# DEFENSE THREAT REDUCTION AGENCY BROAD AGENCY ANNOUNCEMENT HDTRA1-25-S-0001

Amendment 1
Posted December 2024



Research and Development Directorate (RD)
Chemical and Biological Technologies Department (RD-CB)

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

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#### **OVERVIEW INFORMATION**

#### **Agency Name:**

Defense Threat Reduction Agency (DTRA)
Research and Development (RD) Directorate
Chemical and Biological Technologies Department (CB)
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 the initial announcement of this funding opportunity. This BAA is in effect from October 1, 2024 through September 30, 2034. 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 cooperative agreements (CAs) or other transactions (OTs) for research may also be awarded from this announcement. No contracts will be awarded from this announcement. Submissions for this BAA may occur in two ways: 1) in response to the published topics detailed in <a href="https://example.com/Attachment 1">Attachment 1</a> or 2) to a general thrust area as described in <a href="https://example.com/Section 1.5">Section 1.5</a>.

In general, all topic-specific and general thrust area submissions require pre-coordination in accordance with the guidelines in <u>Section 1.5</u> and <u>Section 4.2.1</u>. 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: HDTRA1-25-S-0001

Catalog of Federal Domestic Assistance (CFDA) Number: 12.351

**Dates:** This BAA is open continuously from October 1, 2024 through September 30, 2034. 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 <a href="www.grants.gov">www.grants.gov</a> 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, 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 CAs, and other assistance instruments will be considered on a case-by-case basis. Thirty 30 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. 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.

Fundamental Research includes research performed under grants, CAs, or OTs 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 area. 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 Area 1 is described below. When a specific set of topics has been identified, these detailed needs will be described in <a href="Attachment 1">Attachment 1</a> along with any topic-specific submission instructions, deadlines, anticipated award structure, and funding requirements. Otherwise, preapplication 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 no-topic submissions; Pre-application white papers will only be accepted from the coordinated abstracts under limited circumstances.

- 1.5.1. Thrust Area 1— 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 (https://www.grants.gov), the System for Award Management website (https://sam.gov/), and the DTRA website (https://www.dtra.mil). The DTRA website is not the official sites; applicants are responsible for monitoring both sam.gov and www.grants.gov. Posted amendments supersede all previous versions of the BAA. Note that topics will be listed in <a href="https://www.grants.gov">Attachment 1</a> and will be added/closed with Amendments to this BAA.
- 1.7. All coordination and communication between applicants and the Government will be conducted using the e-mail address associated with this BAA, specified in <u>Section 7</u>. Applicants should include both the administrative email and the relevant thrust area email address. DTRA will not release employee personal contact information.

#### 2. AWARD INFORMATION

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

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

Except for OTs, the Government actions under this BAA shall adhere to the requirements of the DoD Grant and Agreement Regulations (DoDGARS), as appropriate for the type of instrument. DoDGARs can be accessed online at <a href="http://www.ecfr.gov/cgi-bin/text-idx?SID=e5d686f6760f3274b3368f36723fbb7e&mc=true&tpl=/ecfrbrowse/Title32/32CIsubchapC.tpl">http://www.ecfr.gov/cgi-bin/text-idx?SID=e5d686f6760f3274b3368f36723fbb7e&mc=true&tpl=/ecfrbrowse/Title32/32CIsubchapC.tpl</a>. 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.

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 preapplication 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) 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 to the lead organization. All subawards are the responsibility of the award recipient; exceptions will not be made.

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 Area 1, including topics associated with the thrust area, 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. CAs, and OTs 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 Area 1, including topics associated with the thrust area, 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.

#### 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. For foreign-based establishments entirely based outside the U.S. and/or its territories, proof of not-for-profit status may be required.
- Foreign government laboratories. 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 preapplication white paper. Any specific guidance provided in a topic or to an applicant supersedes the information provided herein.

The following entities <u>may not</u> participate as prime awardees nor furnish Principal Investigators (PIs) in awards made under this BAA but <u>may</u> 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 (HDTRA1-25-34-FRCWMD-Call). 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 <a href="http://www.dtrasubmission.net">http://www.dtrasubmission.net</a> and after logging in, follow the link to the 'FY25-34 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 <a href="http://sam.gov">http://sam.gov</a> (Reference 2 CFR 1125).

#### 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 <u>Section 1.6</u>) and each topic (as outlined in <u>Attachment 1</u>) 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 <u>www.grants.gov</u> consist of the forms as detailed in Table 1.

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 1: 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 area 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 Area 1 are provided in Section 7. Coordination of research ideas and efforts must be accomplished via these email addresses, except in cases where a topic specifically states that precoordination 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 <u>Section 7</u>. 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 area. Pre-application white papers will only be accepted from the coordinated abstracts under very limited circumstances.

Topics may be posted in <u>Attachment 1</u> of this announcement that may not require precoordination of an abstract. Please review the topics carefully.

4.2.2. Pre-application white papers and invited proposals **must be** submitted electronically using <u>www.grants.gov</u> and the corresponding application packages linked with this BAA on <u>www.grants.gov</u> (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 preapplication 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 2: Phase I Pre-Application White Paper Package Chart.

Each Phase I application resubmission 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.
- 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 <u>Section 4.2.4</u>.

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 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).

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
	PI Biographical Sketch	Attach to Biographical Sketch field
Research & Related Senior/Key Person Profile Form	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	Publically Releasable Proposal Summary/ Abstract	Attach to Block 7 Project Summary/ Abstract
Project Information Form	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

Table 4: 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 <a href="www.grants.gov">www.grants.gov</a> 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 <a href="www.grants.gov">www.grants.gov</a>:

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 17 – Regarding Disclosure of Funding Sources. By checking "I Agree" you agree to abide

by the following statement: "By signing this application, I certify the proposing entity is in compliance with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 which requires that: (a) the PI and other key personnel certify that the current and pending support provided on the proposal is current, accurate and complete; (B) agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and (c) the PI and other key personnel have been made aware of the requirements under Section 223(a)(1) of this Act. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. code, Title 18, Section 1001)."

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 also carefully review Section 4.5.4 to appropriately evaluate inclusion of Value Added Tax (VAT) or other taxes for assistance awards.

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 Form 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. The budget justification must specifically address VAT and other taxes in accordance with Section 4.5.4.

**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.

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 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.

Applicants should note that in accordance with the instructions for completion of the SF 424, checking of Block 17 is required. Further, applicants should note that by checking block 17 and submitting an application package, you agree to abide by the following statement: "By signing this application, I certify the proposing entity is in compliance with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 which requires that: (a) the PI and other key personnel certify that the current and pending support provided on the proposal is current, accurate and complete; (B) agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and (c) the PI and other key personnel have been made aware of the requirements under Section 223(a)(1) of this Act. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. code, Title 18, Section 1001)."

**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 publicly 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.
- *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:

- **Protection of Human Subjects.** For full discussion, see Section 6.2.2. If the proposed work involves human subjects or the use of human anatomical substances (e.g., biospecimens, blood, tissue, cell lines), either living or post-mortem, applicants are required to: a) justify and b) outline the use, and c) include the source of the human subjects, human biospecimens and/or human data involved in the research. The DTRA Research Oversight Board (ROB) will provide ongoing oversight throughout the duration of the effort to ensure proper approvals are in place. Further information will be required if the proposal is selected for award.
- Animal Use. For full discussion, see Section 6.2.3. If the proposed work involves the use of animals, applicants are required to: a) justify and b) include detailed information on the use of animals, and c) include the location(s) of where the animal work is to be performed. The DTRA Research Oversight Board (ROB) will provide ongoing oversight throughout the duration of the effort to ensure proper approvals are in place. Further information will be required if the proposal is selected for award.
- *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.

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

<u>Attachments Form</u>: 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 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. 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."

**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.

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 <a href="www.grants.gov">www.grants.gov</a> 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 <a href="www.grants.gov">www.grants.gov</a> 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 Controlled Unclassified Information (CUI), other Proprietary information or export-controlled information or be marked as such.
- 4.2.10. Confirmed Proposal Expiration Date. Applicants 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 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 preapplication 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 <u>Section 7</u> 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 <a href="www.grants.gov">www.grants.gov</a>. When sending electronic files, the applicant should allow for potential delays in file transfer from the originator's computer server to the <a href="www.grants.gov">www.grants.gov</a> website/computer server, as well as the

delay associated with the <u>www.grants.gov</u> 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 <u>www.grants.gov</u>, 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 <a href="www.grants.gov">www.grants.gov</a> en masse, but this system does not mark applications as "retrieved" on <a href="www.grants.gov">www.grants.gov</a>. As a result, when applicants check the status on <a href="www.grants.gov">www.grants.gov</a> 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 <a href="Section 7">Section 7</a>. 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 <a href="www.grants.gov">www.grants.gov</a> 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 <a href="www.grants.gov">www.grants.gov</a> 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. Organizations must have an active System for Award Management (SAM) registration, and Grants.gov account to apply for grants. Creating a Grants.gov account can be completed online in minutes, but SAM registrations may take additional time. Therefore, an organization's registration should be done in sufficient time to ensure it does not impact the entity's ability to meet required application submission deadlines.

All organizations applying online through Grants.gov must register with the SAM and will receive a unique entity identifier (UEI) number. Failure to register with SAM will prevent your organization from applying through Grants.gov. SAM registration must be renewed annually. For more detailed instructions for registering with SAM, refer to:

https://www.grants.gov/web/grants/applicants/organization-registration/step-2-register-with-sam.html. Additional information may be found on Grants.gov here:
https://www.grants.gov/web/grants/applicants/organization-registration.html

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. VAT and Other Taxes in Assistance Awards. Prior to proposal submission, the applicant will require any supplier of goods or services to assess and verify potential VAT, excise duties, and other tax implications to avoid the imposition of such charges with respect to the goods and/or services in question to the maximum extent possible.

In instances where the supplier of goods or services is exempt from the VAT, excise duties, or other taxes or is entitled to claim reimbursement thereof, the taxes must not be included in the proposed cost of the award.

In instances where the supplier of goods or services is not exempt from the VAT, excise duties, or other taxes or is not entitled to claim reimbursement thereof, the applicant must itemize the VAT and/or other taxes in the proposal. Further, applicants are advised that prior to the award of any grant or cooperative agreement, DTRA and the recipient will mutually agree upon the use of DTRA funds for the VAT, excise duties, or other taxes, and project activities may be revised accordingly. All applicants may include costs in their proposal to pay for VAT costs associated with lodging, meals, and transportation for travel.

- 4.6. Applicants that Propose Use of OTs.
- 4.6.1. Recommended Award Instrument and Pricing Arrangement. Applicants that propose use of OTs 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 Grant Officer before time and effort are expended in preparing a proposal. All applicants and proposed sub-awardees 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 for Chemical, Biological, Radiological and Nuclear Defense (JPEO), the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD-NCB), or the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (DASD(CBD)). 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. Limitations on OTs. Applicants are advised that an Other Transaction for Research Agreement (10 U.S. Code § 4021) may only be awarded under the following conditions:
  - The focus of the program or project is basic, applied or advanced research;
  - To the maximum extent practicable, the research to be performed under the project does not duplicate research being conducted under existing DoD programs; and
  - Resource share is required and to the extent practicable, the funds from the Government do not exceed the total amount provided by the other party.

#### 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.
- 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.
- 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.

Rating	Description
Outstanding	The proposal is a technically exceptional submission that is pertinent to
<b>(0)</b>	program goals and objectives. The proposal contains multiple strengths
	that will provide significant benefit to the Government, and that far
	outweigh any weaknesses. The risk of unsuccessful performance is low.
Good (G)	The proposal is a technically thorough submission that is pertinent to
	program goals, and objectives. The proposal contains at least one strength
	that will provide benefit to the Government, and that outweighs any
	weaknesses. The risk of unsuccessful performance is low to moderate.
Acceptable (A)	The proposal is a technically adequate submission that is pertinent to
	program goals, and objectives. Strengths and weaknesses are offsetting or
	will have little or no impact on grant performance. The risk of
	unsuccessful performance is no worse than moderate.
Marginal (M)	The proposal is a technically weak submission that is pertinent to program
	goals, and objectives. The proposal has one or more weaknesses which are
	not offset by strengths. The risk of unsuccessful performance is high.
Unacceptable	The proposal does not meet requirements, or is not pertinent to program
(U)	goals and objectives and contains one or more deficiencies. The proposal is
	un-awardable.

Table 5: Definitions of Adjectival Ratings

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 preapplication white paper and invited proposal information including information that may be considered proprietary or otherwise marked with restrictive legends 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.

#### 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 Grants or Agreements Officers may commit resources; this will be done by issuing a grant 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 <u>notification@dtrasubmission.net</u>. **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 <u>Section 4.5.2</u> and <u>Section 4.6.2</u> 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<sup>1</sup>, "...products of fundamental research are to remain

<sup>&</sup>lt;sup>1</sup> Under Secretary of Defense for Acquisition, Technology and Logistics Memorandum, SUBJECT: Fundamental Research, dated May 24, 2010.

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 work involves human subjects or the use of human anatomical substances (e.g., biospecimens, blood, tissue, cell lines), either living or post-mortem, applicants are required to: a) justify and b) outline the use, and c) include the source of the human subjects, human biospecimens and/or human data involved in the research, hereafter referred to as "research."

The DTRA Research Oversight Board (ROB) will provide ongoing oversight throughout the duration of the effort to ensure proper approvals are in place. Further information will be required if the proposal is selected for award. Further information will be required if the proposal is selected for award.

DTRA PMs responsible for the research are required to complete and submit Section A of the DTRA Form 156, available through the DTRA1 Forms Library, to the DTRA Research Oversight Board (ROB) through the ROB Central Mailbox, <a href="dtra.belvoir.rd.mbx.research-oversight-board@mail.mil">dtra.belvoir.rd.mbx.research-oversight-board@mail.mil</a>.

Through an Agreement with DTRA and the U.S. Army Medical Research Development Command, Office of Human and Animal Research Oversight (MRDC OHARO), OHARO must review and approve all DTRA funded or supported research prior to the start of the proposed work. This review requirement is in addition to the DTRA ROB review. Therefore, along with the DTRA Form 156, the DTRA PM/STM must complete and submit the MRDC OHARO form titled "USAMRDC\_ORP\_Proposal Submission\_Form" to the DTRA ROB for review of the proposed work. These forms are available through the ROB DTRA1 Sharepoint site, https://dtra1portal.unet.dtra.mil/RD/ROB/default.aspx. Allow up to four months, from date award is submitted to the DTRA ROB, for regulatory review and approval processes. Applicants are to build the review time into their project schedules.

All work under any award made under this BAA involving research must be conducted in accordance with 32 CFR 219, 10 U.S.C. § 980, and DoD Instruction (DoDI) 3216.02, DTRA Instruction (DTRAI) 3216.01, and, as applicable, 21 CFR parts 11, 50, 56, GCP, the International Council for Harmonization (ICH) as well as other applicable federal and state regulations. Grants, CA's and OT's must include similar language as DFARS clause 252.235-7004 and DTRA Clause 252.223-9002. Non-compliance with any provision of this clause may

result in withholding of payments pursuant to the terms and conditions. The Government shall not be responsible for any costs incurred for research involving human subjects prior to protocol approval by the MRDC OHRO and ROB.

It is the responsibility of the PM to ensure performers are cognizant of and abide by the additional restrictions and limitations imposed by the DoD regarding research involving human subjects and human anatomical substances, specifically in regards to 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).

Through the Component Management Plan (CMP), reviewed and approved by USD(R&E), the DTRAI 3216.01 establishes the DTRA Human Research Protection Program (HRPP), and sets forth the policies, defines the applicable terms, and delineates the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing human subject research, and is managed by the DTRA ROB. The regulations mandate that all DoD activities, components, and agencies protect the rights and welfare of human subjects in DoD funded or supported research, development, test and evaluation, and related activities.

The DTRAI 3216.01 requires that research involving human subjects or human anatomical substances may not begin or continue until the DTRA ROB and MRDC OHRO have reviewed and approved the proposed work. The requirement to comply with the regulations applies to new starts and continuing research for the life of the project, until closure. The completion of a research project requires closure document (e.g., IRB Final Review submission) submitted to the DTRA ROB and/or the MRDC OHRO.

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.

A study is considered to use human anatomical substances if it involves human biospecimens such as peripheral blood mononuclear cells, primary cells, blood, saliva, tissue, etc. Commercially available sources (e.g., a vendor, medical facility's discarded materials, research collaborators, biobanks, repositories) of human anatomical substances require review. This includes cadaveric specimens and substances.

Commercially available cell lines are exempt from this definition and do not require review (note: commercially available embryonic cell lines are not exempt and must be reviewed).

Approval to begin research or to subcontract under the proposed protocol will be provided in writing from the MRDC OHRO and the DTRA ROB Executive Secretary (ES) or Program Manager, in absence of the ROB ES. Both the contractor and the Government must maintain a copy of this approval. Any proposed modifications or amendments to the approved research must be submitted to the DTRA ROB and/or the MRDC OHRO for review and approval. Examples of modifications or amendments to the approved work that would require a new review of the project include, but are not limited to:

- a change of the Principal Investigator (PI);
- a change or addition of an institution (note: review and approval of institution is required),
- elimination or alteration of the informed consent process,

- a change in the human subjects study population (e.g., adding children, active duty, etc.) has regulatory implications
- 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.
- changes in perceived or measured risks or benefits to volunteers that require changes to the study,
- a change in the IRB of record.
- a change that could potentially increase risk to human subjects.
- significant change in study design (i.e., would prompt significant additional scientific review).

Research pursuant to such modifications or amendments must not be initiated without IRB and OHRO approval except when necessary to eliminate apparent and immediate hazards to the subject(s). All unanticipated problems involving risk to subjects or others (UPIRTSOs), suspensions, clinical holds (voluntary or involuntary), or terminations of the research by the IRB or regulatory agencies, the institution, the sponsor, or any instances of serious or continuing noncompliance with the federal regulation or IRB requirements, must be promptly reported to the DTRA ROB and/or MRDC OHRO.

Greater than minimal risk research projects lasting more than one year require IRB and OHRO review at least every 365 days, or more frequently as required by the responsible IRB. ROB review and approval is required annually from the date of Section A of the DTRA Form 156, through recertification of the DTRA Form 156. The awardee must provide documentation of continued IRB review of protocols for MRDC OHRO review and approval. Research must not continue without renewed OHRO and ROB approval unless necessary to eliminate apparent and immediate hazards to the subject(s).

6.2.3. Animal Use. If the proposed work involves the use of animals, applicants are required to: a) justify and b) include detailed information on the use of animals, and c) include the location(s) of where the animal work is to be performed. The DTRA Research Oversight Board (ROB) will provide ongoing oversight throughout the duration of the effort to ensure proper approvals are in place. Further information will be required if the proposal is selected for award.

DTRA PMs responsible for the research are required to complete and submit Section A of the DTRA Form 156, available through the DTRA1 Forms Library, to the DTRA Research Oversight Board (ROB) through the ROB Central Mailbox, <a href="mailto:dtra.belvoir.rd.mbx.research-oversight-board@mail.mil">dtra.belvoir.rd.mbx.research-oversight-board@mail.mil</a>.

Through an Agreement with DTRA, the Animal Care and Use Review Office (ACURO), a component of the USAMRDC Office of Human and Animal Research Oversight (MRDC OHARO) must review and approve all DTRA funded or supported research involving animal use prior to the start of the proposed work. This review requirement is in addition to the DTRA ROB review. Therefore, along with the DTRA Form 156, the DTRA PM must complete and submit the MRDC OHARO form titled "USAMRDC\_ORP\_Proposal Submission\_Form" to the DTRA ROB for review of the proposed work. This form is available through the ROB DTRA1

Sharepoint site, https://dtra1portal.unet.dtra.mil/RD/ROB/default.aspx. Allow up to four months, from date award is submitted to the DTRA ROB, for regulatory review and approval processes. Applicants are to build the review time into their project schedules.

All work under any award made under this BAA involving the use of animals must be conducted in accordance with DoD Instruction (DoDI) 3216.01, DTRA Instruction (DTRAI) 3216.01, and Army Regulation (AR) 40-33. 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. Contracts must include DFARS Clause 252.235-7002 and DTRA Clause 252.235-9001. Other funding vehicles (e.g., grant, OT) must include similar language. Non-compliance with any provision of this clause may result in withholding of payments under the contract pursuant to the terms and conditions. The Government shall not be responsible for any costs incurred for research involving animal use prior to protocol approval by the MRDC ACURO and ROB. It is the responsibility of the PM to ensure performers are cognizant of and abide by the additional restrictions and limitations imposed by the DoD regarding animal-use research.

The DTRAI 3216.01 requires that research using animals not begin or continue until the DTRA ROB and MRDC ACURO have reviewed and approved the proposed work.

Through the DTRA Component Animal Use Management Plan (CAUMP), reviewed and approved by the USD(R&E), the DTRAI 3216.01 establishes the DTRA Animal Use Oversight Program (AUOP), and sets forth the policies, defines the applicable terms, and delineates the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing research involving animal use, and is managed by the DTRA ROB. The regulations mandate that all DoD activities, components, and agencies protect the care and welfare of animals in DoD funded or supported research, development, test and evaluation and training, and related activities. The requirement to comply with the regulations applies to new starts and continuing research for the life of the project, until closure. The completion of a research project requires closure document (e.g., IACUC Final Review submission) submitted to the DTRA ROB and/or the MRDC ACURO.

The DoD definition of animal is "any living or dead vertebrate animal, including birds, cold blooded animals, rats of the genus rattus and mice of the genus mus." "Dead" is defined as animals killed for the direct purpose of conducing RDT&E or training.

Approval to begin research or to subcontract under the proposed protocol will be provided in writing from the MRDC ACURO and the DTRA ROB Executive (ES) Secretary or the ROB PM, in the absence of the ROB ES. Both the awardee and the Government must maintain a copy of this approval. Any proposed modifications or amendments to the approved research must be submitted to the DTRA ROB and/or the MRDC ACURO for review and approval. Examples of modifications or amendments to the approved protocol that would require a new review of the

project include, but are not limited to:

- a change of the Principal Investigator (PI),
- a change or addition of an institution (note: review and approval of institutions is required),
- a change in the duration or intensity of exposure to a stimulus or agent,
- a change in the animal model and/or numbers of animals used,
- a change in the IACUC of record, or
- a significant change to in study design (i.e., would prompt significant additional scientific review).

Research pursuant to such modifications or amendments must not be initiated without IACUC and ACURO approvals.

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 materials, 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: <a href="https://www.gpo.gov/fdsys/pkg/CFR-2002-title32-vol3/pdf/CFR-2002-title32-vol3-sec626-18.pdf">https://www.gpo.gov/fdsys/pkg/CFR-2002-title32-vol3/pdf/CFR-2002-title32-vol3-sec626-18.pdf</a> 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 <a href="http://www.ecfr.gov/cgi-bin/text-">http://www.ecfr.gov/cgi-bin/text-</a>
- idx?SID=ee45add5e352854b7089ce420c7fd0a6&mc=true&tpl=/ecfrbrowse/Title32/32cfr216 m ain\_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.
- 6.2.10. USD (R&E) memorandum dated 8 June 2023 Policy for Risk Based Security Reviews of Fundamental Research. The offeror's submitted fundamental research project proposal shall be subject to Agency security reviews to include screening for conflicts of interest and conflicts of commitment from foreign influence, ties to foreign talent recruitment programs or Confucius Institutes, and assessment of risk in accordance with the factors in the DoD decision matrix published with the memorandum.

The offeror must also agree, as part of its proposal that it shall comply with DoD's follow up annual verification that each participant listed on the research performance progress report – RPRR – is not a participant in a malign foreign talent recruitment program meeting. DoD will conduct periodic spot checks of covered individuals listed on representative samples of fundamental research project proposals selected for award to identify any research security risks that were missed during the initial review.

As of 9 August 2024, DoD is prohibited from funding or awarding a fundamental research proposal in which a covered individual is participating in a malign foreign talent recruitment program or to a proposing institution that does not have a policy addressing malign foreign talent programs.

As of FY24, no US institution of higher education that hosts a Confucius Institute may receive DoD funding unless it has a waiver by the Office of the Secretary of Defense.

Upon review, for selected proposals that necessitate, the offeror shall comply with agreed-upon research security risk mitigation measures as part of the award.

The Government reserves the right to decline award based on research security risks that cannot be mitigated. The offeror will receive a rejection letter if this instance occurs. If the offeror challenges the rejection, OUSD(R&E) will act as mediator and issue a final determination.

6.2.11. Certification Regarding Disclosure of Funding Sources. The offeror shall comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (42 US Code 6605), which requires that covered individuals:

- (A) disclose the amount, type, and source of all current and pending research support received by, or expected to be received by, the individual as of the time of the disclosure;
- (B) certify that the disclosure is current, accurate, and complete; and
- (C) agree to update such disclosure at the request of the Government prior to the award of support and at any subsequent time the Government determines appropriate during the term of the award.

The offeror shall also certify that each covered individual who is employed by the offeror and listed on the proposal has been made aware of the requirements listed above. The disclosure and certification must be made by completing the form or attachment provided with this solicitation (e.g., SF-424 R&R or Disclosure of Funding Sources). Source Reference: Section 223 of the FY21 NDAA, pages 84-86: <a href="https://www.congress.gov/116/plaws/publ283/PLAW-116publ283.pdf">https://www.congress.gov/116/plaws/publ283/PLAW-116publ283.pdf</a>.

Section 223 defines "covered individual" as:

#### An individual who—

- (A) contributes in a substantive, meaningful way to the scientific development or execution of a research and development project proposed to be carried out with a research and development award from a Federal research agency; and
- **(B)** is designated as a covered individual by the Federal research agency concerned.
- 6.2.12. Prohibition on Covered Telecommunications Equipment or Services. Section 889 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Public Law 115-232) prohibits the head of an executive agency from obligating or expending loan or grant funds to procure or obtain, extend, or renew a contract to procure or obtain, or enter into a contract (or extend or renew a contract) to procure or obtain the equipment, services, or systems prohibited systems as identified in section 889 of the NDAA for FY 2019.
- (a) In accordance with 2 CFR 200.216 and 200.471, a recipient and subrecipient are prohibited from obligating or expending grant funds to:
  - 1. Procure or obtain;
  - 2. Extend or renew a contract to procure or obtain; or
  - 3. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
    - For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

- Telecommunications or video surveillance services provided by such entities or using such equipment; or
- Telecommunications or video surveillance equipment or services produced or
  provided by an entity that the Secretary of Defense, in consultation with the Director
  of the National Intelligence or the Director of the Federal Bureau of Investigation,
  reasonably believes to be an entity owned or controlled by, or otherwise connected to,
  the government of a covered foreign country.
- (b) In implementing the prohibition under Public Law 115-232, section 889, subsection (f), paragraph (1), heads of executive agencies administering loan, grant, or subsidy programs shall prioritize available funding and technical support to assist affected businesses, institutions and organizations as is reasonably necessary for those affected entities to transition from covered communications equipment and services, to procure replacement equipment and services, and to ensure that communications service to users and customers is sustained.
- (c) See Public Law 115-232, section 889 for additional information.

COVERED FOREIGN COUNTRY means the People's Republic of China.

- 6.3. Reporting. General requirements are provided below; however, each awardee should check the award agreement 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 or OTs 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).

#### 7. AGENCY CONTACTS

Administrative Correspondence and Questions	dtra.belvoir.rd.mbx.rd-cb-frbaa25-34-a@mail.mil
Thrust Area 1: Fundamental Science for Chemical and Biological Defense	dtra.belvoir.rd.mbx.rd-cb-frbaa25-34-ta1@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. Applicants should include the relevant thrust area email address.
- 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.

#### 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 Area 1 has Seven (7) topics —Topics A1-A7 —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.

- If NOT submitting to one of the specific topic numbers detailed below, use one of the Thrust Area NO TOPIC application packages
- If you ARE submitting to one of the specific topic numbers detailed below, use the applicable Basic Research-Thrust Area 1-Topic A1 to A7 application package

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:

## \*\*\*BASIC RESEARCH TOPICS A1-A7\*\*\*

In accordance with Section 4.2.1, the requirement for abstract pre-coordination is waived for Topics A1-A7; 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 A1-A7 is 7 February 2025. PRE-APPLICATION WHITE PAPERS FOR THESE TOPICS MUST BE SUBMITTED BY 11:59 PM (MIDNIGHT) EST ON 7 February 2025. White papers submitted to Topics A1-A7 may not be considered if they are received after this deadline.

Topics A1-A7 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.

The following topics are Basic Research topics, and proposals should not be solely written with or marketed to a DoD centric application; the offerer should also present a description of the broader implications of their work to our Nation and the whole of society.

DTRA anticipates that the predominance of awards made under Topics A1-A7 will be grants. Pre-application white papers and proposals submitted to Topics A1-A7 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 1, Topic A1: Drug targeted delivery systems with simultaneous pathogenesis monitoring and/or diagnostic capability.

Award Amounts for this topic are anticipated to be between \$400,000 and \$700,000 per year (total dollar value = direct and indirect costs). The larger value efforts (i.e., \$500,000 - \$700,000 per year) should be multi-disciplinary and/or multi-investigator. An increased Award Amount to cover animal studies during the final year is appropriate. 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 option years possible. 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:** DTRA seeks to explore innovative approaches that enable cell or organ targeted drug delivery, targeted monitoring of pathogenesis and/or amelioration of infectious or non-infectious threats *in vivo* during treatment, and cell targeted diagnostics. Of particular interest are active targeted drug delivering systems (e.g. nanobots) that can also be effective for controlled drug release and simultaneously be able to monitor the effect of countermeasures; for example, by detecting changes in biomarkers. Of particular interest is the exploration of nanobot systems; however, other innovative active targeting and monitoring approaches will also be considered.

In recent years, significant advancements in effective treatments and improved diagnostics have occurred because of innovations in the development of biodegradable and/or biocompatible nanomaterials and biosensor technologies. In this regard, nanomaterials can be utilized as targeted delivery systems of anti-pathogenic and anti-inflammatory countermeasures to the infection site for precise drug delivery. In addition, AI/ML methods that are incorporated in these technologies have great potential to not only predict and assess the suitability of nanomaterials for targeted drug delivery, they also can assist in providing models during pathogenesis by analyzing changes in biomarkers during the development of an infection and/or during treatment.

Advances in cell targeting also have the potential to increase the sensitivity and specificity of non-invasive diagnostics. Precise targeting of affected cells or tissues could also enable presymptomatic detection thereby allowing for early treatment before the onset of severe symptoms. Furthermore, with targeted approaches there is potential to improve diagnostics by combining these approaches with fieldable detection technologies for disease monitoring and progression.

**Impact:** Exploration of innovative targeting systems to enable precise drug delivery and controlled drug release to specific organs and cell types will advance our arsenal of more efficacious treatment strategies at lower drug doses for combating infectious diseases (for example viruses) and toxins. Combining targeting systems that include monitoring capabilities also will allow evaluation of cell/tissue-specific status during pathogenesis and during treatment or provide a truly innovative diagnostic capability targeted at the cellular or tissue level of specificity.

**Innovation:** Describe innovative aspects of the proposed research, including the novelty of the targeted drug delivery system, targeting strategy, and monitoring approach.

**Methodology**: Provide a detailed outline of the experimental methods and techniques to be employed, including the selection of target organs or cell types (e.g. in organoids or microfluidic systems) and including appropriate animal models, the design and synthesis of drug delivery systems, and the methods for monitoring pathogenesis or the infection status.

## Research Areas (may include but are not limited to)

## Drug targeting strategies:

- Development of novel drug carriers or delivery systems that can selectively target specific organs and cell types.
- Delivery of a countermeasure against a relevant biological (e.g. a viral or a toxin) threat that can be delivered to the relevant organ and or specific cell types.
- Exploration of active target approaches with a strong emphasis of active targeted drug delivery systems (e.g. nanobots) for targeted and controlled drug release.
- Development and optimization of drug release kinetics to ensure controlled delivery of therapeutic agent(s).

#### Simultaneous monitoring of pathogenesis and infection status:

- Development of techniques to monitor the status of pathogenesis or the infectious (viral) or non-infectious (toxin) threats in real time. Possible techniques may include detection of biomarkers including imaging techniques and biosensors.
- Integration of sensing techniques for highly sensitive and precise monitoring of biological processes/pathogenesis within the biological system, for example detecting changes in biomarkers that can provide early warning signals of relapse or treatment failures associated with the disease.

#### Diagnostics applications:

- Development of techniques to improve diagnostic capabilities. For example, nanobots that can detect toxins or viral proteins for improved immunoassays.
- Exploration of techniques that enable targeting of specific cell types during immunological responses to infectious or non-infectious agents.
- Exploration of targeted approaches that would allow for advancement of fieldable diagnostic detection/imaging technologies.

#### References:

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Zhang Y, Zhang Y, Han Y, Gong X. Micro/Nanorobots for Medical Diagnosis and Disease Treatment. *Micromachines (Basel)*. 2022 Apr 19;13(5):648. doi: 10.3390/mi13050648. PMID: 35630115; PMCID: PMC9146405.

## <u>Thrust Area 1, Topic A2: Exploring Quantum Computing Technology to Advance Basic</u> <u>Research and Accelerate Medical Countermeasure (MCM) Development.</u>

Award Amounts for this topic are anticipated to be \$750,000 per year through the base period to establish proof of concept (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 to establish proof of concept with up to three (3) additional option years possible. 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 a 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.

**Overview**: The Joint Science and Technology Office (JSTO) of the Chemical and Biological Defense Program (CBDP) is actively exploring the feasibility of leveraging quantum computing technology, tools, and capabilities to enhance computational biology, machine learning, and artificial intelligence (ML/AI) models and other areas of in-silico basic research to revolutionize scientific research and exponentially increase the speed and accuracy of Medical Countermeasure (MCM) development.

**Background**: In recent years, the scientific research community has harnessed the power of computational biology, machine learning algorithms, and other cutting-edge in-silico approaches based on classical computing to delve into the complexities of biological systems, biomolecules, molecular characteristics, biochemical interactions, and more. While these methods have yielded significant results, there is a pressing need to address the gaps in computational biology and

several in-silico basic research approaches to develop effective MCMs against emerging biological threats to protect the warfighter.

Biological systems and biochemical interactions are dynamic and influenced by numerous factors, making computational biology and data collection inexact. Quantum mechanics has opened new frontiers in biological and chemical research, offering insights into molecular interactions at the atomic and subatomic levels. Successful quantum computing systems, platforms, software, or processes can simultaneously perform several in-silico biological simulations, predictions, and calculations at speeds more significant than those practically achievable by classical computers. Thus, the integration of quantum computing, with its foundation in quantum mechanics, may present a more robust approach to advancing basic research and accelerating MCM development for the JSTO CBDP.

**Relevance**: The CBDP is exploring the feasibility of leveraging quantum computing approaches in increasing the speed, complexity, and performance of drug discovery to enable optimizing MCM candidates for advanced development and delivery to the Warfighter. Additionally, this topic is exploring the accuracy of quantum computing predictions compared to traditional AI/ML methods for MCM optimization.

Objective: The Joint Science and Technology Office (JSTO) of the Chemical and Biological Defense Program (CBDP) is actively exploring the feasibility of leveraging quantum computing technology, tools, and capabilities to understand the vast space of biological and chemical processes, including, but not limited to, protein folding, drug discovery, cellular pathways, and other biochemical processes, at atomic and subatomic levels to support basic research efforts focused on developing MCMs for biological threats.

As a proof of concept, this effort aims to answer/address the following fundamental questions/capability gaps in understanding how quantum computing methods may be used to aide in the discovery of medical countermeasures for biological pathogens of relevance to CBDP. Specific questions to be explored include, but are not limited to:

- Are Quantum Computing methods more accurate than other ML and classical computing methods for developing rapid response capabilities?
- Which Quantum Computing algorithms increase the speed of predictions without sacrificing accuracy and relevance of output?
- Is there one Quantum Computing approach that outperforms others?
  - o If so, which? How is it measured? What are the use cases?
- Is there quantum computing generalizable to all biological agents? If yes, what are the assumptions? If no, what are the limitations?
- What metrics are most effective at quantifiably measuring and characterizing different quantum computing approaches?
- Can we define a standardized format for data collection and pre-processing including metadata for training, validation, and testing of Quantum Computing in this space?

- Does Quantum Computing reduce the algorithmic complexity and machine learning calculations involved in constructing and analyzing numerous classical computational models?
- Does Quantum Computing provide added value over classical computing approaches (i.e. effectively and efficiently influence optimum basic research outcomes, saving time and cost)?
- How can we integrate quantum computing to training machine learning, deep learning, and artificial intelligence models that supplement basic research.

#### Other Considerations:

Offerors should focus on developing a quantum computing capability, tool, or approach that will significantly advance basic science research supporting MCM development. Questions of interest include, but are not limited to:

- Biological molecule structure prediction (for example RNA, protein, etc.) and function determination.
- Improvement of the data query of all chemical databases for effective drug discovery and development and prediction of drug-ligand interactions.
- Prediction of pathogen (for example, virus, bacteria) interactions with cell receptors and intracellular pathogenic mechanisms (tracking pathogenesis).
- Solve the complexity of biological systems (for example, the metabolic process of individual cells, gene expression pathways, receptor-ligand binding interactions, etc.).
- Predicting potential biological threat mutations of concern and evolutionary trends.

Offerors must provide clear and detailed descriptions of the proposed quantum computing technology and a comprehensive roadmap on how to apply the technology in a specific area of basic research.

Based on this topic, it is anticipated that offerors will propose multidisciplinary teams composed of relevant domain expertise and computational science in interpreting and evaluating complex chemical or biological data sets and computational sciences to translate heterogeneous data types into machine-readable formats for application of advanced analytics.

Offerors are encouraged to propose collaborative partnerships/teaming agreements with external groups (i.e., National Laboratories, DoD Laboratories, Academia, FFRDCs, or UARCs).

Ideally, proposers will team with existing CBDP-funded performers as part of the test and validation option periods.

Solutions that do not incur recurring licensing fees or restricted data rights are preferred.

Offerors shall include a Data Management, Sharing, and Transition Plan for all raw and metadata generated from CBDP funded awards to a CB internal software repository upon completion of the Period of Performance.

Awardees will be required to grant the US Government a Government Purpose Rights licensing agreement to all software and or hardware in perpetuity for all Chemical and Biological Defense

Program (CBDP) uses.

**Impact**: If successful, the end state for this work will support the RD-CB Enabling S&T Basic Research program by providing an evidence base supporting the development of a validated quantum computing approaches capable of providing rapid, high-fidelity predictions for MCM optimization that outperforms current ML based approaches, decreases computational bias, and increases data collection precision and accuracy.

#### References:

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Nezammahalleh H, Ghanati F, Rezaei S, Badshah MA, Park J, Abbas N, Ali A. Biochemical Interactions through Microscopic Techniques: Structural and Molecular Characterization. *Polymers (Basel)*. 2022 Jul 13;14(14):2853. doi: 10.3390/polym14142853. PMID: 35890632; PMCID: PMC9318543.

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# Thrust Area 1, Topic A3: Understanding the effects of infectious agents on the oral microbiome for development of presymptomatic diagnostics.

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. Award amounts for this topic are anticipated to be commensurate with proposed research seeking to investigate, elucidate, or exploit the changes in the oral microbiome in response to infectious agents for the purpose of improving diagnostic tools. It is anticipated that teams with varying expertise are required to meet the metrics outlined below.

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:** The microbiome consists of a complex community of micro-organisms and their genes which plays an important part in human health and disease (1). The role of the microbiome has expanded to healthcare and is most readily evident in the cases of intestinal and fecal microbiota which has utilized NGS to identify important microbial genomic elements in infectious disease diagnostics (2), cancer screening (3), and others (4). While the gut flora has been extensively studied and characterized, little headway has been made to utilize the oral microbiome in a similar fashion.

The oral microbiome is a desirable site for minimally invasive sampling and hence an appealing area for potential diagnostic development. There is limited research on the timing of the oral microbiome response to pathogen exposure within a host. It is unclear whether the microbial landscape will change or elicit specific biomarkers of exposure before, simultaneously, or after a host response has occurred. In addition, there is limited information regarding whether oral commensal organisms provide measurable responses to infectious agent exposures. Therefore, CBMD is interested in gaining foundational knowledge to inform future technology development. Proposal submitters should select an appropriate model system to examine both the host and oral microbiome biomarkers in response to biological agent exposure.

Successful efforts should include any or all the following markers (preference will be given to proposals that address more): changes in the microbial landscape, transcriptomics, genomics, proteomics, metabolomics, miRNAs, volatile organic compounds, or others. Proposals should also outline a comprehensive data collection strategy with a focus on determining the optimal timing for detection of the aforementioned markers. This topic will advance the science to ultimately enable the development of capabilities for pre-symptomatic diagnostics of exposure to biological agents to support the Joint Force.

**Impact**: This topic is inclusive of proposed efforts related to characterization of changes that occur in the oral microbiome in response to infectious agents. Successful efforts from this topic will provide answers to key questions related to leveraging the oral microbiome to improve presymptomatic diagnostics.

**Objective**: Proposals for this topic should address the broad objective of leveraging the oral microbiome to inform and improve diagnostic capabilities for infectious diseases. Research proposals should focus on addressing key information gaps related to the understanding of changes in the oral microbiome in response to infectious agents. Examples of specific research questions that may be addressed include but are not limited to the following:

- What are the temporal differences in the detectability of different mutli-omic markers (mRNA, microbial landscape, proteins), and how can they be leveraged for presymptomatic diagnostics?
- At what specific time points do host markers become detectable compared to microbial markers post-exposure?
- Which analytic approaches can be successfully leveraged to provide key diagnostic information related to changes in the oral microbiome in response to infection?
- Which oral microbiome species elicit robust responses to infectious agents? Are these responses consistent across variable microbiome compositions?
- Are changes to microbiome markers or overall microbiome composition are in response to agent exposure or to host immune/inflammatory response?

#### References:

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Kujiraoka M, Kuroda M, Asai K, Sekizuka T, Kato K, Watanabe M, Matsukiyo H, Saito T, Ishii T, Katada N, Saida Y, Kusachi S. Comprehensive Diagnosis of Bacterial Infection Associated with Acute Cholecystitis Using Metagenomic Approach. *Front Microbiol.* 2017 Apr 20;8:685. doi: 10.3389/fmicb.2017.00685. PMID: 28473817; PMCID: PMC5397476.

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## <u>Thrust Area 1, Topic A4: Identification of Threat Agnostic Mechanisms of Host Response for Medical Countermeasure Discovery.</u>

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. Award amounts for this topic are anticipated to be commensurate with proposed research seeking to investigate, elucidate, or exploit the changes in the oral microbiome in response to infectious agents for the purpose of improving diagnostic tools. It is anticipated that teams with varying expertise are required to meet the metrics outlined below.

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.

**Impact**: The current global landscape is characterized by the emergence of unpredictable chemical and biological threats (CB). The traditional list-based approach to CB defense, while valuable, has inherent limitations in addressing novel pathogens or chemicals of concern. Development of medical countermeasures which mitigate the negative effects of multiple classes of insults, encompassing chemical exposure, infection, or traumatic injury would provide significant utility. This underscores the critical need for a paradigm shift towards a more proactive and adaptable approach: threat-agnostic medical defense based on host responses.

**Objective**: This approach seeks to identify and exploit commonalities in the ways chemical/biological (CB) injuries induce physiological host responses which effect the Warfighter like traumatic injuries. By identifying these shared mechanisms, researchers can develop the basic understanding of how CB injury sequelae develop over time, leading to insights for future broad-spectrum defenses effective against both known and emerging CB threats.

The potential impact of this research is significant and multifaceted:

- Protection of the Joint Force: Development of new diagnostics, prophylactics, and therapeutics to treat CB injury will provide the Warfighter an increased ability to operate freely and return safely from dangerous or compromised environments.
- Faster Response to Emerging Threats: By focusing on common mechanisms rather than
  specific agents, researchers can more rapidly develop and deploy countermeasures
  against novel or unknown threats, protecting life and health, and containing outbreaks
  before they become widespread.

Potential areas of interest - Identifying CB-Agnostic Signatures: This approach centers on developing methods to discern common patterns of physiology, gene regulation and pathology across diverse insults. These patterns, referred to as CB-agnostic signatures, could manifest as specific responses or perturbations in biological pathways that occur regardless of the specific

#### agent involved.

- Multi-Omics Analysis: One promising avenue for identifying such signatures lies in the
  application of advanced data analytics and machine learning to large datasets from multiomics studies. This could involve analyzing data from genomics, transcriptomics,
  proteomics, and metabolomics to identify patterns associated with infection and disease
  progression.
- Post Exposure Response: Research could focus on dissecting commonalities in CB induced physiological responses, such as inflammation, cytokine/chemokine expression, and changes to resident cell populations. By understanding these shared mechanisms, researchers can identify potential targets for broad-spectrum countermeasures.
- Host Response Profiling: Detailed analysis of host responses to infection, particularly the innate immune response, can reveal common pathways activated or suppressed across diverse pathogens. These pathways represent potential targets for modulating the host response to enhance immunity or mitigate harmful inflammation.

#### References:

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# <u>Thrust Area 1, Topic A5: Material Concepts for Transformative Chemical and Biological Defense Solutions.</u>

Award Amounts for this topic are anticipated to be up to \$200,000 (total dollar value = direct and indirect costs) for a base year (12 months) with the potential for one option year (12 months). The proposed award value should clearly substantiate the scope of the effort. Award Amounts for this topic are anticipated to be indicative of the amount of work involved in demonstrating feasibility of highly innovative basic research areas that may serve as the basis for advancement of new concepts for chemical and biological protection and decontamination, and other aspects of this program outlined below. Further guidance on scope and cost may be provided in a full proposal invitation.

**Background**: DTRA's basic research investments relevant to chemical and biological (CB) protection and decontamination have identified materials that demonstrate adsorption, reactivity,

selective permeability, or a combination thereof for a variety of capability concepts. Representative examples include metal-organic frameworks, metal oxide catalysts, biomimetic materials, and polymer composites. While studies with select material classes are on-going, new material solutions are essential to reveal the art of the possible and meet the future Warfighter's needs. For example, reactive materials need to not only decompose chemical targets but also demonstrate sufficient turnover (beyond stoichiometric reactivity). Sustainable, fluorine-free omniphobic materials are needed to provide high surface repellency as an alternative to carbon-fluorine containing materials that have been the gold standard for decades. Improved chemically repellent elastomeric materials are required to enhance the performance of current coatings, tires, gaskets, and hoses made from traditional elastomers. Novel refractive index materials are needed to customize and integrate ocular protection with current and future systems.

**Impact**: This topic will support innovative materials research to advance the scientific state-of-the-art and identify creative material solutions to modernize CB respiratory protection, ocular protection, decontamination, and protective garment technologies.

**Objective**: This topic seeks short-term, fundamental research investigations focused on proof-of-concept studies and collection of preliminary data of new material research initiatives in support of transformative CB defense platform solutions. Studies will explore new scientific opportunities that address material challenges related to CB protection and hazard mitigation technologies. It is expected that research will focus on chemical surrogates, model compounds, and/or toxic industrial chemicals. Example research areas include but are not limited to:

- Materials that demonstrate rapid, efficient turnover, or regenerative function
- Materials that demonstrate adsorptive and reactive functions and are skin compatible.
- Elastomeric materials that demonstrate chemical repellency and barrier properties that enable more facile decontamination strategies.
- Interface and colloid science to generate concepts that demonstrate the ability to enhance reaction rates, diffusion, transport, and/or mechanical properties.
- New tools or methods to characterize interfacial interactions and reaction mechanisms to support novel material and composite development.
- Materials that exhibit unique optical properties, particularly with respect to refractive index to augment the use of external vision correction systems.

#### Additional considerations:

- Priority will be given to innovative material solutions over incremental material development.
- Research must be completed within 12 months (24 months if option period is approved) of award of the agreement.
- No capital equipment may be purchased under this award.

• The Phase II project narrative (technical proposal) should reflect the level of work to be performed within the 12-month base period (and 12-month option period, if proposing), and emphasize the key tasks leading to proof of idea.

#### References:

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### Thrust Area 1, Topic A6: Quantum Sensors for Chemical and Biological Detection

Award Amounts for this topic are anticipated to be between \$350,000 and \$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 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. 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:** DTRA RD-CBPD seeks innovative quantum sensing approaches to demonstrate proof-of-concept for quantum systems that can detect chemical and biological (CB) threats in operational environments under various conditions. Quantum sensors exploit quantum mechanical phenomena (e.g., quantum states and spins, matter-wave duality, coherence, superposition, entanglement [1], and/or quantum correlations) to broaden sensing capabilities. They represent a new generation of transformative sensors with potential to exceed the standard limit for sensing in terms of precision, accuracy, bandwidth, speed, or other factors, such as size, weight, and power. Matter-wave optic technologies, such as atom interferometry, neutron interferometry, and electron holography systems, have demonstrated exclusive sensitivity to atomic, molecular, and solid-state properties and have potential for sensitive environmental monitoring [2,3]. Quantum biosensing also has the potential to revolutionize investigation of complex biological systems, where traditional modes of exploration are often limited by studies of microscopic phenomena with macroscopic tools [4].

**Impact:** This topic will accelerate the development of new quantum sensing approaches to ultimately enable a sensitive and rapid response to the presence of CB threats in the operational environments, thereby increasing situational awareness. If successful, it will also identify promising technological approaches that advance to applied research on quantum sensors to address the agency mission. Advances in quantum sensing components may also potentially aid in the development of quantum computing and networking capabilities.

**Objective:** This topic is focused on design concepts [5] and proof-of-concept demonstration of quantum sensing systems that can be expanded into novel quantum metrology to perform ultrasensitive and selective measurements of CB threats in operational environments.

### Fundamental questions to address may include but are not limited to:

- What materials/design approaches can be developed to measure quantum behavior (spin state, superposition, polarization, entanglement) to interrogate the environment beyond the current-state-of-the art (i.e., NV-center diamonds, non-linear crystals)?
- What design principles can be defined to inform emerging quantum sensing technologies to detect CB threats?
- What novel concepts in Quantum information science and technology can be generated for molecular sensing?
- What fundamental processes and designs will result in quantum sensing technologies with reduced SWAP, compared to current conventional systems?
- What are fundamental properties of quantum sensors that will indicate promising avenues of research (e.g., quantum entanglement)?

Offerors are encouraged to develop R&D collaborations with other organizations in Government, academia, and the private sector to broaden and strengthen their knowledge, experience, and capabilities. Additionally, offerors are encouraged to take advantage of specialized resources in the DoD and other Government agencies such as facilities/capabilities. Multidisciplinary approaches are strongly encouraged.

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# <u>Thrust Area 1, Topic A7: Chemical/biological Triggered Upconverting Nanoparticles and Amplification</u>

Award Amounts for this topic are anticipated to be between \$350,000 and \$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 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 ok, 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: DTRA seeks to understand the fundamental science, design, synthesis, and characterization of an upconverting nanoparticle (or other anti-stokes species) triggered by the presence of biological warfare agent (BWA) or chemical warfare agent (CWA) simulants, surrogates, or model compounds on surfaces. Upconverting nanoparticles absorb multiple photons of low energy to convert and emit a single photon with higher energy when stimulated with light. These nanoparticles and other material species have been applied to biological imaging, diagnosis/therapeutics, photovoltaics and photonics, sensing, lasing and other applications. It is anticipated that utilization of upconverting nanoparticles or other anti-stokes species have distinct advantages including reduction in autofluorescence, photostability, synthetic tunability, down to single molecule detection, narrow emission spectra, high chemical stability, low toxicity, long luminescence lifetime, and high resistance to photoquenching and photobleaching meaning they may have a distinct advantage for use in DoD sensing, imaging, and other applications.

The upconversion process is typically activated by a strong and specific wavelength laser or other light source: light on - upconversion happens, light off - reaction stops – the systems are reliant on the light to work. For chemical and biological contamination visualization, it is

envisioned that a analogous but different mechanism can be developed and leveraged:

- A specific chemical/biological analyte would interact with an upconverting material/particle (or a trigger connected to an upconverting particle)
- Chemical/biological interaction triggers a reaction (or other initiation step) allowing for the absorption of light and an upconversion process.
- Upconverted light species (or other product from upconversion) initiates another reaction initiating a cascading/amplification of the signal from the chemistry/biological analyte of interest.

To date, mechanisms using a conventional on/off upconverting nanoparticle that is triggered by the presence of specific stimuli or trigger to allow for upconversion processes has not been described.

The overarching objective of this topic is to develop a system for specific chemical/biological triggers and on/off chemical or biological "switch" that when combined with upconverting nanoparticles and paired with an amplification mechanism will allow for eventual visual determination of contamination.

The goals of this fundamental research project would be (in the base period) to determine if there is a system for simulant/surrogate/model compounds for chemical or biological materials that can have a reaction that can turn on or "unlock" the ability of the upconverting species to absorb light and conduct those reactions. Ideally the system would be reversible – turning on/off in the presence and absence of the analyte, using switching mechanisms for example. The second gal in the base period is to identify the amplification mechanism and begin studies of synergy between the two main components. The third goal within this fundamental research, after this proof of concept, would be to pair this triggering and switch mechanism with a chemical cascade or amplification for eventual visual signaling.

**Impact**: This topic will support understanding of fundamental aspects of upconverting nanoparticles (or other upconverting species) and potential for triggering by simulant/model compounds and fundamental studies for amplification of signal to reduce quenching and improve optical brightness. If successful, this could guide development of new methods for detection and contamination mapping of chemicals on surface materials.

**Objective**: This research topic seeks to have two major objectives. First, development of a material capable of upconverting light based on trigger by a BWA/CWA simulant or model compound. Second, later in the research, the topic seeks to couple the nanoparticle emission of light to an amplification process that results in potential/actual signal greater than 10-fold above that achieved through a stoichiometric reaction. Proposals should strategize iterative design, synthesis, and laboratory characterization of materials that result in a upconversion reaction scheme from nanoparticles or other materials capable of these effects. It should also characterize responses that support the iterative process of design and synthesis for upconversion of light triggering mechanisms and pairing with amplification reactions. Ideally the developed material should be robust and not easily interfered with from environmental factors: temperature, presence or absence of water/humidity, and pH.

Research area considerations may include but are not limited to:

• Multidisciplinary approaches are strongly encouraged.

- Proposals can focus on any biological or chemical warfare simulant/surrogate/model compound
- Study of upconversion of light (from any anti-stokes capable material) from a triggering event of a simulant/surrogate or model chemical/biological compound interaction.
- Studies for mitigation of brightness issues and quenching
- Success will require pairing of triggering/upconversion materials with amplification.
- Use of enzymatic and pH approaches are strongly discouraged.
- Fundamental proof of concept of upconverting systems for the target chemistry/biology in base period
- Opportunity for stability in varying environments, identification of specificity, sensitivity, and interference potential.
- Although not a requirement for basic research offerors should keep in mind the potential for use in operational environments in the future (power, wavelength, source, and intensity of light etc.)
- Note: Proposals to build sensors, or similar devices will not be considered. Proposals and work should focus on CWA/BWA simulant/surrogate/model compounds only.

Upconverting nanoparticles are not the only anti-stokes shifting materials and the proposed work may incorporate other anti-stokes materials and amplification mechanisms keeping in mind that mechanisms such as self immolative, enzymatic, or materials that will utilize instrumentation such as Raman Spectroscopy to interpret the results are of less interest to this topic. This proposed project should consider only identification of the contamination on surfaces as the goal (e.g. decontamination of the compound within this technology is an advantage but not a goal of this topic).

## Yearly objectives could be but are not limited to:

#### Base Period:

Year 1: Fundamental science of the design, synthesis, and characterization of these materials for applications showing proof of concept for triggering and switching of simulant/surrogate/model compounds with upconverting nanoparticles or other upconverting materials. Demonstration of a proof of concept of an upconversion reaction with a simulant model compound and switches as separate components. Separately, identification of amplification mechanism and begin study of mechanisms and synergy.

Year 2: Fundamental iteration and optimization of the design/synthesis of these material components. Demonstration of proof of concept of an on/off system and upcoverting mechanism demonstrating promise for continued iterative development. Begin to identify challenges for this material and identify potential paths for mitigation. Optimize amplification mechanism and improve synergy with the proof-of-concept materials and begin to combine components.

## Option years:

Year 3: Continued iterative design and development of triggering upconverting system and identification and development of an amplification mechanism that could be coupled to the nanoparticle emission of light that results in a signal greater than 10-fold above that achieved through a stoichiometric reaction with a goal of demonstration of components including

improved triggering/upconversion and amplification.

- Year 4: Continued iterative design and combining components into one system that includes triggering/upconvrsion and amplification. Study of fundamental science of stability of these systems and begin to create model systems for demonstration of utility in applications. Begin to explore potential for surface application (physical or biological (e.g. skin)). Begin studies to understand mechano, hydro, thermal stability, and other potential limitations.
- Year 5: Continued optimization of design, synthesis, and efficiency of these materials and improvement in use in more applicable scenarios and optimize for proof of concept for use in "real world" scenarios.

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#### ATTACHMENT 2: INTELLECTUAL PROPERTY

(Applies to OTs)

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.

<u>Patents</u>. 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.

<u>Data Rights</u>. 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)

<sup>\*</sup>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.