AGREEMENT BETWEEN THE GOVERNMENT OF THE UNITED STATES OF AMERICA AND

THE GOVERNMENT OF GEORGIA CONCERNING THE TRANSITION OF SUSTAINMENT COSTS AND RESPONSIBILIITES

OVER THE UNIFIED LABORATORY SYSTEM FOR DETECTION, EPIDEMIOLOGICAL SURVEILLANCE AND RESPONSE TO ESPECIALLY DANGEROUS PATHOGENS, AND THE RICHARD G. LUGAR CENTER FOR PUBLIC HEALTH RESEARCH IN GEORGIA

The Government of the United States of America (hereinafter the USG) and the Government of Georgia (hereinafter the GoG), hereinafter referred to jointly as "the Parties,"

Recognizing the Agreement Between the United States of America and Georgia Concerning Cooperation in the Area of the Prevention of Proliferation of Weapons of Mass Destruction, and the Promotion of Defense and Military Relations done at Washington July 17, 1997, as extended May 17, 2002, and as amended and extended October 13, 2009 (hereinafter referred to as the Proliferation Prevention Agreement);

Also recognizing the Agreement Between the Department of Defense of the United States of America and the Ministry of Defense of Georgia Concerning Cooperation in the Area of Prevention of Proliferation of Technology, Pathogens and Expertise Related to the Development of Biological Weapons done at Washington December 30, 2002, as amended March 23, 2004, August 30, 2004, November 3, 2005, June 23, 2006, March 6, 2007, March 5, 2008, August 13, 2009, and August 8, 2011 (hereinafter referred to as the Cooperative Threat Reduction (CTR) Cooperative Biological Engagement Program (CBEP) Implementing Agreement);

Having established, pursuant to the Proliferation Prevention Agreement and the CTR CBEP Implementing Agreement, the Unified Laboratory System for Detection, Epidemiological Surveillance and Response to Especially Dangerous Pathogens (hereinafter the ULS), and the Richard G. Lugar Center for Public Health Research in Georgia (hereinafter the Lugar Center), to assist Georgia in countering the threat of bioterrorism and to prevent the proliferation of biological weapons-related materials, technology, and expertise; and

Desiring to transition Sustainment Costs and responsibilities for the operation of the ULS and the Lugar Center from the USG to the GoG;

Hereby agree as follows:

ARTICLE I: SCOPE

 This Agreement, together with its annexes (which constitute an integral part of this Agreement) delineates and memorializes the mutually agreed-upon understandings,

- responsibilities, obligations, and commitments of the Parties with respect to the transition, from the USG to the GoG, of Sustainment Costs and responsibilities for operating the ULS and the Lugar Center.
- 2. This Agreement shall be implemented by the following agencies (hereinafter collectively referred to as the "Implementing Agencies"):
 - a. For the GoG: The Ministry of Labor, Health, and Social Affairs (MoLHSA), the Ministry of Agriculture (MoA), the Ministry of Education and Sciences (MoES), and the Ministry of Defense (MoD);
 - b. For the USG: The Department of Defense's (DoD) Defense Threat Reduction Agency (DTRA).
- 3. The terms of this Agreement shall apply to the Parties and all Implementing Agencies referenced in paragraph 2 of this Article.
- 4. Notwithstanding the termination of the Proliferation Prevention Agreement or the CTR CBEP Implementing Agreement, this Agreement and all activities undertaken in accordance with this Agreement shall be subject to the provisions of the Proliferation Prevention Agreement and the CTR CBEP Implementing Agreement. In the event of any discrepancies between this Agreement and the Proliferation Prevention Agreement or the CTR CBEP Implementing Agreement, the provisions of the Proliferation Prevention Agreement and the CTR CBEP Implementing Agreement shall prevail.

ARTICLE II: DEFINITIONS

- "ULS" shall mean the Unified Laboratory System of Detection, Epidemiological Surveillance and Response to Especially Dangerous Pathogens (EDPs), and shall include the Human Health Laboratories of the National Center for Disease Control and Public Health (NCDC), which includes the Lugar Center, and the Veterinary Laboratories of the MoA (LMA) listed in Annex A to this Agreement.
- 2. "Lugar Center" shall mean the Lugar Center for Public Health Research in Georgia as described in Annex A to this Agreement.
- 3. "Epidemiological Surveillance and Response to Especially Dangerous Pathogens" (EDP) shall mean pathogens belonging to the third or fourth risk group, as designated by the World Health Organization's (WHO) Biosafety Manual.
- 4. "National Center for Disease Control and Public Health" (NCDC) shall mean the Legal Entity of Public Law (LEPL) L. Sakvarelidze National Center for Disease Control and Public Health subject to state control by the MoLHSA of Georgia.

- 5. "Laboratory of the Ministry of Agriculture" (LMA) shall mean the LEPL Laboratory of the MoA of Georgia subject to state control by the MoA of Georgia.
- 6. "Zonal Diagnostic Laboratory" (ZDL) shall mean a zonal diagnostic territorial unit of the NCDC or the LMA.
- 7. "Laboratory Supply Station" (LSS) shall mean a regional diagnostic territorial unit of the NCDC or the LMA.
- 8. "Property" shall mean any tangible or intangible assets created or provided in accordance with the Proliferation Prevention Agreement and the CTR CBEP Implementing Agreement that were, or shall be, transferred to the GoG by the USG.
- 9. "Sustainment Costs" shall mean the costs of maintenance, inspection and operation of the facilities; utilities; security; tooling; information technology (including maintenance of the Electronic Integrated Disease Surveillance System (EIDSS) and the Pathogen Asset Control System (PACS) networks at any site within Georgia); laboratory consumables and supplies, salaries for the Lugar Center local staff; and any other costs necessary for operation of the ULS.
- 10. "Transition Period" shall mean the period beginning on the date of entry into force of this Agreement and ending January 1, 2018, during which the DTRA, on behalf of the USG, will incrementally transfer financial and operational responsibility for the ULS to the GoG as outlined in Annex B to this Agreement.

ARTICLE III: RESPONSIBILITIES

- 1. For the purposes of implementing this Agreement, the Implementing Agencies shall jointly develop and coordinate a non-legally binding Joint Transition Plan (JTP), which they intend to finalize jointly by no later than December 31, 2014. The JTP shall expand upon this Agreement and its Annexes to describe the detailed timelines, funding requirements, actions, and activities of the Implementing Agencies necessary to complete the transition of Sustainment Costs over the ULS and the Lugar Center from the USG to the GoG.
- 2. During the Transition Period DTRA, on behalf of the USG, shall, subject to the availability of appropriated funds:
 - a. Assist the GoG in funding the Sustainment Costs of the ULS in accordance with the timeline, cost information, and delegation of responsibilities outlined in Annex B to this Agreement and as later described in the JTP;
 - b. Assist the GoG and the NCDC in progressing towards meeting the requirements for designation of the Lugar Center as an official World Health Organization (WHO) Collaborating Center;

- Continue funding DTRA-approved research projects and travel costs for appropriate GoG representatives to DTRA-approved international conferences and training events, to be determined on a case-by-case basis;
- d. Coordinate closely with the U.S. Department of the Army, Executive Agent for establishing a collaborative DoD presence at the Lugar Center. The U.S. Department of the Army is not an Implementing Agency under this Agreement, but may take further actions to facilitate a collaborative DoD presence at the Lugar Center. These actions may include the establishment of agreements between appropriate DoD and GoG entities prescribing specific relationships and responsibilities, financial or otherwise, that support DoD's presence at the Lugar Center.
- 3. During the Transition Period, the GoG and its Implementing Agencies shall:
 - a. Assist the USG in funding the Sustainment Costs of the ULS in accordance with the timeline, cost information, and delegation of responsibilities outlined in Annex B to this Agreement and as later described in the JTP;
 - Undertake necessary actions for the NCDC to progress towards meeting the requirements for designation of the Lugar Center as an official WHO Collaborating Center;
 - c. Facilitate the work at the Lugar Center by qualified scientists from other agencies and institutes to foster the "One Health" vision as defined collectively by the Food and Agriculture Organization, the WHO, and the World Organization for Animal Health. Such agencies and institutes shall include, but shall not be limited to, the Eliava Institute and the LMA; and
 - d. Maintain the current level of workforce and operational competencies and capabilities necessary to operate and maintain the ULS effectively, including operation and maintenance (O&M), safety, and internal Lugar Center security personnel trained and currently funded by DTRA, to ensure safe and proper operations of the ULS. The details of the key staff retention and transition of the O&M capability to the GoG shall be described in the JTP.
- 4. Effective January 1, 2018, the GoG shall be responsible for funding all Sustainment Costs and operating the ULS, including equipment replacement costs as well as funding to address contingencies within the ULS. After completion of the Transition Period, the GoG shall ensure sustainment and maintenance of the EIDSS and the PACS for proper functioning of the ULS.
- 5. Any USG personnel present at the Lugar Center shall benefit from the physical security services provided by the Government of Georgia at that Center. The GoG shall cooperate and coordinate with the USG on all matters related to the security of USG personnel who may be present at that Center. Any concerns relating to the Center or USG employees

working at the Center must be immediately addressed through consultations between the GoG and the U.S. Mission.

ARTICLE IV: ENTRY INTO FORCE AND AMENDMENT

- 1. This Agreement shall enter into force upon the date of the later note in an exchange of diplomatic notes between the Parties confirming completion by each Party of all applicable procedures required for entry into force, and shall remain in force for the duration of the Proliferation Prevention Agreement or until December 31, 2019, whichever is later.
- 2. This Agreement may be amended by the mutual written agreement of the Parties.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective governments, have signed this Agreement.

Signed at Tbilisi, this <u>5</u> day of June 2014, in duplicate, in the English and Georgian languages, each text being equally authentic.

FOR THE GOVERNMENT OF THE UNITED STATES OF AMERICA:

PUB. Tel

FOR THE GOVERNMENT OF GEORGIA:

LABORATORIES OF THE UNIFIED LABORATORY SYSTEM OF DETECTION, EPIDEMIOLOGICAL SURVEILLANCE, AND RESPONSE TO ESPECIALLY DANGEROUS PATHOGENS

- 1. Human Health Laboratories of the NCDC include the following:
 - a. Richard G. Lugar Center for Public Health Research (the Lugar Center):
 - i. Central repository for Georgia's museum of Especially Dangerous Pathogens (EDPs);
 - ii. Top-tier Biosafety Level (BSL)-3 diagnostic laboratory;
 - iii. Regional training center for biosafety and security.
 - b. Two (2) Zonal Diagnostic Laboratories (ZDLs) in Kutaisi and Batumi; and
 - c. Seven (7) Laboratory Supply Stations (LSSs) in Gori, Telavi, Poti, Zugdidi, Ozurgeti, Akhaltsikhe, and Amborlauri.
- 2. Veterinary laboratories of the Laboratory of the MoA (LMA) include the following:
 - a. Three (3) veterinary ZDLs in Tblilisi, Kutaisi, and Akhaltsikhe; and
 - b. Eight (8) veterinary LSSs in Dusheti, Marneuli, Gurjaani, Gori, Ozurgeti, Ambrolauri, Batumi, and Zugdidi.

ESTIMATED ANNUAL SUSTAINMENT COSTS BY CALENDAR YEAR FOR THE ULS AND LUGAR CENTER

The annual ULS Sustainment Costs funded by DTRA that DTRA is transferring to the GoG under this Agreement are estimated at \$3.794 million. The GoG shall assume responsibility for these Sustainment Costs gradually during the Transition Period, as indicated in Table 1:

- NCDC's ZDLs and LSSs \$0.705M
- NCDC's Lugar Center \$2.541M
- LMA \$0.548M

Table 1

	2014	2015	2016	2017	2018
MoLHSA	0.364	0.728	1.200	1.800	3.246
MoA	0.0	0.091	0.172	0.277	0.548
TOTAL	0.364	0.819	1.372	2.077	3.794

Figures are in Million USD (\$M) and represent actual costs incurred by the USG during 2012

Calendar Year 2014

- 1. On behalf of the USG, DTRA shall, subject to the availability of appropriated funds:
 - a) Fund the Sustainment Costs for the ULS including procurement and re-supply of ULS consumables with the exception of the electricity costs for the NCDC's Lugar Center;
 - b) Continue maintenance and sustainment of EIDSS and PACS networks as necessary while supporting its transition to the GoG;
 - c) Finalize the JTP;
 - d) Complete the actions necessary for the transfer of ownership to the GoG of all assets, including property and equipment provided by DTRA necessary for the ULS functionality.

2. The GoG shall:

- a) Undertake payment of the electricity costs for the Lugar Center effective May 2014;
- b) Facilitate necessary legal and institutional changes to ensure that, in order to expedite procurement of EDP-related equipment, consumables, and reagents for the ULS, these items are exempt from the requirements of the State Procurement Law of Georgia and subsequent normative acts after the procurement and re-supply responsibilities for these items are transferred to the GoG. The list of the exempted equipment, consumables, and reagents for the ULS shall be approved by the GoG and reviewed once every three years;

- c) Expedite all necessary actions to take ownership of the assets and property provided by DTRA under CBEP Georgia, including the Lugar Center building;
- d) Begin construction of the NCDC Administrative Building at the Lugar Center;
- e) Work with DTRA and its designated contractors to finalize the JTP no later than December 31, 2014.

Calendar Year 2015

- 1. On behalf of the USG, DTRA shall, subject to the availability of appropriated funds:
 - a) Fund the Sustainment Costs for the ULS with the exception of electricity, water, and natural gas for the NCDC's Lugar Center and utilities, security services, vehicle insurance, and lab personnel annual medical examination costs for all Veterinary ZDLs and LSSs;
 - b) Complete upgrades and replacement of outdated and obsolete laboratory equipment at ZDLs, LSSs, and the Lugar Center as prescribed by the Parties in the JTP;
 - c) Transfer responsibility for Internet channels costs and EIDSS and PACS equipment maintenance at all EIDSS and PACS sites.

2. The GoG shall:

- a) Pay electricity, water, and natural gas costs for the NCDC's Lugar Center;
- b) Pay utilities, security services, vehicle insurance, and lab personnel annual medical examination costs for all Veterinary ZDLs and LSSs;
- c) Pay Internet channels costs and accept responsibility for EIDSS and PACS equipment maintenance at all EIDSS and PACS sites.

Calendar Year 2016

- 1. On behalf of the USG, DTRA shall, subject to the availability of appropriated funds:
 - a) Fund Sustainment Costs for the NCDC and Lugar Center, excluding 1) electricity, water, and natural gas for the Lugar Center; and 2) all sustainment costs for all Human ZDLs and LSSs;
 - b) Fund the sustainment costs for the Veterinary ZDLs and LSSs, excluding the utilities, security services, vehicle insurance, lab personnel annual medical examination, and fuel.

2. The GoG shall:

a) Pay Sustainment Costs for the ULS, including: Electricity, water, and natural gas costs for the Lugar Center, and full sustainment costs for all Human ZDLs and LSSs;

- b) Pay Sustainment Costs, including: Utilities, security services, vehicle insurance, lab personnel annual medical examination, and fuel costs for all Veterinary ZDLs and LSSs;
- c) Complete construction of the NCDC Administrative Building at the Lugar Center.

Calendar Year 2017

- 1. On behalf of the USG, DTRA shall, subject to the availability of appropriated funds:
 - a) Fund the Sustainment Costs for the NCDC's Lugar Center, excluding electricity, water, natural gas, and salaries for the local national O&M personnel;
 - b) Fund key positions for the Lugar Center as mentors for the Georgian Building Automation Operator, and for the Facility Chief Engineer, as required;
 - c) Fund office and laboratory supplies, reagents, and consumables costs for Veterinary ZDLs and LSSs.

2. The GoG shall:

- a) Pay full Sustainment Costs for all Human ZDLs and LSSs and, for the NCDC's Lugar Center, pay costs of electricity, water, natural gas, and salaries for the local national O&M personnel, or, if not feasible, retain a third-party O&M contractor to keep the facilities operational;
- b) Pay full Sustainment Costs for Veterinary ZDLs and LSSs, excluding office and laboratory supplies, reagents, and consumables costs.

Calendar Year 2018 and beyond

Effective January 1, 2018, the GoG shall be responsible for funding all costs to sustain and operate the ULS, including equipment replacement costs as well as funding to address any contingencies within the ULS.