THE COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM RESEARCH STRATEGIC PLAN:

ADDRESSING BIOLOGICAL THREAT REDUCTION THROUGH RESEARCH

U.S. Department of Defense

Defense Threat Reduction Agency and

United States Strategic Command Center for Combating Weapons of Mass Destruction

Cooperative Threat Reduction

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

Contents

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 (CBR) is an integral supportive element of a comprehensive program. Research is not an isolated end state objective for the program. Rather, it is 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 supports broader program objectives by integrating with regional/country teams to build sustainment of CBEP capacity building investments through institutionalizing best practices, and resourcing and exercising partner country biorisk management and biosurveillance programs.

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 but face biological threats from a broad, diverse, and dynamic landscape. 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, irrespective of whether disease outbreaks are caused by intentional or accidental release of pathogens of security concern 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 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.

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.

The scope of CBEP's engagement activities increasingly intersects with major USG and international program areas, including national security, force health protection, global health security, science, and development and engagement. CBEP consciously engages and partners 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, Foundation Merieux); and international programs (e.g., Food and Agricultural Organization of the United Nations [FAO], WHO, OIE, and International Criminal Police

Organization [INTERPOL]). These partnerships complement and leverage, rather than duplicate, efforts and capabilities.

The CBEP Research Strategy takes a synergistic approach, leveraging U.S. and international partners to develop integrated research initiatives that support the operational threat reduction mission through generating resources for partner-nation scientists and institutions, and fostering a culture of responsible scientific practice, and generating actionable knowledge for partner countries to conduct accurate and effective disease surveillance. Research engagements provide the opportunity to reinforce good laboratory practices (GLP) by providing mentorship, training, and application of biosafety and biosecurity (BS&S) standards. The return on relationships through scientific diplomacy and research engagements can also lay the foundation for further training, mentorship and capacity building engagements.

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 are 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 of security concern through cooperative international research partnerships.

Mission

Establish and maintain international research collaborations with global partners to inform and enhance operational biosurveillance, enhance global health security, and foster safe, secure and sustainable bioscience capability with partner countries.

STRATEGY and PRIORITIES

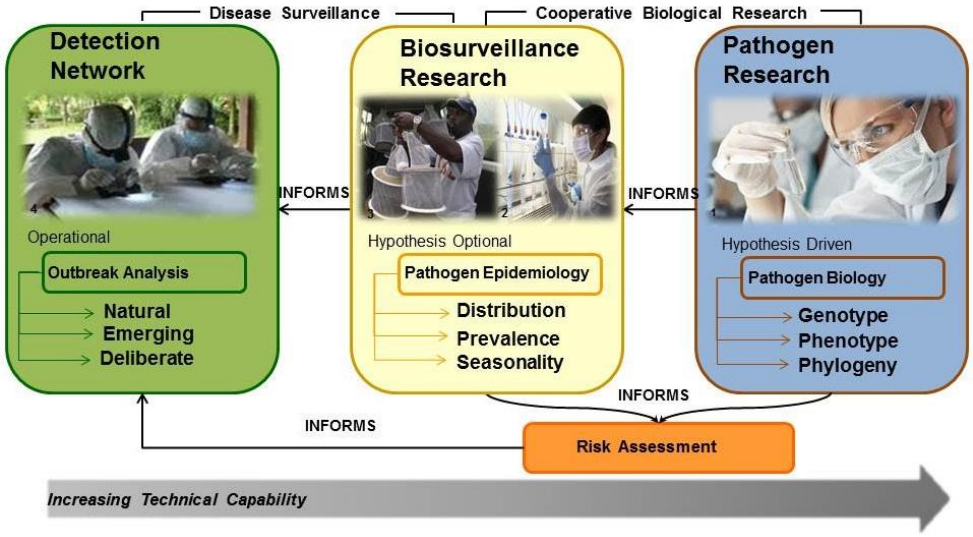

Figure 2: CBEP research supports and informs operational biosurveillance through an improved understanding of pathogens and their risk to global health security.

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 mission requires deliberate integration of CBR with the BS&S and biosurveillance pillars of the program. CBEP research engagements resource and exercise partner biorisk management and biosurveillance programs, and support long-term sustainability of CBEP investments.

Cooperative biological research projects are focused on supporting and bolstering BS&S and biosurveillance capabilities that reduce the threat of pathogens of security concern, 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 inform the international dialogue on biological threats.

In order for CBEP to remain relevant, agile, and sustainable, research projects must be aimed at threat reduction objectives[1] and demonstrate a clear nexus with the biosurveillance mission. The scope of CBEP research priorities include (but are not limited to):

- Understanding the ecology and epidemiology of pathogens of security concern, including HHS and USDA Biological Select Agents and Toxins[2] and pathogens of pandemic

[1] 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.

[2] 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73, *HHS and USDA Select Agents and Toxins List*, updated September 10, 2013. http://www.selectagents.gov/SelectAgentsandToxinsList.html

potential, emerging, and re-emerging infectious diseases (e.g., avian influenza [low and highly pathogenic], African swine fever, Middle East Respiratory Syndrome (MERS), Ebola)

- Differentiating infectious diseases presenting clinical signs and symptoms similar to those of pathogens of security concern (e.g., influenza-like illness, acute febrile illness, fever of unknown origin)

CBEP will not support research projects that have no clear link to its threat reduction mission, are not sustainable for the partner country, or propose activities constituting Dual Use Research of Concern (DURC). These and other requirements and constraints are outlined in Appendix A and illustrated in Figure 3.

CBEP Fundamental Research Scope	
In scope	**Out of scope**

Projects that demonstrate:
• Clear relationships to pathogens of security concern
  • US Biological Select Agents*
  • Pathogens of pandemic potential
  • Emerging or re-emerging infectious diseases
  • Differentiating pathogens of security concern from agents with similar clinical signs and symptoms
• Links to threat reduction mission
• Support of BS&S and biosurveillance capabilities that reduce the threat of pathogens of security concern
  • Rapid, accurate, and safe detection, diagnoses and reporting
• Alignment with both CBEP and partner country infectious disease priorities
• Use of sustainable techniques, procedures, and approaches in appropriate facilities
	Projects that focus on:
	• Dual-Use Research of Concern (DURC)
	• Diagnostic assay / novel technology development**
	• Medical countermeasures
	• Non-infectious diseases
	
	Projects that contain:
	• Establishment of new pathogen repositories
	• No link to pathogens of security concern
	• No clear alignment to threat reduction mission
	• Use of unsustainable techniques, procedures, or approaches in inappropriate facilities
	  • Requires use of supplies or resources not available in country
	• No clear research question or hypothesis
	• No potential to generate knowledge that may result in scientific publications

Figure 3 CBEP research scope includes projects that are aimed at the threat reduction mission, employ biorisk management best practices and principles, and sustainably align with partner country capabilities. CBEP does not support Dual-Use Research of Concern (DURC) or projects that do not demonstrably benefit partner countries.
* Pathogens on the HHS and USDA Biological Select Agent and Toxins List (see Appendix A)
** Field or country-specific validation of new diagnostic assays, novel technologies or equipment may be in scope if meeting other in-scope criteria. See CBEP Position Paper on Diagnostic Development

GOALS and OBJECTIVES

CBEP is committed to fair and open competition of research topics that inform and enhance biosurveillance, and utilizes Broad Agency Announcements and Service Calls as the primary solicitation mechanisms to identify and select research projects (see Appendix B). This research

strategy is designed to guide the research program through coordination with CBEP country and regional teams and 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: 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 Responsible and Ethical 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: Institutionalize a culture of responsible and ethical conduct in biological research through thoughtful experimental design, competitive laboratory capabilities, and implementation of biorisk management practices that result in high-quality data, and active participation in professional societies and the peer-review process.
- Goal 3: Foster Sustainable Partnerships with Key National and International Stakeholders
    - Objective 1: Improve local, regional, and international collaborations to survey, detect, characterize, and report disease.
    - 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.
    - Objective 3: Advance partner country implementation and sustainment of Global Health Security and One-Health initiatives by emphasizing the nexus of disease surveillance and health security.

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; and leveraging resources to improve return on investment. These measures will ensure the CBEP research program continues to achieve local, regional and strategic impacts. 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:
Department of Defense Strategic Policy Guidance for the Cooperative Biological Engagement Program[3],
Strategic Implementation Guidance for the Cooperative Biological Engagement Program[4],
DTRA/SCC-WMD Strategic Plan for FY2012 – 2017[5],
Department of Defense CTR Strategic Plan[6],
National Strategy for Countering Biological Threats[7],
United States Department of Health and Human Services and Department of Agriculture Select Agents and Toxin Rules[8,9],
US Government Policy for Oversight of Life Sciences Dual Use Research of Concern[10],
February 2010 Quadrennial Defense Review Report[11],
National Research Council report "Improving Metrics for the Department of Defense Cooperative Threat Reduction Program"[12],
Implementation Guidance for Partnering with International Organizations to Achieve the Objectives of the Cooperative Biological Engagement Program[13],

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[3] 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, August 21, 2013.

[4] 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, August 21, 2013.

[5] Defense Threat Reduction Agency. *Strategic Plan FY 2012 - 2017*. Fort Belvoir, VA: Defense Threat Reduction Agency, 2012.

[6] Department of Defense. *Department of Defense Cooperative Threat Reduction Strategic Plan DRAFT*, June 2012.

[7] National Security Council. *National Strategy for Countering Biological Threats.* Washington, D.C.: The Office of the President of the United States, 2009.

[8] 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.

[9] 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.

[10] 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.

[11] U.S. Department of Defense. *Quadrennial Defense Review Report: February 2010.* Washington, D.C.: U.S. Department of Defense, 2010.

[12] National Research Council. *Improving Metrics for the Department of Defense Cooperative Threat Reduction Program.* Washington, D.C.: The National Academies Press, 2012.

[13] U.S. Department of Defense. *Memorandum for Director, Cooperative Threat Reduction, Defense Threat Reduction Agency, Through Director, Defense Threat Reduction Agency "Implementation Guidance for Partnering with International*

U.S. Commitment to the Global Health Security Agenda[14]

Defense Threat Reduction Agency and United States Strategic Command Center for Combating Weapons of Mass Destruction (DTRA/SCC-WMD) 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 (Department of Defense Strategic Policy Guidance for the Cooperative Biological Engagement Program) and CTR-O Implementation Guidance (Defense Threat Reduction Agency Strategic Implementation Guidance for the Cooperative Biological Engagement Program). 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/SCC-WMD CBEP, in accordance with the CBR Review Process standard operating procedures (SOP), which is inclusive of CTR-O Implementation Guidance.

The Global Health Security Agenda (GHSA) partners the U.S. government with multiple international partners to work towards a world safe and secure from infectious disease threats and promote global health security. GHSA and CBEP are similar in focus, aligning on 7 out of 9 GHSA objectives, and CBEP coordinates closely with interagency and international partners to leverage efforts towards meeting GHSA objectives. CBEP research will focus on and support those objectives falling within the CBEP mission space.

Organizations to Achieve the Objectives of the Cooperative Biological Engagement Program" Washington, D.C.: Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs, November 18, 2014

[14] U.S. Government. *U.S. Commitment to the Global Health Security Agenda: Toward a World Safe & Secure from Infectious Disease Threats*. September 26, 2014. http://www.cdc.gov/globalhealth/security/pdf/ghs_us_commitment.pdf

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 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.[15] 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

[15] U.S. Department of Defense. *Memorandum for Cooperative Biological Engagement Stakeholders, Biorisk Management Implementation Guidance.* Fort Belvoir, VA: Defense Threat Reduction Agency, 2012.

personnel, and biosafety committees in the determination of risk mitigation procedures and practices as they pertain to the collaborating facility.

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 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, if agreed upon with the government of the partner country, 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.

Appendix B: APPLYING FOR DTRA/SCC-WMD CBEP RESEARCH FUNDING

CBEP Research Objectives and Scope

The Defense Threat Reduction Agency and United States Strategic Command Center for Combating Weapons of Mass Destruction (DTRA/SCC-WMD) Cooperative Biological Engagement Program (CBEP) is continuously seeking new collaborators, partners and international partners to conduct cooperative biological research to inform and enhance disease surveillance and global health security. 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, enhance understanding of endemic pathogens, explore the microbial ecology of endemic organisms, and enhance host country capabilities in support of World Health Organization International Health Regulations and World Organization for Animal Health 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 (CWMD) Research with Global Partners of the Fundamental Research to Counter Weapons of Mass Destruction (FRCWMD) – BAA (HDTRA1-14-24-FRCWMD-BAA).
- U.S. Government partners and Federally Funded Research and Development Centers (FFRDCs) must apply through Thrust Area 6 of the FRCWMD Government Call (HDTRA1-12-17-FRCWMD-Call).

All research ideas MUST be pre-coordinated through submission of an abstract to FRCWMD-TA6@dtra.mil prior to submitting a white paper. White papers (aka Phase I proposal) must be submitted and a full proposal (aka Phase 2 Proposal) invited prior to submission of a full proposal. Phase 1 and Phase 2 proposals to the FRCWMD-BAA must be submitted through www.grants.gov. Phase 1 and Phase 2 proposals to the FRCWMD-Call must be submitted through www.dtrasubmission.net. White papers and proposals will be peer reviewed in accordance with the evaluation criteria published in the BAA and Call 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/SCC-WMD CBEP mission and regional priorities.

Detailed instructions for the FRCWMD-BAA and the FRCWMD-Call can be found through the solicitation links at www.dtrasubmission.net. Please ensure that you are downloading and reviewing the

latest amended full announcement for the most accurate information and instructions. Offerors may submit questions of an administrative nature to HDTRA1-FRCWMD-A@dtra.mil, and of a technical nature to FRCWMD-TA6@dtra.mil.

CBEP Points of Contact

For clarifications or questions about potential research concepts, please reach out to the following CBEP representatives:

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Appendix C: CBEP Position Paper on Diagnostic Platforms

Introduction: As CBEP seeks to enhance partner country capabilities to rapidly and effectively detect and diagnose pathogens of security concern CBEP managers are often questioned on whether the program supports research and development of new diagnostics. In general, CBEP does not support research and development of new diagnostic platforms or technologies currently in development; though exceptions for field testing and evaluation or validation of promising diagnostic platforms may be considered on a case-by-case basis. This paper provides information on CBEP's approach to enhancing diagnostic capabilities in partner nations and at the same time elaborates on OSD Policies position on application of CTR funds to these types of initiatives.

Background: One of CBEP's primary objectives is to enhance partner country capability to rapidly and accurately survey, detect, diagnose, and report biological threat agents to include the growing pathogens of security concern. CBEP accomplishes this objective by providing training/workshops, infrastructure/equipment improvements, enhancing the biosurveillance network in country, facilitating partnerships with international organizations, and sponsoring cooperative biological research (CBR) projects. CBEP-sponsored CBR projects with partner nations must support biosafety and biosecurity (BS&S) and biosurveillance threat reduction goals. Ultimately, the techniques, procedures, and approaches employed 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. A necessary component of this research is that partner country scientists must participate and be significantly engaged.

Discussion: It is noted that available reagents and tests can be cost-prohibitive for low-resource countries to procure for routine use and have a limited shelf-life. In addition, there are limited commercially available reagents or standardized molecular diagnostics tests for detection of pathogens of security concern. In addition, CBEP's strategic policy and implementation guidance includes encouraging the use of modern diagnostics methods employing advanced technologies to identify pathogens of security concern, thus strengthening biosurveillance systems[16] in country. However, research projects that focus extensively on the development of novel diagnostic platforms or technologies that often require skills, equipment, and reagents that are not sustainable or beyond the capability of the partner country to perform or sustain is beyond CBEP scope. In addition, there are other USG and commercial entities that have the mission to fund or conduct research and development to increase sustainability and availability and decrease costs of detection technologies. CBEP consciously engages and partners with other

[16] Department of Defense Strategic Policy Guidance for the Cooperative Biological Engagement Program, 21 August 2013

USG programs to complement and leverage efforts that have the mission to develop novel technology, such as DTRA/SCC-WMD's Joint Science and Technology Office Chemical and Biological Defense (JSTO CBD), JPEO – Critical Reagents Program, and the Department of Homeland Security (DHS), Science & Technology Directorate; however, CBEP does not, in general, directly support research and development of novel diagnostic platforms or technologies.

CBEP may support field testing and evaluation or validation of promising diagnostic platforms through part of a CBR focusing on disease surveillance capability building efforts with partner countries. However, such an effort must undergo a rigorous review process and meet established program criteria to be considered. In these instances the PEB will review the proposal with full country/regional representation on the board. It is imperative that the diagnostics and advanced scientific methods in these efforts are commensurate with the technological capabilities of the country or region. As mentioned above, unproven technologies do not typically align with this guidance, and often result in lopsided proposals, where activities are performed largely by US entities, focused on the diagnostic only, and not in conjunction with partner country scientists.

Conclusion: CBEP encourages and supports the use of proven modern diagnostic platforms in the detection of pathogens of security concern. CBEP focuses on strengthening and deploying diagnostics systems that are sustainable for partner countries, the program traditionally does not support research and development of platforms that are in development. Rather, CBEP leverages research and development efforts from USG and international partner programs for field testing, evaluation, and validation of promising technologies. Regional Science Managers will work closely with their respective Regional Manager to provide a holistic evaluation of such proposals to CBEP.