the heading "Technical Data or Computer Software to be Furnished with Restrictions."

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

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

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

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

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

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

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

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

Date _____
Printed Name _____
Printed Title _____
Signature _____

Applicants responding to this BAA requesting an Other Transaction or Other Transaction for Prototype shall specifically identify any asserted restrictions on the Government’s use of intellectual property contemplated under those award instruments. For this purpose, applicants must propose specific Intellectual Property terms and conditions and a data deliverable list. Further, the applicants must explain why an Other Transaction is necessary and, in particular, how the intellectual property terms and conditions proposed will meet the objectives of this BAA.