CONCEPT OF OPERATIONS

FOR

COUNTERING ESPECIALLY DANGEROUS PATHOGEN THREATS IN ARMENIA

2020 - 2025

JOINT AGREEMENT BETWEEN

GOVERNMENT OF ARMENIA AND

DEFENSE THREAT REDUCTION AGENCY
DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA

Approved by:

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Program Objectives for BTRP-Armenia

1 PURPOSE

- 1.1 The intent of the Program Objectives document and accompanying Concept of Operations (CONOPS) addendum is to describe potential scope of the Biological Threat Reduction Program (BTRP) activities with the executive agents (EAs) of Armenia. BTRP and EAs will prioritize potential areas of scope outlined in this CONOPS based on resource availability, mission objectives, and especially dangerous pathogens (EDP) risks. The CONOPS is not a promise to fulfill all End States but a description of possible areas for mutually established goals, contingent on availability of funds and approval from the Armenian government and the U.S. government.
- 1.2 The Program Objectives document reflects BTRP's mission scope and will serve as a basis for planning BTRP activities in Armenia. This document is not subject to change by any organization other than BTRP.
- 1.3 The CONOPS appended to this document will outline EA and BTRP priority engagement areas and mutually established goals of both EAs and BTRP. Projects derived from the CONOPS will be agreed to by both BTRP and EAs, and may be revised periodically, as needed. The CONOPS is a non-binding plan, however either side can withdraw in case of a failure to meet the agreed upon goals.
- 1.4 Projects will be consistent with and supportive of Armenian government compliance with World Health Organization (WHO) international health regulations and World Organization for Animal Health (OIE) international standards.
- 1.5 BTRP support is contingent on GoAM enforcing proper BS&S measures, to include proper use and maintenance of biosafety equipment (i.e. biosafety cabinets) as well as proper use of personnel protective equipment (PPE). If it is determined by BTRP BS&S assessments that participating laboratories are not in compliance, BTRP will halt all activities and funds until the problem is rectified.

2 SCOPE

- 2.1 This plan shall support and abide by the Agreement Between the Government of the United States of America and the Government of the Republic of Armenia Concerning Cooperation in the Area of Couterproliferation of Weapons of Mass Destruction (signed July 24, 2000 and entered into force November 25, 2002).
- 2.2 CONOPS project activities must focus on achieving the End States below.
- 2.3 BTRP-Armenia engagement focuses on especially dangerous pathogens (EDPs).
- 3 BIORISK MANAGEMENT AND BIOSURVEILLANCE END STATE: Government of Armenia is sustaining BTRP-provided Biosafety and Biosecurity (BS&S) and Biosurveillance (BSV) capabilities (e.g. training institutionalization, laboratory strengthening, and research).
 - 3.1 Securing, Eliminating, and Consolidating Especially Dangerous Pathogen Collections

- 3.1.1 Especially Dangerous Pathogen (EDP) collections are identified, eliminated, and/or consolidated into a minimum number of facilities.
- 3.1.2 Security and control of EDP collections is adequately maintained.

3.2 Facility-Level Biorisk Management Systems and Behavioral Standards

- 3.2.1 Safety equipment/primary barriers are available, operable, and maintained properly.
- 3.2.2 Necessary Personal Protective Equipment is available, selected, and used properly.
- 3.2.3 Facilities are designed and constructed to allow for safe and secure work.
- 3.2.4 Biorisk management programs/policies are documented, implemented, and regularly reviewed.
- 3.2.5 Facilities maintain and adhere to relevant SOPs and utilize other program documents for successful BS&S program implementation.
- 3.2.6 Facility personnel are trained, competent, and adhere to BS&S best practices and demonstrate regional leadership.

3.3 National-Level Regulatory Frameworks

3.3.1 National level regulations, guidelines, and policies for BS&S are in place and practiced, and there are mechanisms for oversight and enforcement of BS&S regulations and/or guidelines.

3.4 Disease Detection

- 3.4.1 Health professionals are trained in and demonstrate relevant clinical skills for disease detection.
- 3.4.2 Clinical protocols/guidelines are developed and used within the country.

3.5 Laboratory Diagnostics

- 3.5.1 Laboratory staff, including those involved in cooperative biological research, are trained on and able to perform sample collection and transport, with emphasis on sample viability and preserving sample integrity.
- 3.5.2 Laboratory staff, including those involved in cooperative biological research, are trained on and able to perform level-specific diagnostic testing.
- 3.5.3 Equipment and reagents are available in-country to permit effective and rapid detection of priority diseases.
- 3.5.4 Written and established protocols (SOPs and job aids) exist and are consistently used for diagnostics and sample referral, within the country and to international labs.
- 3.5.5 The practice and institutionalization of a national public health laboratory system and a national animal health laboratory system are present within the country.

3.6 Epidemiological Analysis and Investigation

- 3.6.1 Epidemiological staff, including those involved in cooperative biological research, are capable of performing routine and timely epidemiological data analysis and investigation.
- 3.6.2 Guidelines and SOPs in place that outline the use of disease thresholds in identifying and declaring an outbreak for select EDPs.
- 3.6.3 Official case investigation forms and case definitions are utilized for select EDPs.
- 3.6.4 Epidemiological staff implement data quality checks to ensure the timeliness, completeness, and accuracy of case reporting.

3.7 Reporting and Communications

- 3.7.1 Reporting duties and reporting chains within the country are documented, effective, and used on a consistent basis by individuals from all organizations to support reporting to international organizations.
- 3.7.2 Communication protocols exist and are exercised on a regular basis for multisectoral and multidisciplinary coordination within the country.
- 3.7.3 Standardized case definitions exist, are available, and used by relevant health professionals.
- 3.7.4 Clinicians, epidemiologists, and laboratorians have access to and use a list of reportable diseases.
- 3.7.5 Information and communications technology (ICT) infrastructure is present within the country to allow trained end users to conduct reporting and surveillance activities via electronic disease surveillance and reporting systems.

4 ONE HEALTH SYSTEM END STATE: The Government of Armenia is implementing a functioning One Health system that includes multi-sectoral ministerial involvement.

4.1 National One Health Framework

- 4.1.1 A national One Heath framework for detection diagnosis, and reporting of EDPs is developed.
- 4.1.2 National legislation in support of One Health initiatives is enacted and/or modified to facilitate implementation.

4.2 One Health Training and Institutionalization

- 4.2.1 Select health professionals (e.g. clinicians, researchers, law enforcement, first responders, environmental scientists, etc.) are trained on the One Health approach to detecting, diagnosing, and reporting EDPs.
- 4.2.2 Healthcare stakeholders are supported in institutionalizing EDPs and One Health education and training in order to maintain a qualified healthcare workforce.
- 4.2.3 Requirements for staffing, training, and deploying Rapid Response Teams (RRTs) are defined.
- 4.2.4 Requirements for staffing, training, and operating EDP Surveillance Coordination Center (ESCC) are defined.

5 REGIONAL AND INTERNATIONAL INTEGRATION END STATE: The Government of Armenia strengthens relationships with regional and international partners through collaborative scientific engagement and data sharing (e.g., Lugar Center in Georgia).

5.1 Regional and International Exchange of Disease Data

- 5.1.1 Guidelines that outline criteria for exchanging disease surveillance with regional and international stakeholders are developed and implemented.
- 5.1.2 Engagement with regional and international organizations focus on disease reporting and prevention.

5.2 Scientific Engagement and Research

- 5.2.1 Scientific engagements and research efforts with regional and international partners focused on EDPs are identified, planned, and implemented.
- 5.2.2 Research findings are published in regional and international scientific publications and presented at regional and international conferences.

Concept of Operations Government of Armenia (GoAM)

BIORISK MANAGEMENT AND BIOSURVEILLANCE END STATE: Government of Armenia is sustaining BTRP-provided Biosafety and Biosecurity (BS&S) and Biosurveillance (BSV) capabilities (e.g. training institutionalization, laboratory strengthening, and reporting).

- 1. **SUSTAINMNET PROJECT:** Sustain laboratory strengthening best practices, BS&S management systems, and culture at GoAM national and regional laboratories.
 - a. PROJECT DESCRIPTION: Facilities, equipment, and consumables present in GoAM laboratories are adequate to meet international biosecurity and biosafety guidelines. GoAM laboratories allocate budgetary resources necessary to procure biorisk management (BRM) supplies and operate and maintain BRM equipment/facilities. GoAM designates staff devoted wholly to implementing, monitoring, and continuously improving BRM programs at GoAM laboratories (i.e., Biosafety Officers). GoAM staff receive adequate and regular training necessary to implement BRM practices.
 - b. This project area addresses Program Objective 3.1, 3.2, 3.5.
 - c. BTRP obligations
 - i. Provide expert advice for the development and implementation of operations and procurement plans for maintaining national laboratory facilities, equipment, and consumable supplies.
 - ii. Train and advise staff on standardizing and evaluating BRM programs and policies across GoAM laboratories.
 - iii. Provide training and advice to establish a GoAM cadre capable of delivering adequate and regular BRM training at GoAM laboratories.
 - Provide expert advice for diagnostic equipment and procure if determined to be necessary.
 - v. Assess GoAM readiness to assume full responsibility for BS&S capacities and capaiblities.
 - d. GoAM obligations:
 - i. EDP collections are identified and properly protected
 - ii. Allocate budgetary resources necessary to maintain adequate BRM supplies.
 - iii. Allocate budgetary resources necessary to operate, maintain, certify, and/or calibrate critical BRM equipment.
 - iv. Designate staff necessary to implement and regularly review BRM programs and procedures across GoAM laboratories.
 - v. Establish Biosafety Officer (BSO) positions in GoAM laboratories.
 - vi. Designate BRM staff trainers capable of delivering adequate and regular BRM training.
 - vii. Assume full responsibility for BS&S capacities and capabilities NLT 31 Dec 2023.
- * BS&S Compliance: BTRP support is contingent on GoAM enforcing proper BS&S measures, to include proper use and maintenance of biosafety equipment (i.e. biosafety cabinets) as well as proper use of personnel protective equipment (PPE). If it is determined by BTRP BS&S assessments that participating laboratories are not in compliance, BTRP will halt all activities and funds until the problem is rectified.

- BIOSURVEILLANCE PROJECT: Implement systems and procedures necessary for the rapid determination and reporting of EDP occurrence and communication across sectors and international borders.
 - a. PROJECT DESCRIPTION: GoAM and its executive agents (NCDCP, SSFS) establish and implement reporting duties, communications protocols, and case definitions across Armenia's surveillance network. Also GoAM ensures its laboratory network is properly configured to support rapid determination of outbreaks, to include the utilization the Electronic Integrated Disease Surveillance System (EIDSS) to report and analyze disease data.
 - b. This project area addresses Program Objective 3.3, 3.4, 3.6, 3.7, 5.1.
 - c. BTRP obligations:
 - i. Provide laboratory network analysis and recommendations for laboratory network structure optimized to rapidly identify and categorize outbreaks.
 - ii. Support development and implementation of guidelines and SOPs for routine and timely epidemiological data analysis and investigation.
 - iii. Provide training and advice on basic and advanced epidemiology principles, concepts, and procedures.
 - iv. Assist in the development and implementation of guidelines that outline criteria for exchanging disease surveillance data with national and international stakeholders
 - v. Provide and install EIDSS hardware and software, while providing corresponding training
 - vi. Assess GoAM readiness to assume full responsibility of BSV capacities and capabilities.
 - d. GoAM obligations:
 - i. Implement a unified national sample transport system to facilitate the most efficient and safest flow of samples within the laboratory network
 - ii. Establish a national reference laboratory system to rapidly and effectively identify EDPs and potential outbreaks.
 - iii. Establish and utilize tiered laboratory system to facilitate most efficient use of laboratory resources.
 - iv. Establish and maintain trained cadre of epidemiologist experts capable of health surveillance, monitoring and analysis, investigation of disease outbreaks, epidemics and risk to health.
 - v. Establish and manage health promotion and disease prevention programs.
 - vi. Share disease data with EAs, stakeholders, and international partners.
 - vii. Notify WHO of all reportable EDP disease events.
 - viii. Assume full budgetary responsibility for maintaining and operating EIDSS according to the Transition and Sustainment Plan.
 - ix. Assume full responsibility for national biosurvelliance capacities and capabilities NLT 31 Dec 2024.
- 3. **INSTITUTIONLIZATION PROJECT**: Institutionalizing BS&S, BSV, and One Health best practices and culture within Armenian human and animal health professionals
 - a. PROJECT DESCRIPTION: The Government of Armenia (GoAM) enacts BRM regulations, including oversight, enforcement, education/training, and attribution mechanisms in alignment with international standards. GoAM enacts a consistent biosecurity/biosafety curriculum and training requirements across all governmental and academic institutions focused on disease detection, prevention, and treatment.
 - b. This project area addresses Program Objective 3.2, 3.3, 3.4, 3.5, 4.2

- c. BTRP obligations:
 - Provide Subject Matter Expert advice and mentorship for GoAM leadership and staff in developing legislation, regulations, and other governing documents for establishing effective BRM frameworks.
 - ii. Execute BS&S, BSV, and One Health continuing training, with a focus on trainthe-trainer (T3) model
 - iii. Provide technical assistance in the production of BS&S, BSV, and One Health standard operating procedures (SOPs) and job aids
 - iv. Provide technical assistance for curriculum development in the areas of BS&S, BSV, and One Health in support of a unified national BRM curriculum.
 - v. Assess status of BS&S, BSV, and One Health curriculum institutionalization and GoAM readiness to assume full responsibility of curriculum institutionalization.

d. GoAM obligations:

- i. Develop and enact BRM regulatory framework reforms consistent with World Health Organization (WHO), International Health Regulations (IHR), and/or World Organization for Animal Health (OIE) best practices.
- ii. Assign a governmental organization to lead, execute, and approve BRM institutionalization curriculum development.
- iii. Coordinate curriculum development amongst national BRM institutionalization stakeholders, to include human and veterinary health agencies, educational institutions, research organizations, and private industry.
- iv. Utilize T3 development model to grow and maintain a cadre of BS&S, BSV, and One Health trainers
- v. Assume full responsibility of national BS&S, BSV, and One Health curriculum institutionalization NLT 31 Dec 2022.

ONE HEALTH SYSTEM END STATE: The Government of Armenia is implementing a functioning One Health system that includes multi-sectoral ministerial involvement.

- 1. **ONE HEALTH PROJECT:** Develop and implement a national One-Health framework for detection, diagnosis, and report of EDPs.
 - a. PROJECT DESCRIPTION: GoAM enacts regulations that support the implementation of a One Health policy within Armenia for the detection, diagnosis, and reporting of EDPs. Select health professionals and personnel (e.g. clinicians, researchers, law enforcement, first responders, environmental scientists, etc) are trained on One Health approach and institutionalize One Health framework within GoAM.
 - b. This project area addresses Program Objective 4.1, 4.2
 - c. BTRP obligations:
 - i. Support GoAM in developing and institutionalizing a One Health framework for detecting, diagnosing, and reporting EDPs
 - ii. Train select health professionals and personnel across multiple ministries on the One Health approach with a focus on an integrated and inter-governmental response to potential biological incident
 - iii. Assist GoAM in defining requirements for staffing, training, and deploying epidemiological rapid response teams (RRTs) in order to ensure sufficient workforce for outbreak investigation and response efforts.
 - iv. Assist GoAM in defining requirements for staffing, training, and operating EDP Surveillance Coordination Center (ESCC) in order to ensure coordinated efforts for outbreak investigation and response efforts.

- v. Support healthcare stakeholders in institutionalizing EDPs and One Health education and training to maintain a qualified healthcare workforce
- vi. Assess GoAM readiness to assume full responsibility for One Health capacities, capabilities, processes and procedures.

d. GoAM obligations:

- i. Implement a unified national One Health framework across all ministries that have a role in combating EDPs and/or a role in response to a biological incident, whether naturally occurring or man-made.
- ii. Staff, train, and deploy RRTs in response to potential biological incidents
- iii. Commit to developing a cadre of One Health trainers capable of providing this training.
- iv. Institutionalize One Health education throughout national, regional, and academic biorisk organizations.
- v. Assume full responsibility for national One Health capacities, capabilities, processes and procedures NLT 31 Dec 2025.

REGIONAL AND INTERNATIONAL INTEGRATION END STATE: The Government of Armenia strengthens relationships with regional and international partners through collaborative scientific engagement and data sharing (e.g., Lugar Center in Georgia).

- 1. **INTEGRATION PROJECT:** Engage cross-border and regional activities that strengthen biosurveillance and share BS&S, BSV, and One Health best practices.
 - a. PROJECT DESCRIPTION: GoAM engages with regional and international partners on issues concerning BS&S, biosurveillance, and One Health via bilateral collaboration and multi-lateral events, such as the Biosafety Association of Central Asia and the Caucuses (BACAC). GoAM also establishes guidelines that outline criteria for exchanging disease surveillance data with regional and international stakeholders.
 - b. This project area addresses Program Objective 3.7, 5.1
 - c. BTRP obligations:
 - i. Assist GoAM in the development and implementation of guidelines that outline criteria for exchanging disease surveillance data and BS&S/BSV/One Health best practices with national and international stakeholders.
 - ii. Fund travel and associated expenses for relevant regional and international organizational conferences focused on BS&S, EDP related disease surveillance, and One Health initiatives.
 - iii. Provide assistance in hosting regional and international events within Armenia
 - iv. Assess status of GoAM regional and international BS&S, BSV, and One Health integration and GoAM readiness to assume full responsibility for regional and international integration.

d. GoAM obligations:

- i. Exchange disease surveillance data and BS&S/BSV/One Health best practices with national and international stakeholders
- ii. Allow local Armenian BS&S, BSV, and One Health personnel to travel to regional and international events, working with DTRA and embassy staff to facilitate attendance at such events.
- iii. Integrate into relevant regional and international BS&S/BSV/One Health organizations (e.g. BACAC) working towards reducing risk from biological events
- iv. Inviting regional and international BS&S/BSV/One Health partners to Armenia for further engagements

- v. Assume full responsibility of national BS&S, BSV, and One Health integration efforts NLT 31 Dec 2024.
- RESEARCH PROJECT: Perform grant-worthy, peer-reviewed research on EDPs that reinforces internationally accepted best practices and norms in research and professional development.
 - a. PROJECT DESCRIPTION: Armenian researchers collaborate with international experts in developing research projects funded through BTRP and other international funding sources. Staff learn best practices in biosurveillance and biorisk management, and incorporate those practices in their home institutions. Staff also forge collaborative relationships with Armenian and international researchers focused on reducing biological threats of EDPs. Armenian researchers participate in international conferences and fora, and share research on EDPs and related topics.
 - b. This project area addresses Program Objectives 3.4, 3.5, 5.2.
 - c. BTRP obligations:
 - i. Provide limited equipment and supplies.
 - ii. Mentor staff developing grant applications, manuscripts, research proposals, and conference submissions.
 - iii. Fund travel expenses for relevant conference attendance of researchers performing EDP-related research or disease surveillance.
 - iv. Fund cooperative biological research with Armenians, U.S. and international experts that builds Armenian capacity to detect and address EDPs.
 - v. Continue to fund cooperative research focused on addressing EDPs past year 2025.
 - d. GoAM obligations:
 - i. Commit budgetary resources to sustain new capabilities acquired during research projects.
 - ii. Authorize and support Armenian scientists from across the national EDP research scientific community, including government, academic, and hospital research organizations, to participate in regional and international conferences.
 - iii. Follow international norms for authorship, peer review, and attribution in publications, abstracts, posters, and presentations.
 - iv. Allocate resources to start funding national biological research as a supplement to BTRP funding NLT 31 Dec 2024.