DEFENSE THREAT REDUCTION AGENCY BROAD AGENCY ANNOUNCEMENT HDTRA1-24-S-0002

29 April 2024



Cooperative Threat Reduction Directorate Biological Threat Reduction Program

Biological Threat Reduction with Global Partners

Original Posting Date: 29 April 2024

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OVERVIEW INFORMATION

Agency Name:

Defense Threat Reduction Agency (DTRA) Cooperative Threat Reduction (CTR) Directorate Biological Threat Reduction Program (BTRP) 8725 John J. Kingman Road, MS 6201 Fort Belvoir, VA 22060-6201

Funding Opportunity Title: Biological Threat Reduction with Global Partners Broad Agency Announcement (BAA)

Announcement Type: This is an initial announcement of this funding opportunity. Submissions for this BAA must align with the BTRP mission, topic areas of interest, and lines of effort (LOEs) as described in Sections 1.1-1.4, and follow the instructions in Section 4.

Funding Opportunity Number: HDTRA1-24-S-0002

Assistance Listing Number: 12.351

Dates: This BAA is open continuously from 29 April 2024 through 28 April 2029. Submissions aligning to the BTRP mission, general topic areas, and LOEs may occur at any time this BAA is in effect. Applicants should take care to note requirements and timelines for submitting Abstracts, White Papers, and Full Proposals. In some circumstances, specific scientific topics (e.g., persistent, unaddressed regional concerns) will be published as additional Attachments (via Amendment to this BAA), and these 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.

Additional Overview Content: This BAA, in addition to any amendments issued in conjunction with this BAA, will be posted to the Grant Opportunities website (www.grants.gov), the General Services Administration System for Award Management website (sam.gov), and the DTRA website (www.dtra.mil). The DTRA website is not the official site; applicants are responsible for monitoring both sam.gov and www.grants.gov. Posted amendments supersede all previous versions of the BAA.

All administrative coordination and communication between applicants and the Government will be conducted using the email address associated with this BAA, specified in <u>Section 7</u>. BTRP will not release employee personal contact information.

1 FUNDING OPPORTUNITY DESCRIPTION

The Defense Threat Reduction Agency (DTRA) Cooperative Threat Reduction (CTR) Biological Threat Reduction Program (BTRP) protects the United States, its Armed Forces, and our allies from biological threats by strengthening the capabilities of partner nations and the international community to prevent, detect, and prepare for disease outbreaks. BTRP supports international health security efforts to address diseases caused by U.S. Biological Select Agents (https://www.cdc.gov/selectagent/SelectAgentsandToxinsList.html), pathogens of pandemic potential, and emerging (and reemerging) infectious diseases. BTRP achieves its mission through collaboration with partner countries and the international community to minimize the threat of deliberate, accidental, and natural infectious disease outbreaks through enhanced detection, diagnosis, and reporting capabilities and biosecurity and biosafety measures. This Broad Agency Announcement (BAA) is an extramural endeavor that seeks to bring funding to biosurveillance studies that support biosecurity and biosafety (BS&S) capability building, incountry partnerships, and other needs appropriate to meet BTRP's mission interests.

BTRP utilizes international engagements to promote science and technical collaborations with partner nations, regional and international organizations, and the global scientific community to foster and maintain ethical, constructive, and sustainable partnerships that address health security threats. In addition to increasing the knowledge and mitigation of risks posed by potential disease causing pathogens and approaches that build effective capacities and capabilities to reduce those risks, these projects are intended to develop strong international relationships through technical assistance that will enhance the ability of partner nations to contribute to global disease awareness and improve their domestic public health posture. Scientific studies evaluated and awarded through the BAA are one part of comprehensive country and regional engagements BTRP develops and maintains. Projects are designed to be relevant, cooperative, impactful, and contributory to enduring capabilities. There is a strong preference for science projects that are multi-sectoral/multi-institutional, build upon prior BTRP investments, and facilitate cooperation and transparency with local, national, regional, and/or international partners. Additionally, BTRP encourages that projects supported through the BAA be coordinated with activities from other U.S. government, academic, and international organizations programs.

This announcement solicits ideas and topic-based Abstracts, White Papers, and Full Proposals for cooperative scientific studies that offer a significant contribution to support, enhance, and inform partner country systems to detect, diagnose, and report diseases; instill BS&S best practices and principles; foster sustainable bioscience capability development with partner countries; and establish collaborative partnerships with BTRP partner countries.

BTRP specifically seeks proposals aligning to the overall technical areas below. Periodically, detailed needs will be described in Attachments along with any topic-specific submission instructions, deadlines, anticipated award structure, and funding requirements.

1.1 <u>Study focus areas.</u> BTRP counters biological threats by supporting and strengthening capabilities that are foundational to operational biosurveillance systems and thus seeks proposals for studies designed to enhance safe and detection, diagnosis and reporting of

pathogens. Specific topic areas of study interest include:

- (1) Improving understanding of the burden, incidence, prevalence, or distribution of endemic, novel, or emerging/re-emerging diseases
- (2) Strengthening understanding of environmental or population risk factors influencing transmission or zoonotic spillover (e.g. cultural practices, infection prevention and control, migratory and grazing pathways) to develop prevention or mitigation strategies
- (3) Evaluating detection or diagnostic methodologies (e.g., evaluating commercial offthe-shelf kits in a country's biosurveillance system, designing effective detection protocols)
- (4) Evaluating or designing effective and self-sustaining training programs to enhance partner nation capabilities to detect and diagnose disease.
- (5) Testing or evaluating biosecurity or biorisk management protocols to develop an evidence base to inform local biosecurity or biosafety guidelines
- 1.2 <u>Mission considerations:</u> BTRP engagements are comprised of multiple projects and activities that fall along defined lines of effort (LOEs). These LOEs are part of a framework that BTRP uses to measure program success. When proposing to topic areas outlined above, or to topic areas introduced as amendments to this BAA, submissions should consider these LOEs to the fullest extent possible.
 - LOE 1: Consolidating and Securing Pathogens
 - Studies should be designed so as to reduce the size and scope of reference sample collections and/or not promote development of new or expanded repositories to support study goals.
 - LOE 2: Facility-Level Biorisk Management Systems and Culture
 - Biorisk management is a core mission area of the BTRP and should be included in the technical approach so that proposed studies clearly articulate building and reinforcing biorisk management best practices across the spectrum of project activities.
 - LOE 3: National-Level Regulatory Frameworks
 - Studies should incorporate and reinforce international best practices for biosafety and biosecurity aligned with partner country laws and regulations, and support a culture of responsible and ethical scientific conduct.
 Submissions should include thoughtful experimental design and appropriate laboratory approaches that result in meaningful data in accordance with the highest domestic and international ethical standards (e.g., institutional review boards, ethical review committees).
 - LOE 4: Disease Detection
 - Studies should be designed to provide actionable information to support disease detection goals and should reinforce disease detection capabilities

provided by BTRP, to include provided equipment and training.

- LOE 5: Laboratory Diagnostics
 - To the fullest extent possible, studies should include BTRP-engaged laboratory facilities, use commercial-off-the-shelf (COTS) or locally available consumables and supplies, and leverage BTRP-provided training and equipment for laboratory diagnostics.
- LOE 6: Epidemiological Analysis and Investigation
 - Studies should be designed to support animal and human public health biosurveillance goals, including increasing awareness of endemic pathogens and identifying trends and patterns that may indicate the presence of higher risks to populations.
- LOE 7: Reporting and Communication
 - Studies should aim to use national reporting systems, where applicable, and stimulate integration and interoperability of disease surveillance systems by advancing implementation and sustainment of global health security and One Health initiatives, and emphasizing the nexus of disease surveillance, biorisk management, and health security.
- 1.3 <u>BTRP will not consider proposals that contain any of the following</u>: (1) risks to the Program's threat reduction mission; (2) Dual Use Research of Concern (DURC) or related activities; (3) medical countermeasures development; or (4) pathogens/diseases that other U.S. agencies have dedicated missions to address (e.g., HIV/AIDS, malaria, rabies, tuberculosis).
- 1.4 <u>Geographic scope</u>: BTRP is interested in collaborative engagements with foreign partners in any of the following: countries of the Former Soviet Union (FSU), Africa, Southeast Asia, and Middle East/South Asia. BTRP encourages applicants to develop projects in conjunction with foreign institutions in BTRP-engaged countries. Projects may consist of collaborations with a single partner country or regional/trans-regional efforts spanning multiple BTRP-engaged countries. Additional geographic areas may be sought as Amendments to this BAA.

2 AWARD INFORMATION

2.1 Award Types. Awards made as a result of this announcement will be either grants or cooperative agreements. Each of these award instruments offers different advantages, liabilities, and responsibilities for applicants and the Government.

Applicants must specify in their application their recommended approach (e.g., grant or cooperative agreement); 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 prepriced options.

The Government actions under this BAA shall adhere to the requirements of the DoD

Grant and Agreement Regulations (DoDGARs). The DoDGARs can be accessed online at https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-C/part-21/subpart-C. See also 22 Code of Federal Regulations (CFR), which can be accessed online at https://www.ecfr.gov/current/title-32/part-22. 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.

The number of individual awards BTRP will make each year is subject to the availability of funds. The predominance of awards are anticipated to be grants. Payments on grants will be made in advance, subject to the conditions described in 2 CFR 200.305.

- 2.2 Subawards. Subawards are permitted. Subawards may be used to carry out a portion of the proposed project. Awards may have multiple subawards. Awards will be made by a single award (e.g., grant or cooperative agreement) to the prime awardee. All subawards are the responsibility of the prime awardee; exceptions will not be made.
 - There is no limitation on the number of subawards. BTRP will review and consider the proposed subawards for all White Papers and Full Proposals. The prime awardee will be responsible for transferring funds to all subawardees.
- 2.3 Award Values. Awards may range in value depending on the nature and the scope of work. All awards are subject to the availability of funds. Selection and award of projects under this BAA is highly competitive and the costs of proposed work should be carefully controlled as detailed herein or as indicated in the invitation instructions.
- 2.4 Period of Performance and Award Structure. Efforts may be proposed for a total of up to 5 years to include a base period of no longer than 3 years and additional years as possible options. Additional guidance regarding award structure may be provided in specific topic Attachments (via Amendment to this BAA) or in communications with the applicant to include the coordination of the Abstract or in the debrief summary of the White Paper. Any specific guidance provided via Amendment to this BAA or from the official administrator email (Section 7) supersedes the information provided herein.
- 2.5 The Government may offer funding for any Full Proposals or portions of proposals at any time during the open period of this BAA.

3 ELIGIBILITY INFORMATION

- 3.1 Abstracts, White Papers, and Full Proposals submitted for the BAA will be considered from the following U.S. and foreign institutions as follows:
 - Accredited degree-granting colleges, universities, and academic institutions.
 - Industrial and commercial entities, including small businesses.
 - Not-for-profit entities with a portfolio predominantly in research and foreign government laboratories. Proof of 501(c)(3) status from the Internal Revenue Service may be required. For foreign-based establishments entirely based outside the U.S. and/or its territories, proof of not-for-profit status may be required. Foreign based

government laboratory equivalents include (but are not limited to) those residing in a country's Ministry of Defense, Ministry of Health, Ministry of Agriculture, Ministry of Education and Science and Food Safety AgenciesC.

The following entities are not eligible to receive funds nor furnish Principal Investigators (PIs) in awards made under this BAA but may participate as collaborators, including as Co-PIs, on an applicant's proposal. The following entities must submit their proposed collaboration work under a separate Government Call solicitation:

- 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 (www.acq.osd.mil/dpap/dars/dfars/html/current/235_0.htm).
- DOE-sponsored FFRDCs.

Note: The separate Government Call solicitation will include full eligibility and submission instructions. Federal laboratories (including DoD and DOE) and FFRDCs may be eligible to submit Abstracts, White Papers, and Full Proposals in response to separate Government Call solicitations. 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. Awards made under the separate Government Call solicitation will be Interagency Agreements/Interagency Orders and/or Military Interdepartmental Purchase Requests (MIPRs), in accordance with all applicable requirements under The Economy Act, 48 CFR 17.502-2 (31 U.S.C. 1535), or a more specific non-Economy Act authority, where applicable.

- 3.2 Cost Sharing or Matching. In general, cost sharing or matching is not required for applications to the BAA. However, BTRP reserves the right to require cost sharing or matching on a case-by-case basis. Such instances will be specifically detailed in Amendments to this BAA or from the official administrator email (Section 7).
- 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 sam.gov.

4 APPLICATION AND SUBMISSION INFORMATION

- 4.1 General information
- 4.1.1 Address to Request Application Package. This announcement contains all information required to submit an Abstract, White Paper, and Full Proposal.
- 4.1.2 Form of Application Submission. Submission to this BAA is conducted in three phases: Abstract (Phase 0), White Paper (Phase I), and Full Proposal (Phase II). For Phases I and II, up to one revised submission may be requested per phase. Specific information on

- each phase is detailed below.
- 4.1.3 Applicants are responsible for ensuring compliant and final submission of their Abstract, White Paper, and Full Proposal package. Note that this also applies to applicants using third party systems to submit application packages and appendices. Any submission that does not conform to the requirements outlined in the BAA and in the invitation for submission may not be reviewed or considered further at the discretion of BTRP.
- 4.1.4 BTRP will not review Abstracts, White Papers, and Full Proposals that are not submitted in the English language.
- 4.1.5 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 consideration. Applicants may also be removed from consideration if the applicant and the Government fail to negotiate final proposal details within a reasonable period of time as determined by the Government's business judgment.
- 4.1.6 All submissions must be completely UNCLASSIFIED; submissions must not contain Controlled Unclassified Information (CUI) or be marked as such.
- 4.1.7 Marking Guidance for White Papers and Full Proposals and Disclosure of Proprietary Information other than to the Government. White Papers and Full Proposals submitted in response to this BAA may contain technical and other data that the applicant does not want disclosed to the public or used by the Government for any purpose other than application evaluation. Public release of information in any White Paper and/or Full Proposal submitted will be subject to existing statutory and regulatory requirements.

If proprietary information which constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting national security, is provided by an applicant in a White Paper and/or Full Proposal, it will be treated in confidence, to the extent permitted by law, provided that the following legend is included on the front page of the White Paper and/or Full Proposal:

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

Any other legend may be unacceptable to the Government and may constitute grounds for removing the White Paper and/or Full Proposal from further consideration without assuming any liability for inadvertent disclosure.

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

"Use or disclosure of the White Paper and/or Full Proposal data on lines specifically identified by asterisk (*) are subject to the restriction on the front page of this White Paper and/or Full Proposal."

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

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

By submission of a White Paper and/or Full Proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. BTRP will obtain a non-disclosure agreement from the evaluator that proprietary information in the White Paper and/or Full Proposal will only be used for evaluation purposes and will not be further disclosed or utilized.

- 4.2 Abstract submission
- 4.2.1 Applicants must submit Abstracts via email (Section 7). Please note that attachments to emails other than an Abstract may not be reviewed.
- 4.2.2 Abstracts may be submitted at any time. In general, submission of an Abstract will initiate pre-coordination with a BTRP technical Point of Contact (POC). BTRP reserves the right to waive pre-coordination for topics on a case-by-case basis and will state the waiver applies within individual topic descriptions published as additional Attachments (via Amendment to this BAA).
- 4.2.3 Abstracts should be 250 words or less and briefly describe the proposed effort including: area of interest addressed; intended project outcomes aligned to LOEs; and the country/countries where the project will take place, with relevant participating institution(s).
- 4.3 White Paper submission
- 4.3.1 Based on evaluation of the Abstract and result of pre-coordination, selected applicants will be notified by email of invitation to submit a White Paper, with corresponding submission instructions. Applicants have 60 days from the date of this invitation to submit the White Paper. If the submission is not feasible within this 60-day window, the abstract must be re-submitted to ensure the interest in the White Paper remains. Invited 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). White Papers may be evaluated at any time after submission. White papers for specific topic areas published

- as Amendments to this BAA should follow the timelines specified in that Amendment.
- 4.3.2 BTRP will not review White Papers that are not invited, unless specified in specific topic areas published as Amendments.
- 4.3.3 White Papers may be up to four pages. Any pages submitted for the White Paper that exceed the limit of four pages may 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.
- 4.3.4 At a minimum, the White Paper should include the following:
 - A project abstract that concisely (less than 250 words) summarizes the proposed project and demonstrates relevance to the topic being addressed. The abstract should not contain any proprietary data or markings.
 - A description of how the proposed project will address specific biological threat reduction topic areas with partner countries, including whether the project leverages any prior BTRP investments
 - A brief description of experimental designs and methodologies.
 - A description of how the proposed project will produce demonstrable and enduring outcomes, including how the project will contribute to sustainable detection, diagnostic, and reporting capabilities.
 - A list of the BTRP LOEs to which the project will align. A list of LOE numbers is sufficient. No supporting narrative is required.
 - Cost estimate by year and total dollars required to accomplish the project as presented in the White Paper (no details or breakout of costs is required).
 - A brief description of the role and contribution of each participating institution/department, including the level of effort and roles of partner nation scientists.
 - 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.
- 4.3.5 Revised White Paper Submission and Content. On a limited basis a revised White Paper may be requested by the Government based on the review of the original White Paper. Revised white papers will be requested when additional information on the technical approach, sustainability of methodologies, and/or capabilities addressed is needed before consideration for inviting a Full Proposal. Revised White Papers must conform to the standards for White Papers detailed in this section. At a minimum, the revised White Paper should address the issues and questions detailed in the debrief summary. In addition to making revisions directly within the White Paper, applicants are encouraged to provide an Issue Resolution document based on the additional information requested in the debrief summary to expedite review of the revised White Paper. This Issue Resolution document, similar to a 'response to the reviewers' submitted with revised

manuscripts, should: a) reference the location, throughout the revised White Paper, where the applicants specifically addressed each individual request, and b) briefly describe how each request was specifically addressed.

- 4.4 Full Proposal submission
- 4.4.1 Invitations for Full Proposal submission may occur any time after White Paper evaluation. Note that Full Proposal invitations may be limited to available program funds.
- 4.4.2 BTRP will not review application packages and Full Proposal submissions that were not invited.
- 4.4.3 The due date for invited Full Proposal submissions will be provided in the letter of invitation. The applicant will be allowed at least 45 days to prepare a Full Proposal submission; there is no penalty for early submissions. An extension for submission of the Full Proposal submission may be requested by emailing the administrative email address in Section 7 prior to the deadline for the proposal submission. Approval or declination of the extension request will be in the discretion of the Government. Full Proposals may be evaluated at any time after submission.
- 4.4.4 Invited Full Proposals must be submitted electronically using www.grants.gov and the corresponding application packages linked with this BAA on www.grants.gov (under the "Packages" tab).
- 4.4.5 Registration with www.grants.gov. Applicants should note that each organization must complete a one-time registration in order to submit Full Proposal(s) through www.grants.gov. Please see the following web link on information about registering with www.grants.gov: https://www.grants.gov/web/grants/applicants/organization-registration.html. If your organization is already registered in www.grants.gov, no further action should be required.
 - The registration process requires multiple steps and may take up to 4 weeks to complete depending on your organization.
- 4.4.6 The Full Proposal application package posted to www.grants.gov includes the forms and appendices as detailed in Table 1. BTRP reserves the right to consider incomplete application packages and required appendices and to request any missing information via email. Should the applicant fail to provide all the requested information either as part of the www.grants.gov submission or in response to email requests, BTRP may elect to not consider the proposal further.

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 and Microsoft Excel spreadsheet	Attach to Section K in budget period one

RR Sub-award Budget Attachment(s) Form (if applicable)	Individual sub-award budgets and corresponding Microsoft Excel spreadsheets	Attach a separate budget with justification and Microsoft Excel spreadsheet for each sub-award		
	PI Biographical Sketch	Attach to Biographical Sketch field		
Research & Related	PI Current/Pending Support	Attach to Current & Pending Support field		
Senior/Key Person Profile Form	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	Publicly 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		
	Appendix 1 – SOW	Upload as Appendix 1		
Appendices	Appendix 2 – Quad Chart	Upload as Appendix 2		
rippendices	Appendix 3 – Supporting Documentation	Upload as Appendix 3		

Table 1: Full Proposal Package Forms and Appendices.

- 4.4.7 File Format. Documents should be uploaded as a Portable Document File (PDF) format. Applicants should confirm that conversion to PDF maintains formatted, legible submission materials, particularly spreadsheet data. Perform a virus check before uploading any files to www.grants.gov as part of your application package. If a virus is detected, it may cause rejection of the file. Do not lock or encrypt any files you upload to www.grants.gov as part of your application package. Movie and sound file attachments will not be accepted.
- 4.4.8 BTRP-specific instructions for forms and appendices are as follows:

4.4.8.1 SF 424 (R&R) Application for Federal Assistance:

- Block 1 Type of Submission. Applicants should indicate the Full Proposal 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 identification number assigned by DTRA to the corresponding White Paper submission. If the last submission was a revised White Paper, enter the White Paper identification number for the revised submission.

- Block 5 Applicant Information. You must provide a Business Office Point of Contact (BPOC) with an email 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.
- 4.4.8.2 *RR Budget Form:* The Research and Related Budget Form provided as part of the application package for the Full Proposal 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. As part of the budget justification, applicants will be requested to provide their current rate agreement and the rate agreement of their subaward(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 awardee or any subawardees. All costs proposed shall be in United States Dollars.

The following costs are considered to be unallowable and should not be included in any proposals:

- Catering (such as food and beverage, coffee breaks, alcohol, etc.)
- Parties or celebrations
- Entertainment
- Other than economy airfare
- Foreign taxes in excess of \$500 per transaction
- Fee/Profit, Facilities Capital Cost of Money (FCCM), Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration.
- Additional information regarding allowable and unallowable costs can be found at the following location: https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-E.
- Other costs as determined by the Government.
- Applicants should plan and budget for travel to accommodate the meetings outlined below:
- Project Launch Meeting: Applicants should plan a project launch meeting to be held within the first three months after a project is awarded with in-country stakeholders. Attendees to this meeting should include but are not limited to the PI and Co-PIs, and all relevant in-country stakeholders. This meeting is distinct from administrative or technical kick-off meetings that would be held with the Grant/Agreement Officer's Representative and the Grant/Agreement Officer, which may be held virtually. Under circumstances when travel is not feasible, the project launch meeting may be held in an approved virtual environment.
- Conferences/Workshops/Symposia: Applicants are strongly encouraged to attend an
 internationally recognized conference, workshop, or symposium in the field of study
 each calendar year (one at minimum). Study results 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 collaborating
 partner country scientists supporting the study, as appropriate.
- Annual Technical Review: Applicants should plan to attend annual technical
 program review meetings to be held in partner countries or in a mutually agreed
 upon host country when travel to particular a partner country is restricted. Under
 circumstances when travel is not feasible, annual technical review meetings may be
 held in an approved virtual environment.
- Project Closeout Meeting: Applicants should plan a project closeout meeting to be conducted within the last 90 days of the project. Attendees to this meeting should include but are not limited to the PI and Co-PIs and the Contracting/Grant Officer's Representative. Under circumstances when travel is not feasible, the project closeout meeting may be held in an approved virtual environment.
- Applicants should also plan and budget for resources needed to address reporting requirements and regular progress reviews as outlined in Section 6.3.

- 4.4.8.3 <u>Budget Justification</u>: Applicants are required to submit a budget justification. The budget justification should be prepared as outlined in the instructions for the Research and Related Budget and uploaded as an attachment to Section L "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) costs were determined to be fair and reasonable. The budget justification should identify all basis of estimates relating to estimated costs and delineate separately the basis for both the applicant and subaward(s). These budget justifications should be in a narrative that supports the proposed estimates for the following:
 - Labor costs, to include level of effort and salary requested
 - Labor categories
 - Other direct costs (excluding travel)
 - Equipment (to include quantities, part/make/model numbers and any other specifications to permit ease of evaluation)
 - Materials (to include quantities, part/make/model numbers and any other specifications to permit ease of evaluation)
 - Travel (to include a breakout of each proposed trip, number of travelers, departure and destination location, number of days, ground transportation methods, airfare, basis for per diem (meals and lodging), and any other proposed travel related costs). Please note that on the first and last days of each proposed trip, the meals and incidentals (M&IE) cannot exceed 75% of the allowable M&IE rate.
 - Indirect Costs: The budget justification should identify all indirect cost rates (such as fringe benefits, F&A, etc.) and applicable allocation bases. If composite rates are used, provide the calculations used in deriving the composite rates. Provide copies of current rate agreements, as applicable. Indirect costs for grant and cooperative agreements should be proposed in accordance with the DoDGARs. Entities without negotiated indirect cost rate agreements should propose the 10% de minimis.

The Government does not anticipate the need to provide any hardware or software to execute the proposed work. However, BTRP will review and consider any hardware/software requests for all White Papers and Full Proposals on a case-by-case basis. The budget justification should address sustainability costs a partner country will incur once the project is over, if any, for any such hardware/software requests.

Documentation to support all proposed costs should be included in the budget justification file. All supporting documentation must be in English with costs presented in United States Dollars.

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- 4.4.8.4 <u>Microsoft Excel Spreadsheet:</u> Applicants are required to submit a Microsoft Excel spreadsheet that should correspond with and be easily traceable to the RR Budget Form and budget justification. The spreadsheet should include all proposed costs for the applicant and any subawards, and it should be in Microsoft Excel with working formulas unlocked and intact with no hidden rows or columns or macros. Lump sums without any supporting information will not be accepted. The spreadsheet should delineate the applicant and any subaward(s) with working formulas for proposed estimates for labor costs, indirect costs (to include base and all individual percentage(s) used in calculation), other direct costs (excluding travel), travel, equipment, and materials.
- 4.4.8.5 *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. Microsoft Excel spreadsheets that correspond and are easily traceable to the subaward RR Budget Form and budget justifications are required. The spreadsheet should include all proposed costs for any proposed subawards, and it should be in Microsoft Excel with working formulas unlocked and intact with no hidden rows or columns or macros. Lump sums without any supporting information will not be accepted. The spreadsheet(s) should contain working formulas for proposed estimates for labor costs, indirect costs (to include base and all individual percentage(s) used in calculation), other direct costs (excluding travel), travel, equipment, and materials. Applicants are responsible for ensuring their subaward proposals are complete and compliant.
- 4.4.8.6 <u>Research and Related Senior/Key Person Profile Form (Expanded)</u>: 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. The PI (and Co-PIs) in the region of interest should be included as key personnel.

A biographical sketch is required for each PI and Co-PI on the project. BTRP does not have a preference for the format of the biographical sketch; however, it should be limited to one page per person. The biographical sketch should be uploaded as an attachment to the corresponding field on the Research and Related Senior/Key Person Profile Form.

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

- A list of all current projects the individual is working on, in addition to any future support the individual has applied to receive, regardless of the source.
- Title and objectives of the other 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 projects or will receive if other proposals are awarded.
- Name and address of the agencies and/or other parties supporting the other projects.
- Period of performance for the other projects.
- 4.4.8.7 **RR Personal Data Form:** 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, BTRP will include with each Full Proposal application package the Research and Related Senior/Key Person Profile (Expanded) form and the Research and Related 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.

4.4.8.8 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." BTRP will collect and post via the Defense Technical Information Center (DTIC) basic information about all awards made under the 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 expected contributions to biological threat reduction. 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 BTRP for use in fulfillment of Section 8123 of the FY15 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-

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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. Note that Co-PIs from federal laboratories must submit a separate proposal package via the corresponding Government Call solicitation (see Section 3.1). Narratives for BAA and Government Call submissions aligned to the same project must reference the identifier numbers and projects for related submissions, and should describe the applicant's specific contribution to the overall effort.

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.* A clear description of the topic area to be investigated (including which BTRP LOEs the project will primarily address), the objectives/goals of the study, and major milestones/expected outcomes.
- *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 the prime awardee organization's management plan for the proposed project; list supporting and collaborating centers, and the roles/responsibilities of each identified subawardee supporting the project. All participating facilities in each partner country should be fully described with a discussion of how any unique capabilities, capital equipment, and/or computer platforms will be transitioned to the participating country partners.
 - Narratives must also describe the extent and duration of the relationship/collaboration between the universities/institutes/entities and/or scientists, clearly differentiating the role of partner nation personnel and international staff. Teams with pre-existing collaborative relationships and those which propose to establish new collaborations will be considered, provided teams can supply documentation to demonstrate that an operational framework exists to support the proposed work. Please see the description of Appendix 3 below for information on submission of this documentation.
- *Relevance*. Provide an explanation of how the proposed project is relevant to the topic area and advancing safe and secure detection, diagnosis, and reporting capabilities. When addressing how the proposed project advances capabilities, applicants must clearly outline the anticipated outcomes gained from the investment and justify the scientific contribution of each participating institution. This should include descriptions of the BTRP LOEs that the project aligns to, and an impact statement outlining how and by what magnitude the project improves the partner nation's capacity, capability, or sustainability in biosecurity, biosafety, and biosurveillance.
- *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, as well as clearly define which project partners will be performing the tasks. If project partners are submitting related proposals for the same overall project effort (e.g., under a separate Government Call, see section 3.1), clearly identify related proposals but be specific in each proposal about the work that will be done only in that proposal. Tasks must be grouped by project year; base and option years should be clearly labeled. All proposed training should be described, including how the success of each training event will be assessed and how relevant training activities will be sustained after conclusion of the project. All capability building activities (e.g., training, skills development, improved proficiencies, etc.) must be included, as well as the objectives, end-states, target participants and alignment to BTRP Domains and Competencies Training Framework (DCs) (Attachment 1).
- Sample Repository. Narratives must clearly identify how the applicant plans to maintain samples collected during the proposed effort, along with relevant metadata, for at least 12 months after the project end date. Applicants must provide a plan and schedule for final disposition of samples collected in support of the effort in accordance with the highest level of domestic and international scientific standards. Sample maintenance plans should reflect that samples and the data collected from those samples are the property of the nation where samples are collected.
- Regulatory, Ethical, and Oversight Approvals. For additional discussion, see Section 6.2.2. Applicants shall provide justification for any sampling strategies, the source of collected samples, and address any required ethical and oversight requirements. Applicants shall include a timeline for securing the appropriate country, regulatory, ethical, and oversight approvals in the proposal, prior to the proposed start of any work, or submit written evidence that approvals are secured. Applicants should plan on DTRA Oversight Board reviews taking up to 4 months to complete. Further information may be required if the proposal is successful, including provisional protocol numbers, review board point of contacts, or letters of support from partner country institutions or ministries, where applicable.
- *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.
- 4.4.8.9 <u>Disclosure of Lobbying Activities (SF-LLL) Form:</u> The Disclosure of Lobbying Activities Standard Form-LLL, if applicable, should be completed.
- **4.4.8.10** <u>Appendices:</u> The appendices should be used to include the following three items with the application:
- 4.4.8.10.1 **Appendix 1 Statement of Work (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 describe the activities to be performed, as well as clearly define which project partners will perform the tasks. The proposed SOW must 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 project is being pursued and what knowledge is being sought.
- *Scope:* Include a statement of what the SOW covers including the topic area to be investigated, objectives/goals, and major milestones and schedule for the effort, including which BTRP LOEs the project will primarily address.
- *Background:* The applicant must identify appropriate documents, including publications that are applicable to the project to be performed. This section includes any information, explanations, or constraints that are necessary in order to understand the hypothesis and scientific impact on capabilities being addressed in the work. It may also include previously performed relevant studies and preliminary data.
- description of tasks which represent the activities 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 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 work 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 proposed milestones must be presented by project year and task in the same sequence as in the Project Narrative/Technical Proposal. The SOW should include major overarching tasks to be completed and an anticipated schedule. The tasks must be definite, realistic, and clearly stated and should consider reporting requirements.

If the proposed work will include securing government, regulatory, ethical, or other oversight approvals, these should be included as separate tasks with clearly defined milestones.

The schedule should include proposed base period and option year breakdowns, ensuring that the base period has objectives which, upon completion, provide clear value to the Government independent of exercising option years. Required approvals should be considered when proposing these breakdowns. 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."

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4.4.8.10.2 **Appendix 2 – Quad Chart.** The quad chart must be presented on one 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 "Appendix 2" of the appendices. The quad chart should specifically address the performers of the work being proposed under the submission, and clearly note whether work will be covered under a separate project submission (see section 3.1).

4.4.8.10.3 Appendix 3 – Supporting Documentation.

Operational Framework: Narratives must also describe an operational framework to support the proposed work. This includes, but is not limited to, the extent and duration of the relationship/collaboration between the universities/institutes/entities and/or scientists. Teams with pre-existing collaborative relationships and those which propose to establish new collaborations will be considered, provided teams can supply documentation to demonstrate that an operational framework exists to support the proposed work. Each of the following should be provided as a single document, in the order specified:

- Specific identification of foreign PIs/Co-PIs and job titles for other members of the foreign study team.
- Detailed description of the relationship between the proposed project and current efforts at the foreign institution.
- Description of facilities and any other evidence of suitability of foreign collaborators and sites. In the event that the foreign component will require country, regulatory, ethical, and/or oversight approvals, documentation or a plan to secure approvals must be provided.
- Foreign PI letter of collaboration describing, at minimum, the suitability of the proposed work with respect to ongoing efforts at the foreign institution, merit of the proposed collaboration, the scope and magnitude of participation by all participating foreign scientists, and the expected mutual benefits.

BTRP Domains and Competencies Training Framework (DCs) Matrix: Applicants must complete the DCs matrix to demonstrate the anticipated alignment of capability building activities to the DCs (<u>Attachment 1</u>).

Protocol Risk Assessment Tool (PRAT): Applicants will be provided a copy of the PRAT file following their invitation to submit a Full Proposal and complete it in its entirety for each institution participating in the project. Additional instructions for completing the PRAT are found within the file. The completed PRAT file(s) should be emailed (Section 7) as a Portable Document File (PDF) format within 2 weeks of the Full Proposal submission. Do not attempt to include the PRAT(s) with the www.grants.gov submission.

4.4.9 Revised Full Proposal Submission and Content. On a limited basis a revised Full Proposal may be requested based on the review of the original Full Proposal. Revised proposals will be requested when more information on the project scope, technical approach, capabilities, and/or cost is required before the proposal could be further

considered for award. Applicants whose proposals are of interest to BTRP may be contacted to provide additional information prior to the final funding decision. This request for further information may include revised budgets or budget explanations, revised SOWs, and other information, as applicable, to the proposal. Additional instructions may be provided in the request for a revised proposal. Revised Full Proposals must conform to the standards for Full Proposals detailed in Section 4.1.5.

Submissions should be made with the appropriate Full Proposal application package and should be completed in accordance with the instructions provided in the notification email. In addition to making revisions directly within the proposal, applicants must provide an Issue Resolution document based on the additional information requested in the debrief summary to expedite review of the proposal. This Issue Resolution document, similar to a 'response to the reviewers' submitted with revised manuscripts, should: a) reference the location, throughout the various proposal sections, where the applicants specifically addressed each individual information request, and b) briefly describe how each request was specifically addressed.

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 Full Proposal submission is a "Changed/Corrected Application."
- Block 4b Agency Routing Identifier. Enter the corresponding White Paper ID.
- Block 4c Previous <u>www.grants.gov</u> Tracking ID. Enter the Full Proposal ID for the original Full Proposal submission.
- 4.4.10 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 Grant/Agreement Officer via the administrative email address listed in Section 7.
- 4.4.11 Submission Dates and Times.

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

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

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 appendices are submitted to www.grants.gov after the exact time and date specified in this announcement or in any written communications

provided by BTRP, the application may be considered "late" and may not be reviewed.

If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be submitted to www.grants.gov by the exact time specified by BTRP 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.

- 4.4.12 Other Submission Requirements.
- 4.4.12.1 Compliance with Appendix A to 32 CFR 28. All awards require certifications of compliance with Appendix A to 32 CFR 28 regarding lobbying. Applicants 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, applicants should submit the Disclosure of Lobbying Activities (SF-LLL) Form in accordance with Section 4.4.8.9.

5 APPLICATION REVIEW INFORMATION

- 5.1 Evaluation Criteria. The five evaluation criteria to be used for responses received to this BAA are as follows:
 - 1. Technical/Scientific Merit:
 - a. Enhancing early warning capabilities for pathogens. The objective of this criterion is to assess the extent to which the proposed project will enhance detection, diagnosis, and reporting capacities and capabilities to reduce the impact of disease outbreaks on the health security of local, regional, and global stakeholders.
 - b. Strengthening local/regional biosurveillance networks. The objective of this criterion is to assess the extent to which proposed project strengthens partner country biological threat reduction capacities and/or capabilities through improved cooperation between local, regional, and/or global partners.

2. Value to Mission Goals:

- a. Alignment with BTRP country/regional goals. The objective of this criterion is to assess the extent to which the proposed project is aligned with, and advances, LOEs and DCs. Aside from scientific merits, proposed projects should have quantitative and/or qualitative measures that accurately capture the proposed benefits as a product of capacity, capability, or sustainability improvements.
- b. Supporting transition and sustainability of detection, diagnosis, and reporting capacities. The objective of this criterion is to assess the extent to which the proposed project will provide and/or strengthen capacities and/or capabilities (including equipment, laboratory workflows, trainings, etc.) that can be realistically transferred to, and sustained by, partner country collaborators after conclusion of the project.
- 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 and proposed team have the requisite skills, and resources necessary to carry out the proposed project.
- 4. Cost Realism: 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. Dual-Use Potential: The objective of this criterion is to ensure that DTRA maintains the highest possible level and transparency and compliance with all international scientific and non-proliferation norms. Proposals that contain dual-use risks or Dual-Use Research of Concern (DURC) will not be funded. For a full discussion see Section 6.2.4.
- 5.2 Review and Selection Process. Abstracts, White Paper and Full Proposal selection will be 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 Abstract, White Paper, and Full Proposal submitted 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 Abstract/White Paper/Full Proposal as it relates to alignment to BTRP requirements, rather than against other pre-application White Papers/Full Proposals for research in the same general area.

Abstracts will be reviewed for alignment to the topic areas and scope listed in this BAA. Those that align to topic and scope will initiate pre-coordination with the appropriate BTRP POC.

White Paper evaluation will be based on the two equally weighted criteria of (1) Technical/Scientific Merit and (2) Value to Mission Goals. The criteria will be scored as Outstanding, Good, Acceptable, Marginal, or Unacceptable. Any criterion scored as "Unacceptable" will render the White Paper "Not Selectable," and the White Paper will not be considered further.

The Full Proposal evaluation will be based on the five criteria listed above. Of these, the first two 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, Good, Acceptable, Marginal, or Unacceptable. The fourth and fifth criteria of (4) Cost Realism and (5) Dual-Use Potential will be scored as either Acceptable or Unacceptable. Any criterion scored as "Unacceptable" will preclude the proposal from being found "Selectable," and the proposal may not be considered further.

Rating	Description
Outstanding (O)	Proposal is an exceptional submission. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Good (G)	Proposal is a thorough submission. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low. May be recommended for acceptance but at a lower priority than submissions rated 'Outstanding'.
Acceptable (A)	Proposal is an adequate submission. Strengths and weaknesses are offsetting or will have little or no impact on performance. Risk of unsuccessful performance is no worse than moderate. May be recommended for acceptance but at a lower priority than submissions rated either 'Outstanding' or 'Good'.
Marginal (M)	Proposal is a weak submission. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
Unacceptable (U)	Proposal is not pertinent to program goals and objectives and contains one or more deficiencies. Proposal is not awardable.

Table 2: Evaluation Scoring Definitions

Other factors that may be considered are duplication with other studies, program balance, past performance and budget limitations. At any point during the application process, the Government reserves the right to perform a review of past performance.

BTRP strongly encourages and may give preference to submissions that demonstrate a significant contribution (significant is defined as a minimum of 50% of total value) by one or more partner country institutions. Additional guidance regarding participation of partner country institutions may be provided via Amendment to this BAA or in communications with the applicant to include the coordination of the Abstract or in the debrief summary of the White Paper.

BTRP also strongly encourages and may give preference to submissions that demonstrate a contribution from Historically Black Colleges and Universities (HBCUs), Minority-serving Institutions (MSIs) (e.g. 1890 Land Grant Institutions) in the U.S.

Preference will be given to projects where partner nation early career scientists (including undergraduate and graduate students) are supported by the awards. Details regarding the participation and value of the research to early career scientists are expected in the White Paper and Full Proposal. Any specific guidance provided via Amendment to this BAA supersedes the information provided herein.

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 reserves the right to make awards without exchanges with applicants; however, the Government reserves the right to conduct exchanges if determined necessary. The Government also reserves the right to request applicants consider revisions to submitted Full Proposals to increase the clarity and/or strength of the proposal. Applicants may decline to participate in any revisions to application packages requested by BTRP.

5.3 BTRP 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 2 CFR 200.1). 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 2 CFR 200.206 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 BTRP to use both Government and non-Government personnel to assist with the review and administration of submittals for this BAA. All Abstracts, White Papers, and Full 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 activities proposed.

Further, participation in this BAA requires BTRP support contractors to have access to White Paper and Full 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 Full 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 White Papers and/or Full Proposals, selection/non-selection for award, etc.) via email 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 emails.

A notice of selection should not be construed as an obligation on the part of the Government; only duly authorized personnel may commit resources, this will be done by issuing a grant or cooperative agreement 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 the administrative email address provided in <u>Section 7</u>.

Applicants must be aware that it is their responsibility to ensure: (1) correct email addresses are provided at the time of submission, (2) this email notification reaches the intended recipient(s), and (3) the email 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 email messages.

If for any reason there is a delivery failure of these email 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.

This BAA focuses on fundamental research, as defined by DoD and detailed in Section 1.1 of this BAA. Per DoD policy¹, "...products of fundamental research are to remain unrestricted to the maximum extent possible." Furthermore, "The DoD will place no other restrictions on the conduct or reporting of unclassified fundamental research, except as otherwise required by statue [sic], regulation, or Executive Order." The Fundamental Research Exclusion provides that the information and software (except certain encryption source code) that result from fundamental research are outside the scope of the International Traffic in Arms Regulation (ITAR) (22 CFR Parts 120-130) and the Department of Commerce regarding the Export Administration Regulations (EAR) (15 CFR Parts 730-774) and may be disclosed to non-U.S. persons without specific U.S. Government authorization. Proprietary research, industrial development, design, production, and product utilization the results of which are restricted and government-funded research that specifically restricts the outcome for national security reasons are not considered fundamental research. Therefore, the Fundamental Research Exclusion does not apply and authorization is required prior to disclosure to non-U.S. persons.

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

- Finally, the Fundamental Research Exclusion does not permit the transfer of export controlled materials or items abroad, even to research collaborators, unless another exclusion or exemption is available.
- 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 ITAR and the Department of Commerce regarding the EAR. Please note that the prime awardee is responsible for monitoring export control compliance of all subawardees.
- 6.2.2 Regulatory, Ethical, and Oversight Requirements. As a condition precedent to receipt of DTRA funding, applicants must ensure that the appropriate country, regulatory, ethical, and oversight approvals are secured. Applicants shall include a timeline for securing the appropriate approvals in the proposal, prior to the proposed start of any work, or submit with the full proposal package written evidence, to include a provisional government approvals, provisional protocol numbers and Institutional Review Board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) point of contact information. Further information may be required if the proposal is successful, including provisional protocol numbers, review board point of contacts, or letters of support from partner country institutions or ministries, where applicable.

All studies under any award made under this BAA must be conducted in accordance with applicable regulations governing the type of study, which could include: 32 CFR 219, 10 U.S.C. § 980, 21 CFR parts 11, 50, 56, Good Clinical Practice, 9 CFR parts 1-4, (U.S.C. 2131-2156), National Institutes of Health Publication No. 86-23, as well as other applicable federal and state regulations and partner nation laws. In cases where they are differences between countries in regulatory, ethical, or oversight standards, the highest standards shall be applied.

Studies may not begin until the DTRA Oversight Board has reviewed and approved the study protocols. This review is separate from, and in addition to, designated IRB and/or IACUC reviews. Written approval to begin work will be provided in writing from the DTRA Oversight Board. Any proposed modifications or amendments to the approved protocols must be submitted to the performing institution's IRB and/or IACUC and the DTRA Oversight Board for review and approval. Work pursuant to such modifications or amendments must not be initiated without IRB and/or IACUC and DTRA Oversight Board approval.

Projects lasting more than one year require review at least annually, or more frequently as required by the responsible IRB and/or IACUC. The awardee must provide documentation of continued IRB and/or IACUC review of protocols for DTRA review and approval in accordance with the award. Study changes must be reviewed in advance.

Clauses addressing regulatory, ethical, and oversight requirements will be included in all grants and cooperative agreements. Non-compliance with any provision of these clauses may result in withholding of payments under the award pursuant to the award's payments clause(s) and/or award termination pursuant to the award's termination clause(s). The Government shall not be responsible for any costs incurred for work prior to project approvals.

- 6.2.3 Biosafety and Biosecurity 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 working with biosafety level 3 and 4 material, a Facility Safety Plan must be prepared and made available during the project award phase in accordance with 32 CFR 626.18. For awards made 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 studies using select agents not begin or continue until DTRA has reviewed and approved the proposed agent use. See URL: https://www.gpo.gov/fdsys/pkg/CFR-2002-title32-vol3/pdf/CFR-2002-title32-vol3-sec626-18.pdf for a copy of 32 CFR 626.18.). BTRP encourages studies with limited to no biosafety level 4 materials or requirements.
- 6.2.4 Dual Use Potential. DTRA is committed to maintaining the highest possible level and transparency and compliance with all international scientific and non-proliferation norms. In accordance with National Science Advisory Board for Biosecurity (NSABB) recommendations, DTRA will not support studies 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. Moreover, 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 dual-use risks or DURC will not be funded, and projects will continue to be monitored for dual-use risks throughout the lifetime of the project. 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 work 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 work 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.
- Military Recruiting. This is to notify potential applicants that each award under this 6.2.5 announcement to an institution of higher education, with exception of any grants awarded to institutions of higher education entirely located outside the United States and/or its territories, must include the following term and condition: "As a condition for receipt of funds available to DoD under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 CFR 216) that has a policy of denying, and that it is not an institution of higher education that effectively prevents, the Secretary of Defense from obtaining the following for military recruiting purposes: (A) entry to campuses or access to students on campuses; or (B) access to directory information pertaining to students. If the recipient is determined, using procedures in 32 CFR 216 to be such an institution of higher education during the period of performance of this agreement, and therefore to be in breach of this clause, the Government will cease all payments of DoD funds under this agreement and all other DoD grants and CAs, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of award." 32 CFR 216 may be accessed electronically at http://www.ecfr.gov/cgi-bin/text
 - idx?SID=ee45add5e352854b7089ce420c7fd0a6&mc=true&tpl=/ecfrbrowse/Title32/32cf r216_main_02.tpl . If your institution has been identified under the procedures established by the Secretary of Defense to implement Section 558 of Public Law 103-337, then: (1) no funds available to DoD may be provided to your institution through any grant, including any existing grant; and (2) your institution is not eligible to receive a grant in response to this BAA. This is to notify potential applicants that each award under this announcement to an institution of higher education, with exception of any grants awarded to institutions of higher education entirely located outside the United States and/or its territories, must include the following clause: 32 CFR 22.520 (DoDGARs 22.520), Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education.
- 6.2.6 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)).
- 6.2.7 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).
- 6.2.8 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 subawardees 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 subawardees 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.
- 6.2.9 Development of Training Materials. If the proposed activities involve the development of training materials or Standard Operating Procedures (SOPs), applicants must seek written review and approval of those training materials from the Grant/Agreement Officer's Representative (if assigned) and Grant/Agreement Officer at least 60 days prior to implementation of training or distribution of SOPs. Both the awardee and the Government must maintain a copy of this approval. Any proposed modifications to the approved trainings or SOPs must be submitted for review.
 - 6.3 Reporting. General requirements are provided below; however, each awardee should check the award agreement and its 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 and must be provided to the Grant/Agreement Officer's Representative and Grant/Agreement Officer. Reports should contain updates to the sample management plans and equipment provision information. 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 the terms and conditions of the award document. A copy of the final technical report should be provided to the Grant/Agreement Officer's Representative (if assigned) and Grant/Agreement Officer. 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 July 1 of each year. Grants effective after January 31 will not require a Federal Financial Report until July 1 of the following year.
- 6.3.4 Foreign Travel Reports. Within 30 days after foreign travel to BTRP partner countries, the PI may be required to submit a trip report in a BTRP-provided format summarizing the highlights of the trip.
- 6.3.5 Biannual Training Activity Report (TAR). If the work involves training, PIs may be expected to submit TARs, in a BTRP-specified format, reporting training activities and

outcomes.

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

7.1 All correspondence regarding administrative or technical content of this BAA must be addressed to dtra.belvoir.ct.mbx.ctr-baa@mail.mil.

DTRA will not release employee personal contact information.

ATTACHMENT 1: BTRP DOMAINS AND COMPETENCIES TRAINING FRAMEWORK MATRIX

		DOMAINS																								
	Dom	ain 1	Do	omair	12		Dom	nain 3		D	omair	ı 4		D	omair	ı 5		D	omair	1 6	D	omair	ı 7	D	omair	1 8
										-		CON	MPE1	TEN(CIES			-	•							
Training Task	1.1.1	1.1.2	2.1.1	2.1.2	2.1.3	3.1.1	3.1.2	3.1.3	3.1.4	4.1.1	4.1.2	4.1.3	5.1.1	5.1.2	5.1.3	5.1.4	5.1.5	6.1.1	6.1.2	6.1.3	7.1.1	7.1.2	7.1.3	8.1.1	8.1.2	8.1.3
Ex. Task 1.3.2:				X			X										X									
Conduct																										
laboratory-																										
based																										
diagnostic																										
trainings																										

Instructions: This matrix helps track and capture the alignment of training and professional development activities to BTRP's Domains, Competencies, and Proficiencies (DCPs) Framework.

Please note: Alignment is only required to the competency level definitions shown below.

- 1. In the left-hand column of the above chart, list every training activity to be performed on a separate line, using their task or sub-task number (ex. Task 2; subtask 2.1; subtask 2.1.1)
- 2. Place an x or tally against the competencies that align to the training activity. Competency decisions can be made by determining using the definitions listed below and determining if a) the training subject matter corresponds to the defined competency or b) if the training outcome corresponds to the defined competency. Please note: training activities can align to multiple competencies across the eight (8) domains.
 - (*Note*: *If completing an annual report, stop at step 2; if drafting a full proposal, continue to step 3)*
- 3. Once completed, list the aligned competencies under its corresponding training activities in the grant proposal.

Domain	Domain Definition	Competency	Competency Definition				
1. Disease recognition and prevention of spread	1.1 Understanding of disease in the following realms: morbidity, mortality, transmission, control, disease	1.1.1 Disease characteristics and impact	Disease characteristics and epidemiology of pathogens and the diseases they cause, including etiology, signs and symptoms, morbidity, mortality, risk factors, incubation period, period of communicability, mode of transmission, clinical presentation, mechanisms of spillover, reservoir species, spatiotemporal and geographic distributions of affected populations, and demographic characteristics of affected populations (species/age/sex/occupational status/ etc.), including outcomes on population health.				
	presentation and distribution, and impact.	1.1.2 Clinical Infection control and animal health biosecurity	Understanding of basic infection prevention and control procedures related to pathogens for human and animal clinical settings in line with GHSA and IHR milestones (when applicable), including standard precautions (PPE use; disinfection; sterilization); environmental infection control; laboratory testing; nosocomial infections, including AMR; and animal health biosecurity principles, procedures.)				
2. Disease identification, detection, confirmation, and reporting	2.1 Positive identification of diseases and reporting to appropriate authorities.	2.1.1 Sample collection	Knowledge, understanding and proficiency with procedures for safely and securely collecting appropriate specimens/samples for testing of pathogens (human; animal; environmental), especially pathogens, and handling and packaging of samples for transport to diagnostic testing laboratories, based on national and international guidelines and best practices, while ensuring specimens will are maintained in condition required for testing (cold chain and or fixation, etc.)				
		2.1.2 Test procedures (presumptive/	Knowledge, understanding and proficiency with procedures for conducting screening, diagnostic, and confirmatory testing and interpreting test results for pathogens from different types of samples				

		confirmatory)	using different types of tests (ELISA, PCR, etc.), including test accuracy, reliability, specificity, and sensitivity and quality control/quality assurance (QA/QC) measures needed to validate testing results.
		2.1.3 Reporting	Knowledge, understanding and proficiency in policies and procedures for disease notification and/or bi-directional reporting of biosurveillance and laboratory data through national information-sharing systems, or to notify regional/international authorities such as WHO/FAO/WOAH of a disease, other significant epidemiological event, or potential public health emergency of international concern (as appropriate to roles and responsibilities at each operational level).
3. Analytics and assessment	3.1 Appropriate study design, data analysis, and implementation of processes, as applies to each discipline.	3.1.1 Study design and ethics	Knowledge and understanding of scientific methodologies and study design principles (hypothesis development, study plan development, sampling design, strategy for data collection and analysis) and application of biosurveillance study ethics to responsibly address safety, security, and ethical issues related to the study aims and hypotheses, including understanding of issues around dual-use research of concern.
		3.1.2 Methodologies and analysis	Knowledge, understanding and proficiency in the use of statistical and other relevant methodologies for biosurveillance studies including practices and approaches for data collection, use and interpretation of statistical data analyses, data visualization, and use of statistical data software tools.
		3.1.3 Dissemination of	Knowledge, understanding and proficiency in the dissemination of study findings through peer-reviewed scientific journal publications,

		findings and outreach to stakeholders	conference presentations and public outreach activities, including engagement with appropriate stakeholders and partners at national, regional, and international levels.
		3.1.4 Resource mobilization and management	Knowledge, understanding and proficiency in the planning, acquisition, mobilization, allocation, management and tracking of financial and non-financial resources for projects, including proposal development and grant writing.
4. Management, leadership, and advocacy	4.1 Critical skills, knowledge and behaviors necessary to effectively manage projects and programs,	4.1.1 Plan, implements, and evaluates a project or program	Knowledge, understanding and proficiency in program planning, implementation, monitoring and evaluation, including development and measurement of appropriate indicators, and advocacy, or management/oversight of the process.
	lead teams, champion solutions, inspire action, and sustain	4.1.2 Apply program management techniques throughout the	Knowledge, understanding and proficiency in program management, including timeline and deliverables management, team building, and generating high-level stakeholder support.

	programs.	project or program	
		4.1.3 Lead culturally diverse teams to complete a project or program	Knowledge, understanding and proficiency in developing and leading culturally diverse teams, ensuring collaboration among team members, and mentorship of future team leaders.
5. Quality management systems	5.1 Knowledge, skills, and abilities required for developing a culture of quality. Operations, services, and infrastructure	5.1.1 Physical environment and equipment	Knowledge, understanding and proficiency with facility and equipment operations and maintenance, and facility management policies and procedures, in support of establishing a culture regarding physical environment and equipment necessary for pathogen detection, management, and control, or management/oversight of these operations, in a system that meets applicable standards, professional guidelines, and customer requirements for ensuring and maintaining quality and continually improving services.
	integrated in a system that meets applicable standards, professional guidelines, and customer requirements for ensuring and	5.1.2 Qualified, well-trained, and competent workforce	Knowledge, understanding and proficiency with the principles, processes, and methodologies for workforce development and sustainment in relation to biothreat detection, management, and control, including workforce planning, training, refresher training, continuing education, and/or professional development, in a system that meets applicable standards, professional guidelines, and national licensing requirements where applicable.
	maintaining quality and	5.1.3 Materiel resource	Knowledge, understanding and proficiency with procedures and policies for procurement and inventory management of materiel

	continually improving services.	management	resources, including supply chain systems, operations, and infrastructure, or management/oversight of these processes.
		5.1.4 Quality review practices and procedures	Knowledge, understanding and proficiency with quality assurance, quality control, and/or quality management review practices and procedures, based on national or international best practices.
		5.1.5 Document management	Knowledge, understanding and proficiency with document and information management policies and procedures, and program documentation and records/archival management processes.
6. Outbreak preparedness and biosurveillance	6.1 Use of operational guidelines, identification and analysis of outbreak	6.1.1 Operational guidelines	Knowledge, understanding and proficiency with development and implementation of outbreak preparedness, biosurveillance, investigation, laboratory practices, and response planning and operations guidelines, including case definitions, and demonstrated ability to use related operational tools such as emergency preparedness and response plans, contingency plans, SOPs, and job

	situations, and effective communication		aids when available. Special note and care should be given to documents designed for health care workers directly combatting an outbreak.
	with stakeholders.	6.1.2 Identification and analysis	Knowledge and proficiency with principles and processes for developing and maintaining disease outbreak situational awareness capabilities, including coordination and communication or reporting across biosurveillance, laboratory, and other data sources, epidemic intelligence, data analysis, and field epidemiological and outbreak investigation techniques, such as contact tracing, and decision-making in support of these activities.
		6.1.3 Communication systems	Knowledge and proficiency with development, implementation, and sustainment of communications systems for outbreak situational awareness and response, including multisectoral and intrasectoral coordination (including via emergency operations centers or equivalent assets), operational risk communication, and public risk communication.
7. Biosafety	7.1 The application of knowledge, techniques, and equipment to prevent accidental exposure to and release of pathogens.	7.1.1 Biohazard Identification and classification	Knowledge, understanding and proficiency with identification and classification of biohazards associated with pathogens, for laboratories, hospitals, other biomedical and clinical facilities, and the community, including biohazard risk assessment and characterization, and biohazard identification policies and compliance procedures.
		7.1.2 Biohazard Control Measures (e.g., personal	Knowledge, understanding and proficiency with development and implementation of international best practices and procedures for biothreat biosafety and biohazard control measures (substitution,

		protective equipment, safety practices and equipment, facility design, and administrative controls).	elimination, mitigation) for personnel, equipment, facilities (laboratories, hospitals, and other biomedical and clinical facilities) and the community.
		7.1.3 Biohazard Incident Management	Knowledge, understanding and proficiency with development and implementation of policies, procedures, and operational guidelines, including emergency operation communications systems, for Biohazard Incident Management for pathogen outbreaks, releases or exposures.
8. Laboratory biosecurity	8.1 Prevent theft, misuse, loss, or deliberate release of pathogens.	8.1.1 Biosecurity Risk Identification	Knowledge, understanding and proficiency with principles and procedures for Biosecurity Risk identification, risk assessments, characterization and compliance with recommended international standards and best practices to prevent the loss, theft, or misuse of biological organisms and laboratory/ biosurveillance study technologies.
		8.1.2 Biosecurity Risk Mitigation	Knowledge, understanding and proficiency with international best practices for Biosecurity Risk Mitigation, and related risk reduction approaches to enhance physical security, personnel reliability, material control and accountability, transport security, and information security/cybersecurity, and the development and implementation of Biosecurity Risk Mitigation strategies for laboratories, facilities, and personnel to prevent the loss, theft, or misuse of biological organisms, especially pathogens, and laboratory/biosurveillance study technologies.

8.1.3 Biosecur Incident Management	Knowledge, understanding and proficiency with international best practices for Biosecurity Incident Management, and development and implementation of Biosecurity incident management policies and procedures for suspected or confirmed illicit access to pathogens, intruder alerts, and other biosecurity incidents.
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ATTACHMENT 2: SPECIAL TOPICS

No special topics are currently announced.

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