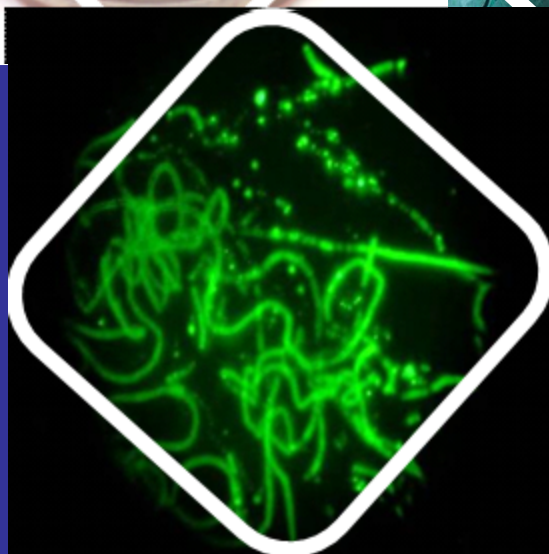
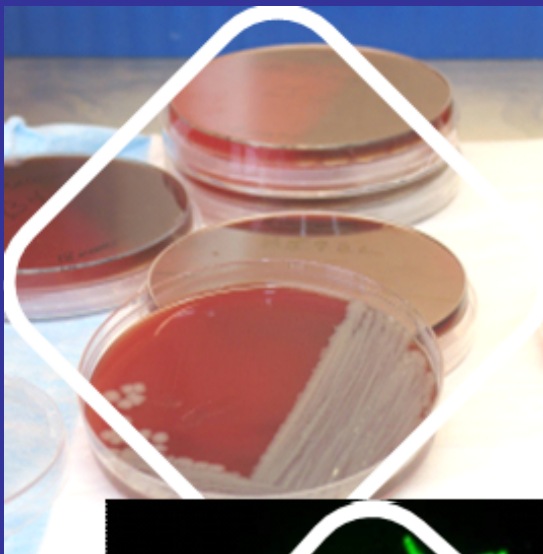




# THE COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM (CBEP) RESEARCH STRATEGIC PLAN: ADDRESSING BIOLOGICAL THREAT REDUCTION THROUGH RESEARCH



U.S. Department of Defense  
Defense Threat Reduction Agency  
Cooperative Threat Reduction

Photos from the National Center for Disease Control, Republic of Georgia

October 2013

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## EXECUTIVE SUMMARY

Among the many threats and concerns to U.S. and global security that have arisen in the past several decades, the most challenging are those associated with the complex threats posed by infectious disease agents and their impacts on national, regional and global health security. The global community places security surrounding the development, possession and use of biological weapons among the highest priorities for policy, diplomacy, defense, response and recovery, and multilateral action. The U.S. Department of Defense (DoD) Cooperative Threat Reduction (CTR) Cooperative Biological Engagement Program (CBEP) directly addresses global health security threats by working with partner nations to improve biosafety, biosecurity, and disease surveillance for traditional select agents (weapons-usable biological material) and emerging pathogens that may cause public health emergencies of international concern (PHEIC). In execution of CBEP's threat reduction mission, cooperative biological research is an important supportive element of a more comprehensive program. Research is not an isolated end state objective for the program. Rather, it serves as an "enabler" to engage partner country scientists in peaceful and ethical application of the biological sciences with a focus on improved biosurveillance and threat reduction. The CBEP research program integrates with capability building efforts managed by individual regional/country teams to identify and execute focused and coordinated research projects with global partners that address local and regional health security priorities.

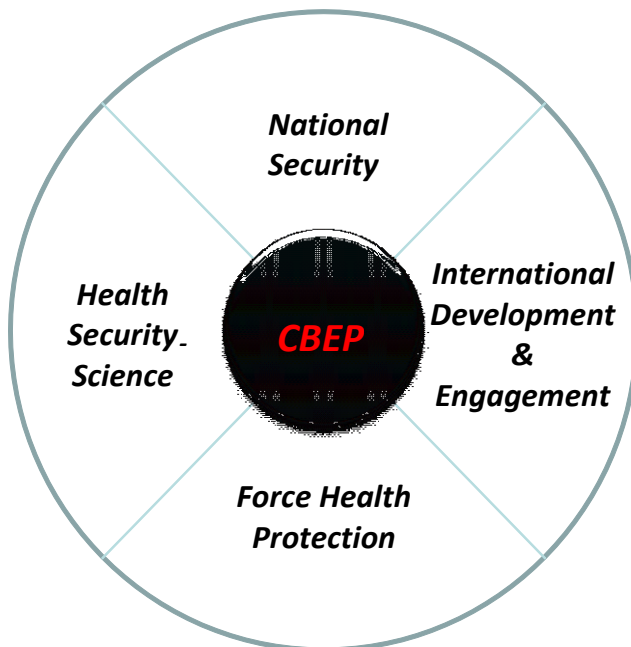
The CBEP Research Strategic Plan supports the implementation of national, departmental, and agency policies and priorities (see Appendix A), and provides a comprehensive approach to furthering threat reduction research that informs and enhances operational biosurveillance. The CBEP research program builds upon CBEP goals to develop and enhance sustainable partner country capabilities to:

- Employ biorisk management best practices and principles;
- Conduct a modern and proactive disease surveillance mission;
- Comply with World Health Organization (WHO) International Health Regulations (IHR) and World Organization for Animal Health (OIE) reporting guidelines; and,
- Promote and implement the One-Health concept.

## INTRODUCTION

The CTR Program has historically focused biological threat reduction efforts on eliminating the biological weapons (BW) programs and associated infrastructure of the former Soviet Union (FSU). In this capacity, CTR has successfully redirected the efforts of former weapons scientists to endeavors that focused on advancing science and national capacities for peaceful purposes. The program has made significant strides in eliminating BW infrastructure in the FSU, and in recent years began expanding into new countries that do not have a history of BW development. CBEP has adopted a commensurate emphasis on scientific engagement to improve biosafety, biosecurity, and disease surveillance capabilities through research, training, technology transfer, infrastructure improvement, and sustainment. This emphasis on biosafety, biosecurity, and disease surveillance reduces risks associated with infectious diseases, and is indiscriminate to whether disease outbreaks are caused by the misuse of science or caused by endemic threats to public and animal health.

While efforts to engage FSU countries continue, new partner countries have been added in Africa, the Middle East, South Asia, and Southeast Asia. The expanded, complex, and dynamic



**Figure 1.** CBEP capability building and research activities are at the intersection of national security and force health protection with health security science and international development & engagement.

nature of CBEP engagements includes increasing opportunities for substantial coordination with U.S. Government (USG) stakeholders to achieve synergistic collaborations with positive, whole-of-government outcomes.

The scope of CBEP's engagement activities increasingly intersects with major USG and international program areas, including national security, force health protection, health security, science, and development and engagement. CBEP must, therefore, consciously engage and partner with other DoD and USG entities (e.g., Army, Navy, Armed Forces Health Surveillance Center [AFHSC], Chemical and Biological Defense Program [CBDP], Department of Homeland Security [DHS], Department of Health and Human Services [HHS], Department of Agriculture [USDA], Federal Bureau of Investigation [FBI], and Food and Drug Administration [FDA]; United States Agency for International Development [USAID]); non-

governmental organizations (e.g., World Bank); and, international programs (e.g., Food and Agricultural Organization of the United Nations [FAO], WHO, and OIE). These partnerships must complement and leverage, rather than duplicate, efforts and capabilities.

The CBEP Research Strategy takes a synergistic approach, leveraging multiple U.S. and international partners to develop integrated research initiatives that support the operational biosurveillance/threat reduction mission. At the same time, research engagements provide the opportunity to reinforce good laboratory practices (GLP) by providing mentorship, training, and application of biosafety and biosecurity (BS&S) standards.

This strategy provides guidance for how research projects within CBEP will be planned, coordinated, and executed. A broad range of research activities support the CBEP mission; however, partner countries differ in their security situations, technical capabilities, and research priorities. These factors will continue to evolve through the course of each CBEP engagement.

Based on the criteria and considerations outlined in this strategy, individual regional science plans have been developed to support a consistent and focused approach to research engagements across CBEP without attempting to apply a “cookie cutter” approach. As necessary and appropriate, individual country science plans may also be developed to further refine integration of science projects with regional/country engagement strategies.

## **VISION and MISSION**

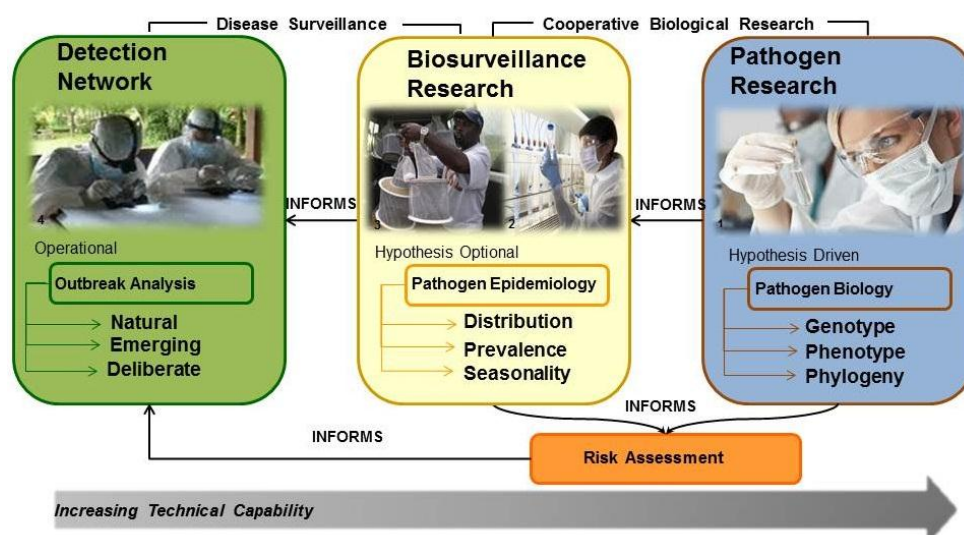
### **Vision**

*To reduce the threat to the U.S. and global health security, from the spread of pathogens causing dangerous infectious diseases through engagements in cooperative international research partnerships.*

### **Mission**

*Enhance global health security and foster safe, secure and sustainable bioscience capability through joint scientific collaborations with global partners to inform and enhance operational biosurveillance.*

## STRATEGY and PRIORITIES



**Figure 2:** CBEP research supports and informs operational biosurveillance through an improved understanding of pathogens and their risk to global health security.

CBEP reduces the threat to the U.S. and global health security from the spread of pathogens causing dangerous infections and diseases, whether natural or manmade. Effective execution of the CBEP biosurveillance mission requires deliberate integration of its three primary lines of effort – BS&S, infectious disease reporting, and cooperative biological research – to ensure development of sustainable threat reduction capabilities in partner countries.

Cooperative biological research projects are focused on supporting BS&S and biosurveillance threat reduction efforts, while addressing infectious disease priorities of both CBEP and its partner countries. Ultimately, the techniques, procedures, and approaches must be sustainable for the partner country, and linked with appropriate training, to promote global health security, reinforce norms of safe and responsible conduct, obtain timely and accurate insight on current and emerging risks, and transform the international dialogue on biological threats.

In order for CBEP to remain relevant, agile, and sustainable, research projects are not limited to or determined by narrow set of specific biological agents, but rather must be aimed at threat reduction objectives<sup>1</sup> and demonstrate a clear nexus with the biosurveillance mission. The scope of CBEP research projects include (but are not limited to):

- HHS and USDA Biological Select Agents and Toxins
- Pathogens of pandemic potential, emerging, and re-emerging infectious diseases (e.g., antimicrobial resistant [AMR] pathogens, avian influenza [low and high pathogenic], African swine fever, severe acute respiratory syndrome)

<sup>1</sup> U.S. Department of Defense. *Memorandum for Division Chief, Cooperative Biological Engagement Program, Guidance for Research Scope and Boundaries within the Execution of the Cooperative Biological Engagement Program*. Fort Belvoir, VA: Defense Threat Reduction Agency, 2012.



- Microbial ecology of endemic pathogens (e.g., community relationships, near-neighbor associations, gene expression, protein function, biomarkers, cell signaling)
- Differentiating co-syndromic infections associated with select agent etiologies (e.g., influenza-like illness, acute febrile illness, fever of unknown origin)

## GOALS and OBJECTIVES

CBEP is committed to fair and open competition of research topics that inform and enhance biosurveillance. It will maximize the use of Broad Agency Announcements and Service Calls as solicitation mechanisms to identify and select research projects. This research strategy is designed to guide the CBEP research program through coordination with USG and international partners to develop cooperative research projects of mutual interest to both the U.S. and global partner institutes and achieve the goals outlined below:

- Goal 1: Support Biosurveillance and BS&S Capability Building Efforts
  - Objective 1: Inform and enhance operational biosurveillance strategies and implementation through improved understanding of endemic disease burden and pathogen biology.
  - Objective 2: Institutionalize responsible biorisk management best practices with partner country scientists.
  - Objective 3: Develop, select, and execute projects to achieve integration with CBEP regional/country plans and in close coordination with CBEP regional/country teams.
- Goal 2: Engage Partner Country Scientists in Hypothesis-Driven Research
  - Objective 1: Support local, national, and regional priorities for understanding and mitigating human and animal disease risk (e.g., small, focused projects within individual countries linked by broad, integrating projects that include regional partners).
  - Objective 2: Improve international collaborations to survey, detect, characterize, and report disease.
- Goal 3: Promote One-Health Initiative
  - Objective 1: Emphasize the nexus of human and animal health, and seek to further understanding of disease transmission between animals and humans.
  - Objective 2: Advance partner country sustainment of global health security initiatives.
- Goal 4: Foster an International Culture of Responsible and Ethical Conduct in Biological Research
  - Objective 1: Transition to a culture of responsible and ethical conduct in biological research through thoughtful experimental design and good laboratory practices that result in high-quality data, and active participation in professional societies and the peer-review process.

- Objective 2: Train partner country researchers to think critically in the pursuit of ethical research and to be competitive in soliciting funding from the international scientific community.

## **SUMMARY and WAY FORWARD**

CTR has made critical contributions to global biological threat reduction, global biosecurity and biosafety, and advancing U.S. and partner nation health protection capabilities. The CBEP research program will continue this history of success through process improvement; integration with regional/country teams; investing in continual professional development of regional science teams as acquisition professionals; and, through leveraging resources to improve return on investment and achieve local, regional and strategic impact. CBEP will use this strategy as a platform to guide, execute, and integrate improvements and changes to the overall program and its components using a systems approach.

The CBEP research program will continue to build upon existing programs; adapt to change; craft new opportunities that are regionally relevant and tailored to new partners; and, continue to advance U.S. priorities and interests. Emerging and future partnerships will address current and emerging infectious disease threats and their impacts in new and innovative ways. Creating and integrating new consortia of partners and stakeholders will position CBEP to overcome tough and persistent challenges, leverage the value and benefits of CBEP in new yet measurable ways, and strengthen the pertinent global community of science.



## Appendix A: PROGRAM REQUIREMENTS

There are several international and national guidelines and regulations, as well as USG Security strategies, which provide requirements to CBEP in the conduct of cooperative biological research. The most significant of these are outlined below.

### U.S. Government and DoD Guidance

The following USG documents inform the CBEP Research Strategy:

DTRA Strategic Plan for FY2012 – 2017<sup>2</sup>,  
 Department of Defense CTR Strategic Plan<sup>3</sup>,  
 National Strategy for Countering Biological Threats<sup>4</sup>,  
 United States Department of Health and Human Services and Department of Agriculture Select Agents and Toxin Rules<sup>5,6</sup>,  
 US Government Policy for Oversight of Life Sciences Dual Use Research of Concern<sup>7</sup>,  
 February 2010 Quadrennial Defense Review Report<sup>8</sup>.  
 National Research Council report “Improving Metrics for the Department of Defense Cooperative Threat Reduction Program”<sup>9</sup>

Defense Threat Reduction Agency (DTRA) receives policy guidance from the Office of the Secretary of Defense (OSD) for CTR Policy (CTR-P) and implementation guidance from OSD Acquisition Technology and Logistics (AT&L) Cooperative Threat Reduction Oversight Office (CTR-O) in the execution of the program. These offices are key partners in achieving CBEP mission success. The CBEP Research Strategy is formulated by key elements drawn from CTR-P Guidance (Memorandum for the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs, “Department of Defense Strategic Policy Guidance

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<sup>2</sup> Defense Threat Reduction Agency. *Strategic Plan FY 2012 - 2017*. Fort Belvoir, VA: Defense Threat Reduction Agency, 2012.

<sup>3</sup> Department of Defense. *Department of Defense Cooperative Threat Reduction Strategic Plan DRAFT*, June 2012.

<sup>4</sup> National Security Council. *National Strategy for Countering Biological Threats*. Washington, D.C.: The Office of the President of the United States, 2009.

<sup>5</sup> 42 CFR Parts 72 and 73. *U.S. Department of Health and Human Services Rule on the Possession, Use and Transfer of Select Agents and Toxins*. US Government Printing Office, The Federal Register, 2008, and revised 2011.

<sup>6</sup> 7 CFR Part 331 and 9 CFR Part 121. *U.S. Department of Agriculture Rule on the Possession, Use and Transfer of Select Agents and Toxins*. US Government Printing Office, The Federal Register, 2008, and revised 2011.

<sup>7</sup> U.S. Government. *U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern*. <http://oba.od.nih.gov/oba/biosecurity/pdf/> 2012.

<sup>8</sup> U.S. Department of Defense. *Quadrennial Defense Review Report: February 2010*. Washington, D.C.: U.S. Department of Defense, 2010.

<sup>9</sup> National Research Council. *Improving Metrics for the Department of Defense Cooperative Threat Reduction Program*. Washington, D.C.: The National Academies Press, 2012.

for the Cooperative Biological Engagement Program”<sup>10</sup> and CTR-O Implementation Guidance (Memorandum for Director, Cooperative Threat Reduction, Defense Threat Reduction Agency, Through Director, Defense Threat Reduction Agency, “Strategic Implementation Guidance for the Cooperative Biological Engagement Program”<sup>11</sup>). All research projects across CBEP must be grounded firmly within the scope of the CTR strategic policy objectives to address the biological threat outlined in CTR-P Guidance and contribute to associated implementation activities outlined in CTR-O Implementation Guidance. The CTR strategic policy objectives specific to addressing the biological threat are as follows:

1. Dismantle, destroy, and prevent the sale, theft, diversion, or use of stockpiles of BW, means of delivery, and BW-related equipment, technology, and infrastructure.
2. Enhance partner country/region’s capability to identify, consolidate, and secure collections of pathogens and diseases of security concern in order to prevent the sale, theft, diversion, or accidental release of such pathogens and diseases.
3. Enhance partner country/region’s capability to rapidly and accurately survey, detect, diagnose, and report biological terrorism and outbreaks of pathogens and diseases of security concern in accordance with international reporting requirements.

CBEP research must abide by the requirements and constraints outlined in CTR-P and CTR-O guidance documents, most notably: CBEP-sponsored research must improve understanding and capacity to reduce biological threats *without* enhancing capabilities that could be used to produce BW or BW infrastructure. In addition, Cooperative Biological Research (CBR) proposals must be reviewed by CTR-O, CTR-P, and DTRA CBEP, in accordance with the CBR Review Process standard operating procedures (SOP), which is inclusive of CTR-O Implementation Guidance.

## Regulations and Standards

International agreements with partner nations for cooperative research engagements are developed to ensure all work being performed under DoD support conforms to the relevant U.S. laws, regulations, and policies, as well as the generally accepted international agreements and norms or requirements of partner nations. The applicability of such DoD and U.S. Federal statutes, including but not limited to the Federal Acquisition Regulations (FAR), Defense Federal Acquisition Regulations (DFAR), and Animal Welfare Act/Regulations (AWA/AWR), is not dependent upon the budget activities funding the work, the mission of the DoD organization conducting or supporting the research, the security classification of the research, the location of the research in the U.S. or a foreign country, or whether the research is conducted under a

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<sup>10</sup> U.S. Department of Defense. *Memorandum for the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs*. “Strategic Implementation Guidance for the Cooperative Biological Engagement Program.” Washington, D.C.: Office of the Assistant Secretary of Defense for Global Strategic Affairs, 2013.

<sup>11</sup> U.S. Department of Defense. *Memorandum for Director, Cooperative Threat Reduction, Defense Threat Reduction Agency, Through Director, Defense Threat Reduction Agency* “Strategic Implementation Guidance for the Cooperative Biological Engagement Program” Washington, D.C.: Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs, 2013.

program that is not considered research for other purposes. Effective implementation of these agreements requires that all DoD and internationally supported personnel involved in acquisition and research activities have a clear and common understanding of the relevant statutes, thereby ensuring the protection of the rights, welfare and well-being of any subjects involved in the sponsored activities. Key guidelines and standards that help define CBEP research are outlined below.

## Biosafety and Biosecurity Guidelines

Biosafety and biosecurity is a pillar of CBEP that directly contributes to threat reduction by:

- (1) Ensuring that samples are stored, handled and transported safely and securely at all levels (field and laboratory) through establishment or enhancement of biosafety and biosecurity standards in partner countries, and
- (2) Securing and consolidating Select Agents in a minimum number of pathogen repositories.

In order to obtain international scientific funds from private sector and governmental sources, the research in a country must comply with U.S., DoD, and international biosafety and biosecurity guidelines, standards and regulations. Guidelines for enhancing biosafety and biosecurity standards using a risk-based approach commensurate with local needs, abilities and operating environments are provided in CBEP Biorisk Management Implementation Guidance.<sup>12</sup>

Establishing or enhancing biosafety and biosecurity standards provides for: (1) the safety of the clinicians, laboratory scientists, and the country's population "writ large" to prevent incidents where the chance of a potential outbreak is increased, and, (2) the protection of Select Agents, their associated research and other valuable biological material from adversaries with intent and capability to acquire or misuse them or disrupt the integrity of the mission the research supports. CBEP research projects must be designed to support development of local biosafety and biosecurity programs, and include active involvement of local biosafety officers, security personnel, and biosafety committees in the determination of risk mitigation procedures and practices as they pertain to the collaborating facility. In addition, CBEP funded research must comply with the U.S. Government Policy on dual use research of concern.

Pathogen repositories and associated knowledge management systems provide research and disease management communities with crucial resources to advance their respective missions, goals, objectives, and accomplishments regarding threat reduction and public health. Centralized repositories with high quality management, security, and sample accountability provide for many significant advantages with respect to infectious disease threat reduction over distributed, poorly organized, secured and managed facilities. This approach supports threat reduction by not only reducing the number of repositories where pathogen collections are housed, but by ensuring that such repositories are designed, constructed and managed in accordance with U.S., DoD and international biosafety and biosecurity guidelines, regulations, standards and best practices as determined by a risk assessment and articulated in CBEP Biorisk Management Implementation

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<sup>12</sup> U.S. Department of Defense. *Memorandum for Cooperative Biological Engagement Stakeholders, Biorisk Management Implementation Guidance*. Fort Belvoir, VA: Defense Threat Reduction Agency, 2012.

Guidance. It is essential that prior to engaging in research of any type that the setting in which research will be conducted meets these requirements. Alternatively, samples can be shipped to an appropriate reference laboratory or CBEP collaborator facility located outside of the partner country. When developing research proposals and later during project execution, the storage and long-term or final disposition of any collected materials should be considered in relation to the overall CBEP strategy for the partner country, particularly the biosecurity and biosafety priorities.

### **Animal and Human Use Guidelines**

Research with priority pathogens must be conducted in laboratories and in animal vivaria under appropriate biological safety conditions as determined by a risk assessment (e.g., biosafety level (BSL)-2, animal biosafety level (ABSL)-2, BSL-3 and ABSL-3), and appropriate safety and security measures must be taken in clinical, laboratory and field settings. Research involving human clinical subjects also must meet international standards for ethical human studies. In addition, animal research must be conducted according to international and U.S. DoD animal care and use standards for humane and ethical reasons and to protect the integrity of the results.

# Applying for DTRA CBEP Research Funding

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## CBEP Research Objectives and Scope

The Defense Threat Reduction Agency's (DTRA) Cooperative Biological Engagement Program (CBEP) is continuously looking for new collaborators and partners to conduct international biological research. Projects that are hypothesis-driven and contain substantive engagement with and contribution by partner country institutions and scientists are appropriate for CBEP research funding. Research projects that support CBEP objectives in partner countries include those that promote One Health, improve disease surveillance capabilities, enhance understanding of endemic pathogens, explore the microbial ecology of endemic organisms, and enhance host country capabilities in support of World Health Organization (WHO) International Health Regulations and World Organization for Animal Health (OIE) reporting standards. Pathogens of interest include biological Select Agents and Toxins, pathogens of pandemic potential, emerging and re-emerging infectious diseases, and pathogens that are co-syndromic with associated select agent etiologies such as Influenza-Like Illness or Acute Febrile Illness. CBEP does not support research topics that involve Dual-Use Research of Concern or focus on disease agents that are sexually transmitted, non-infectious, or do not pose a threat to global health security.

Research projects supported by CBEP must align with CBEP's overarching goals to reduce the threat to U.S. and global health security and are expected to produce results suitable for scientific publication.

## Applying to the Broad Agency Announcement (BAA) and Government Call (Call)

CBEP welcomes research funding applications from domestic and foreign academic, private, and government institutions, and has multiple solicitations available for proposals.

- Academic institutions, non-governmental organizations, industry, foreign laboratory equivalents, and members of the private sector must apply through Thrust Area 6: Cooperative Counter Weapons of Mass Destruction (WMD) Research with Global Partners of the Fundamental Research to Counter Weapons of Mass Destruction (FRCWMD) – BAA (HDTRA1-09-14-FRCWMD-BAA).
- U.S. Government partners and Federally Funded Research and Development Centers (FFRDC) must apply through Thrust Area 6 of the FRCWMD Government Call (HDTRA1-12-17-FRCWMD-Call).

All research ideas MUST be pre-coordinated by submitting an abstract to [FRCWMD-TA6@dtra.mil](mailto:FRCWMD-TA6@dtra.mil). A meeting or teleconference with CBEP may be requested following review of the abstract. A white paper may be welcomed following review of the abstract, but this must be formally communicated by [FRCWMD-TA6@dtra.mil](mailto:FRCWMD-TA6@dtra.mil) prior to submission of a white paper (Phase I Proposal). Similarly, following the white paper review, a full proposal (Phase II Proposal) must be formally invited prior to submission. Phase I and Phase II proposals to the FRCWMD-BAA must be submitted through [www.grants.gov](http://www.grants.gov). Phase I and Phase II proposals to the FRCWMD-Call must be submitted through [www.dtrasubmission.net](http://www.dtrasubmission.net). Detailed instructions for the FRCWMD-BAA and the FRCWMD-Call can be found through the solicitation links at [www.dtrasubmission.net](http://www.dtrasubmission.net). Please ensure that you are downloading and reviewing the latest amended full announcement for the most accurate information and instructions.

White papers and full proposals will be reviewed in accordance with the evaluation criteria published in the BAA and in coordination with appropriate CBEP Regional and Country Managers. To be successful, a white paper and/or proposal must align with both the DTRA CBEP mission and current regional priorities.

## CBEP Points of Contact

For clarifications or concerns, please reach out to the following CBEP representatives:

Dr. Peter Pesenti, Chief Scientist – [peter.pesenti@dtra.mil](mailto:peter.pesenti@dtra.mil)  
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