

**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE U.S. DEPARTMENT OF AGRICULTURE MARKETING AND REGULATORY
PROGRAMS,
THE U.S. DEPARTMENT OF AGRICULTURE RESEARCH, EDUCATION, AND
ECONOMICS,
AND
THE DEPARTMENT OF HOMELAND SECURITY
SCIENCE AND TECHNOLOGY DIRECTORATE
FOR
NATIONAL BIO AND AGRO-DEFENSE FACILITY COLLABORATION**

This is a Memorandum of Understanding (MOU) between the U.S. Department of Agriculture (USDA) Marketing and Regulatory Programs (MRP), the USDA Research, Education, and Economics (REE), and the Department of Homeland Security (DHS) Science and Technology Directorate (S&T). When referred to collectively, USDA MRP, USDA REE, and DHS S&T are referred to as the "Parties."

1. BACKGROUND:

- 1.1. On June 20, 2019, the Parties entered into a Memorandum of Agreement (June 20th MOA) that outlined the process for the transfer of operational responsibility for the National Bio and Agro-Defense Facility (NBAF) from DHS S&T to USDA.
- 1.2. Within this June 20th MOA, Phase 4 of the transition noted that, following the attainment of Full Operational Capability (FOC), the Parties would develop a process for addressing DHS priorities for research and development for foreign, emerging, and zoonotic diseases at NBAF and establish a new agreement between the Parties in support of that process. DHS S&T agreed to identify areas of mission synergy between the Parties for future interagency scientific collaboration at the NBAF.
- 1.3. Concurrent with the transfer of the Plum Island Animal Disease Center (PIADC) to DHS as part of the Homeland Security Act of 2002 (codified at 6 U.S.C. 190), since 2004 USDA and DHS S&T have coordinated a biological countermeasures research program at PIADC in response to the threat of agricultural terrorism.
- 1.4. Coordination of the USDA and DHS S&T biological countermeasures research program has occurred through the use of interagency agreements in support of scientific activities addressing national security needs (e.g., research, development, testing and evaluation (RDT&E) for countermeasures, and gap-filling studies involving disease pathogenesis and transmission).
- 1.5. DHS has a continued interest in the mission of protecting U.S. agriculture and maintaining collaboration with NBAF as a national and international laboratory asset for this purpose. DHS S&T has the statutory role for RDT&E (6 U.S.C. 182) and the Office of National Laboratories has the DHS S&T role for partnered RDT&E laboratory environments.
- 1.6. DHS S&T currently administers the National Biodefense Analysis and Countermeasures Center (NBACC) which is managed and operated by Battelle National Biodefense Institute (BNBI) as a Federally Funded Research and Development Center (FFRDC). Through NBACC, DHS provides a critical biocontainment laboratory capability that supports national security interests by providing the scientific basis for the characterization of biological threats and bioforensic analysis to support attribution of their planned or actual use. The FFRDC contract includes a Work for Others (WFO) program to provide a mechanism for other federal agencies or non-federal entities to utilize NBACC's biological subject matter expertise and unique laboratory capabilities.

2. PURPOSE & SCOPE:

- 2.1. The purpose of this MOU is to define an initial framework under which the Parties will plan and establish a mechanism for engagement regarding national security-related R&D needs at NBAF as outlined in Homeland Security Presidential Directive 9: Defense of U.S. Agriculture and Food, the National Biodefense Strategy, and subsequent national security policies as appropriate.
- 2.2. It is anticipated that the nature of the relationship between the Parties at NBAF will evolve over time; therefore, the intent of this MOU is to provide a foundational guidance for the types of interactions that may occur between the Parties.
- 2.3. A strategic interagency partnership between the Parties at NBAF will support a focus on national security, including interagency RDT&E requirements.
- 2.4. This MOU will focus on the roles within the Parties agricultural biodefense mission relative to NBAF and will provide a mechanism for periodic review and update as those responsibilities may evolve and change.
- 2.5. This MOU does not seek to identify all USDA or DHS S&T activities related to national security, biodefense, agriculture defense, or related. Where those activities identify a specific opportunity for collaboration between USDA and DHS S&T at NBAF, they will be considered, as appropriate, through review and update of the MOU.
- 2.6. To clarify the Parties' responsibilities during planning and execution of transferring NBAF operational responsibility to USDA in advance of attaining FOC, in the June 20th MOA, the Parties identified two distinct areas of collaborative opportunity defined as follows:
 - a. **Threat Risk Assessment and Research Prioritization.** To determine which transboundary, emerging animal diseases and zoonotic pathogens present the greatest intentional and unintentional (naturally occurring) risk to animal health, human health and national security. Outputs will inform analysis and decision making leading to research prioritization at the NBAF.
 - b. **Research and Collaboration.** To support the related, but distinct USDA and DHS S&T food and agriculture missions. Includes threat characterization and classified research, RDT&E involving biological countermeasures (vaccines, biotherapeutics and diagnostics), subject matter expert collaboration and information sharing, and partnerships.
- 2.7. It is recognized that the collaborative program areas identified in Section 2.6 and described in greater detail in Section 4 may evolve and change over time and will be reviewed at a minimum of every 12 months after signing to ensure consistency with Parties' current, respective missions and scopes of activities.
- 2.8. This MOU does not seek to supersede any existing or limit or preclude any future interagency partnerships between the Parties and other DHS Components or other Departments/Agencies.
- 2.9. USDA and DHS S&T are committed to working with partners and stakeholders across the U.S. government; State, Local, Tribal, and Territorial governments; food and agriculture sector; academia; and international community to support the national security and agricultural biodefense mission of NBAF and, where appropriate, will seek to modify the areas of collaborative opportunity and related responsibilities based on stakeholder feedback.

3. AUTHORITIES:

- 3.1. The Consolidated Appropriations Act, 2018, Pub. L. 115-141 and the Consolidated Appropriations Act, 2019, Pub. L. 116-6 which authorize transfer of NBAF from DHS S&T to USDA.
- 3.2. 6 U.S.C. §§182(4)(5)(11), and (12) which authorizes DHS S&T to conduct its research mission on behalf of DHS.

4. AREAS OF COLLABORATIVE OPPORTUNITY:

Specific areas of opportunity for collaboration between the parties relative to the operational and strategic needs of NBAF are defined below.

4.1. Risk Assessment and Research Prioritization

- a. Risk Assessments – Risk assessments are needed to inform which transboundary, emerging animal disease, and zoonotic pathogens present the greatest risk to animal health, human health, and national security. For the purposes of NBAF, outputs from these assessments will be used to drive research priorities. Based on knowledge of emerging threats, realized through interagency activities or those being addressed directly through the DHS S&T bio threat characterization activities inclusive of activities at NBACC, it is anticipated that the NBAF mission and programs will address risks originating from both intentionally-occurring and unintentional/naturally-occurring sources. Accordingly, collaborative responsibilities of the NBAF Parties will contribute to this mission aspect.
- b. Research Prioritization –DHS S&T’s insight and roles involving the domains of both agricultural defense and biodefense can provide valuable inputs and perspective in the review of NBAF scientific portfolio activities and will benefit DHS S&T, USDA, and the interagency. Based on knowledge of emerging threats realized through interagency activities or those being addressed directly through the DHS biothreat characterization activities, DHS S&T can support and inform NBAF program prioritization (and resource requests) and gap-addressing activities in order to contribute to aligning facility efforts with the most pressing national security threats.

4.2. Research and Collaboration

- a. Threat Characterization and Classified Research – NBAF will provide a unique environment for threat characterization involving pathogens identified through USDA intentional/unintentional surveillance programs necessitating handling in BSL-3 Ag and/or BSL-4 laboratory spaces. Additionally, NBAF may have the capability to conduct classified research and only NBAF will be authorized to work on live foot and mouth disease virus. DHS S&T’s NBACC supports intelligence assessments, preparedness planning, response activities, emerging threat characterization and bioforensic analyses. Therefore, threat characterization work in collaboration with NBACC may be necessary to inform research, development, testing, and evaluation of diagnostics and countermeasures for agents of concern relative to the NBAF mission.
- b. Agricultural and Biological Countermeasure RDT&E– DHS and USDA have a need to develop emerging technologies and products for use by both agencies and interagency operational components to include, but not limited to, laboratory work to assess detection technologies for infectious materials and assessment of disinfection and decontamination technologies for neutralization of infectious material.
- c. Subject Matter Expert Collaboration and Information Sharing – Building on the success of collaboration and information sharing achieved at PIADC, continued engagement on operational and strategic needs relative to the NBAF mission is a priority for all Parties.
- d. Partnership – USDA will develop and lead implementation of a framework to engage creative partners and collaborators well beyond the walls of NBAF and stimulate the entire bio and agro-defense sector. Collaboration between USDA and DHS through this framework is essential for achieving this goal and accelerating access to research and technology by the

sector. Additionally, USDA and DHS will collaborate on partnerships to bridge the gap to decrease risk for private sector investments in veterinary medical countermeasures development for transboundary diseases. Through the Biological Development Module (BDM) at NBAF, basic and applied research can be expedited to develop tools and technologies through more rapid technology transfer, providing a mechanism for the private sector to partner with government to test proof of concept and optimize processes to get products to market.

5. RESPONSIBILITIES:

Responsibilities outlined below are not intended to be a comprehensive listing of the contributions of the Parties in these respective mission spaces. Rather, this description is intended to provide a framework for how the parties will work together to address the areas of collaborative opportunity for NBAF as described in Section 4. Additional activities, collaborations, and partnerships related to these areas of opportunity can and should inform decisions, recommendations, and next steps for the NBAF mission.

5.1. USDA Responsibilities:

- a. Provide analysis of unintentional/naturally occurring sources based on active and passive disease surveillance from national and international programs and work collaboratively to ensure this information is accurately characterized in risk assessments related to the NBAF mission.
- b. In collaboration with DHS components and interagency partners as appropriate, contribute to the development, conduct, and evaluation of analyses to determine the scope and impact of biological events related to the NBAF mission.
- c. Lead NBAF annual stakeholder meetings including a homeland security focused meeting and knowledge gap workshops which facilitate collaboration with DHS S&T as a key stakeholder to inform national security research priorities related to the NBAF mission.
- d. Provide subject matter expertise to collaborate on and conduct laboratory work to understand agent characteristics, e.g., virulence, mechanisms of pathogen transmission, and surface stability identify opportunities that may help accelerate the advancement of emerging, zoonotic diseases through BSL-4 initiatives.
- e. Collaborate with NBACC to develop and maintain relationships with operational personnel to support facility standup and operation, develop protocols and procedures, share information, and evaluate lessons learned.
- f. Establish a framework and mechanism for DHS S&T to support research, development, testing, or evaluation to further their own mission activities subject to availability of funding that it does not interfere with USDA's ability to complete NBAF mission priorities. The framework will include working with DHS to identify other government, academic, or industry laboratories to support their mission needs.
- g. Include DHS S&T as a strategic partner and collaborator in the USDA framework to encourage innovation in the bio and agro-defense sector and expedite development of tools and technologies through more rapid technology transfer and other mechanisms as appropriate.
- h. Provide on-site space for two DHS S&T employees to support national security priorities relative to the NBAF mission.
- i. Include DHS S&T as a member of the NBAF Board of Directors (BOD). The BOD ensures NBAF is operated to meet the mission requirements of USDA as well as inclusion of DHS collaborative needs.

5.2. DHS S&T Responsibilities:

- a. Consolidate analyses of risk from intentional threats and associated R&D support needs in collaboration with DHS components and participate in collaborations with USDA and the intelligence community to assess the collective understanding of adversaries' capabilities.
- b. Conduct analyses to determine the scope and impact of potential biological events through modeling and simulation studies. This work will include, but not be limited to, planned DHS S&T activities such as biological threat characterization projects which are part of the broader suite of core activities and projects within the DHS S&T-led Probabilistic Analysis of National Threat, Hazard, and Risk ("PANTHR") strategic program.
- c. Establish a mechanism for ongoing collaboration between NBAF and NBACC to foster the capability to conduct research driven by requirements derived from classified sources.
- d. Provide subject matter expertise to collaborate on and conduct laboratory work at NBACC to understand agent characteristics, e.g., virulence, mechanisms of pathogen transmission, and surface stability and identify NBACC opportunities that may help accelerate the advancement of countermeasures for emerging, zoonotic diseases through BSL-4 initiatives.
- e. Identify and support the collaboration of NBACC subject matter expertise for facility standup and operations especially related to BSL-4 laboratory and animal procedures with USDA.
- f. Consolidate operational requirements within the research and development needs of DHS components as they relate to the NBAF mission and convey these requirements through participation in the NBAF annual stakeholder and homeland security meetings and knowledge gap workshops.
- g. Participate as a strategic partner and collaborator in USDA's framework to encourage innovation in the bio and agro-defense sector; use its Other Transaction Authority ("public private partnerships") to help address its priorities in order to hasten and maximize collaboration in the interest of national security-relevant scientific activities; and execute the Countermeasure Technology Product Prototyping and Transition to Commercialization Program (TCP2) through projects at NBAF, other government, academic, and industry laboratories to include the use of Long-Range Broad Agency Announcements, CRADAs, and MOUs.
- h. Maintain a strategic presence at NBAF to support national security priorities related to the NBAF mission that may include: (1) a Scientific Program Manager to coordinate food and agriculture R&D Laboratory requirements from DHS components; develop DHS agricultural defense strategic and tactical R&D plans; manage the DHS ag defense countermeasure RDT&E portfolio and annual budget; and serve as a liaison to the NBAF Director and (2) a Scientific Advisor to manage and execute a DHS Technology and Countermeasure Product Prototyping and Commercialization Program; conduct technology scouting activities associated with understanding external cutting edge and disruptive technology landscape, and capabilities that can be applied to DHS R&D requirements; manage RDT&E projects and transition to industry partners; manage DHS S&T interagency agreements w/ NBAF; and serve as a liaison with NBAF research leaders.
- i. Participate as a member of the NBAF BOD.

6. GENERAL PROVISIONS:

POINTS OF CONTACT: The following points of contact (POC) will be used by the Parties to communicate in the implementation of this MOU. Each Party may change its POC upon reasonable notice to the other Party.

For the USDA—

Elizabeth Lautner
Associate Deputy Administrator, Diagnostics and Biologics
USDA Animal and Plant Health Inspection Service (APHIS)
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Steven Kappes
Associate Administrator, Office of National Programs
USDA Agricultural Research Service (ARS)
Phone 301-504-5084
steven.kappes@usda.gov

For the DHS—

Julie Brewer
Director, Office of National Laboratories
DHS Science and Technology Directorate
Phone 202-254-6454
julie.brewer@hq.dhs.gov

Timothy Barr
NBAF Program Manager, Office of National Laboratories
DHS Science and Technology Directorate
Phone 785-320-6811
timothy.barr@hq.dhs.gov

REVIEW OF AGREEMENT: This MOU will be reviewed annually on or around the anniversary of its effective date.

MODIFICATION: This MOU may be modified, as needed, by the written agreement of the Parties, duly signed by their authorized representatives.

TERMINATION: This MOU may be terminated at any time upon the mutual written consent of the Parties.

TRANSFERABILITY: This MOU is not transferable except with the written consent of the Parties.

ENTIRE AGREEMENT: It is expressly understood and agreed that this MOU embodies the entire understanding between the Parties.

EXPIRATION DATE: This MOU expires five (5) years after its effective date, unless extended by mutual agreement of the Parties during the last annual review.

EFFECTIVE DATE: This MOU takes effect beginning the day the last Party signs.

DISPUTES: Disputes related to this MOU shall be resolved in accordance with instructions provided in the Treasury Financial Manual Volume I, Part 2, Chapter 4700, Appendix 10, Intragovernmental Business Rules.

NO BENEFICIARIES: This MOU is not intended to, and does not create, any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity, by a party against the United States, its agencies, its officers, or any person.

7. FINANCIAL DETAILS:

The Parties and their respective agencies and offices will handle their own activities and utilize their own resources, including the expenditure of their own funds, in pursuing these objectives and Role. Each Party will carry out its separate activities in a coordinated and mutually beneficial manner.

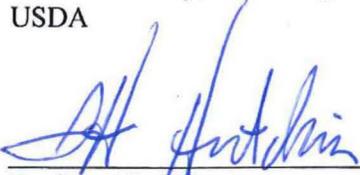
Nothing in this MOU shall obligate either Party to obligate or transfer any funds. Specific work projects or activities that involve the transfer of funds, services, personnel, or property among various agencies and offices of the Parties will require execution of separate agreements and be contingent upon the availability of appropriated funds. Such activities must be independently authorized by appropriate statutory authority. This MOU does not provide such authority. Negotiation, execution, and administration of each such separate agreement must comply with all applicable statutes and regulations.

IN WITNESS WHEREOF, the Parties hereto have caused this MOU between USDA MRP, USDA REE, and DHS S&T to be executed as of the date of the last signature:

For the U.S. Department of Agriculture:

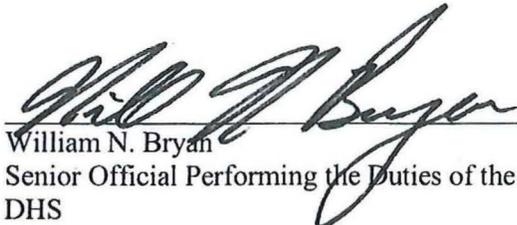


Date: 1.7.2020
Gregory Ibach
Under Secretary, Marketing and Regulatory Programs
USDA



Date: 1/7/2020
Dr. Scott Hutchins
Deputy Under Secretary, Research, Education, and Economics
USDA

For the Department of Homeland Security:



Date: 12/13/2019
William N. Bryan
Senior Official Performing the Duties of the Under Secretary for Science and Technology
DHS