

## **CENTER OF EXCELLENCE (COE)**

### **COOPERATIVE AGREEMENT TERMS AND CONDITIONS** **GRANTS AND FINANCIAL ASSISTANCE DIVISION (GFAD)**

A recipient under this funding opportunity must comply with the FY 2025 Department of Homeland Security Standard Terms and Conditions, v. 3 (Apr. 18, 2025). **However**, Paragraphs C. IX and C.XVII(2)(a)(iii) do not apply to any federal award under this funding opportunity to the extent their application is limited by the injunction in *San Francisco v. Trump*, No. 3:25-cv-01350 (N.D. Cal.), or any other litigation, so long as that injunction is in force. The FY 2025 Department of Homeland Security Standard Terms and Conditions, v. 3 (Apr.18, 2025) are attached for reference.

## **ARTICLE I. ADMINISTRATIVE TERMS AND CONDITIONS**

### **A. RESEARCH PROJECT AND MANAGEMENT: AWARD-SPECIFIC TERMS AND CONDITIONS AND/OR RESTRICTIONS**

1. Recipient shall submit all projects and programs funded under this Award to the Department of Homeland Security (DHS) for review and approval using [GrantSolutions.gov](https://www.grantsolutions.gov).
2. Recipient shall compete fully and fairly, to the maximum extent practicable, all projects funded under this Award unless DHS has approved otherwise.
3. The DHS Science and Technology Directorate (S&T) is committed to the protection of privacy, civil rights, and civil liberties in all performed or supported research. Recipient and all persons participating in any research project supported by this Agreement (including any subrecipient, contractor, partner, collaborator, consultant, or researcher) shall comply with the following:
  - a. Recipient supported under this award may not employ deceptive or covert practices to collect data. Only approved false identities may be used to collect data.
  - b. Recipient may not provide research data containing Personally Identifiable Information (PII) to law enforcement, intelligence, or investigative agencies, unless required by law or court order.
  - c. Recipient may not use S&T funding to support the collection, maintenance, use, or dissemination of individuals' personally identifiable information based on the content of their speech and how they express themselves non-violently, their associations, how and whether they choose to worship, and how they choose to non-violently express their concerns or positions to government. Accessing (viewing or examining) such PII but not collecting, maintaining, using, or disseminating it is permissible. Similarly, event or activity information that does not include personally identifiable information is permissible.
  - d. Non-violent forms of political activism and the political views held by individuals or groups may not provide the basis for Recipient to collect PII.
  - e. Recipient will respect the privacy settings set by individuals on websites, only collecting publicly available social media information (e.g., open-source information).
  - f. Keywords used to query publicly available information must be designed in such a way as to not profile, target, or discriminate against any individual based on the content of their speech and how they express themselves non-violently, their associations, how and whether they choose to worship, and how they choose to non-violently express their concerns or positions to government. See, e.g., Department of Justice guidance.

- g. Web scraping is not permissible. Established key words must be used to search for data.
  - h. When sourcing from social media, Recipient must abide by the established Terms of Service of any internet service provider(s) or other publicly available information platforms—including social media companies—from which the information is collected. Recipient will access and retain a copy of the relevant Terms of Service of each website accessed, and review monthly the Terms of Service for each website accessed within the last 30 days. If the Terms of Service have been updated, a copy of the updated Terms of Service must be retained.
  - i. When engaging in social media emotion analysis Recipient must provide independent, peer-reviewed proof of efficacy before research commences.
    - (i) If some form of emotion analysis is necessary, it will be made based upon the subject's words and images.
    - (ii) Emoticons alone, or the like, will not be used to determine an individual's emotional state.
    - (iii) Any risk analysis based on publicly available or social media information will not include emotion analysis or monitoring.
  - j. Recipient will refrain from using any tools that attempt to predict future behavior of an individual or anticipate a specific emotional response based upon interpretation of past displayed emotions.
  - k. When developing risk profiles or assessments Recipient must not utilize predictive analysis unless the efficacy of the predictive analytic technique or methodology has been peer-reviewed and independently validated. Any research using predictive analysis requires a description of how unintended bias is accounted for and controlled, and how data provenance is tracked and maintained by any party collecting the data.
  - l. Recipient shall anonymize any data collected to protect individual privacy.
  - m. Before any data collected as part of this research is archived or publicly released the Recipient shall conduct a review to ensure that there is no PII, and that no secondary PII may be used to unmask research participants identity.
  - n. Flowdown Requirements. The Recipient shall include the substance of this section in all sub-awards/contracts at any tier under which any person participates in any research project supported by this agreement, including any research project that may use, generate, or have access to government facilities and Controlled Unclassified Information (CUI) or classified information.
4. Recipient shall submit annual workplans for the activities for this Award to DHS for review and approval by May 1, 2025. Modifications to any project or program funded under this award should be submitted to DHS for review and approval before initiating new work.
- a. Annual workplans must provide information on the overall activities of the Center. The workplan shall include:
    - (i) Summary of the Center's strategic vision and activities;
    - (ii) Summary of Center communication and transition activities;
    - (iii) Summary of Center management efforts including management decision making apparatus and review process to monitor project progress;
    - (iv) Detailed descriptions on each Center project (including sub-Recipient projects) to include:
      - Abstract (objectives, outcomes, value proposition)
      - Objective/Purpose
      - Baseline

- Research Methodology, including proposed data sources and indication as to whether any of these sources hold any sensitivities (as outlined in Article I., Section A., Item 11.)
  - Project milestones
  - Performance metrics used to evaluate progress and assessments of current concept of operations and baselines/state of the art in use
  - Transition plans to include development steps, intellectual property management plans, and market specific considerations
  - Stakeholder engagement
  - Potential programmatic risks to completion and risk mitigations
  - Project outcomes and outputs, including information on how project outcomes will advance or impact current policies, procedures, technologies, or capabilities; and,
  - Project budgets and justification.
- (v) Budget information categorized by both object class and project, including budget justification and how the project aligns to the priorities outlined in the DHS Strategic Plan and/or mission(s) area. DHS requires Centers to submit a budget that maps to the key competencies and activities necessary for a Center to deliver useful technologies and knowledge products to the Department. The competency areas also align to the criteria DHS utilizes to evaluate its Centers of Excellence Program. Centers should allocate resources in the following categories: Administration and Execution, Research and Development, Education and Training, Customer Outreach and Communication, and Transition. The following categories should be included in the budget request. Centers should work with their DHS Program Officer (i.e., Program Manager) to identify minimum expenditures in each category necessary to address Biennial Evaluation Criteria:
- (1) Administration and Execution (labor)
    - Director
    - Executive Director
    - Professional Project Management Staff and Financial Staff
    - Travel to sub-contractor sites
  - (2) Research and Development
    - Principal Investigator and supporting investigators (labor)
    - Data acquisition (licenses, fees, etc.)
    - Materials
    - Supplies
    - Equipment
    - Facilities
    - Project travel (consistent with (4) Customer Outreach and Communication, see below) (see Article II., Section O. for additional travel guidance).
  - (3) Education and Training
    - Staff (labor)
    - Scholarships
    - Fellowships
    - Internships

- Workforce development classes/webinars/seminars
  - Course and curriculum development (labor)
  - Summer workshops (labor, facilities, materials)
  - MSI program support (labor)
- (4) Customer Outreach and Communication
- Professional Strategic Communications Expert (labor)
  - Communications support staff (labor)
  - Travel for all Center functions to DHS customers including project level travel
  - Communication services, products, materials
  - Annual meeting and outreach events – not including travel (technical and customer engagements)
- (5) Transition
- Technology development professional (labor)
  - IP due diligence costs (labor legal)
  - Business planning evaluations – financial modeling to support stage gate decisions (labor business)
  - IP submission costs e.g., trademark, copyright expenses
  - Market assessments (labor)
  - Licensing costs for background IP
  - Initial operations and maintenance costs (vendor services)
  - Unit testing and evaluation – (labor, facilities, supplies/ equipment/materials)
  - Concept or technology integration costs (in customer environments or to meet final customer requirements, e.g., Federal Information Security Modernization Act (FISMA) accreditation)
5. Recipient shall organize and participate in technical review of the research and education efforts funded under this Award annually, at a minimum, or as determined by the DHS Program Officer.
  6. Recipient shall participate in a DHS-managed biennial review of the Center’s progress against milestones, scientific quality, and assessment of customer relevance for the activities funded under this Award. The DHS Program Officer will select a review panel of subject matter experts representing government, industry and academia, to the extent practicable.
  7. Recipient shall participate in at least two DHS S&T outreach events per year for the purposes of sharing information on the research, development, and education efforts funded under this Award.
  8. Recipient agrees to work with the technology transfer office of Recipient’s institution to engage in technology transfer and commercialization activities, as appropriate.
  9. DHS has an interest in publications generated from DHS-funded research for program awareness. Recipient shall include in progress reports a list of publications produced under this Award during the relevant budget period to the DHS Program Officer. DHS encourages Recipients to keep the DHS Program Officer informed about the anticipated release of publications. Please refer to Article II., Section L. for information on Enhancing Public Access to Publications.
  10. Co-Authoring of Reports and Articles. Papers, presentations, or other documents co-authored by a DHS employee and a Center of Excellence (COE) researcher will be subject to DHS’s publications approval process prior to dissemination of the publication by the authors. Recipient shall submit these publications to the DHS author for DHS clearance at least sixty (60) days prior to dissemination of the publication. Recipient agrees to submit all required DHS

clearances with the publication materials to the DHS Program Officer of Record.

11. Information Protection Plan. The Parties agree that all research conducted under this Award is intended to have publicly releasable results.
  - a. Accordingly, no research under this Award should involve, use, or generate sensitive or CUI, which includes PII, and/or classified information (see Item 11.i. of this section for Definitions).
  - b. As a condition of access to this COE, DHS agrees not to provide the Recipient any data or information that is sensitive, CUI, or classified, i.e., information or data that would not be released completely in response to a request under the Freedom of Information Act, 5 U.S.C. § 552. (Note: any work that may involve, use sensitive or CUI or classified information from DHS should be discussed/scoped with the DHS Program Manager under the auspices of the Recipient's Basic Ordering Agreement which provides controls for these sensitive activities).
  - c. Should the Recipient inadvertently receive any data or information from DHS that the Recipient has reason to believe may be sensitive or CUI or classified, within 24 hours, the Recipient shall notify the DHS Grants Management Specialist and Program Manager named in the award documents to discuss what was received and plan for remediation.
  - d. Each Recipient shall develop an Information Protection Plan that incorporates policies and procedures that properly define, recognize, and protect sensitive or CUI or classified information.
    - (i) The Recipient will review the Information Protection Plan at least annually and update as necessary for new or existing areas of research that may involve sensitive or CUI information.
    - (ii) Recipient will submit their Information Protection Plan, noting any updates each year along with annual workplan submission to the DHS Program Officer for review and comment by May 1, 2025.
    - (iii) All submissions of Information Protections Plans should include a signature page indicating document concurrence from the COE Director and a representative from the University's Sponsored Research Office.
  - e. Recipient further understands and agrees that despite the best efforts of the Parties to avoid research under this Award that involves, uses, or generates sensitive or CUI or classified information, the possibility exists that such information could nonetheless be involved, used or generated and be subject to protection by law, executive order, regulation or applicable DHS policies. The Recipient is, therefore, responsible for compliance with all applicable laws, regulations and policies. Nothing in this Award shall be construed to permit any public disclosure of sensitive or CUI and/or classified information in violation of these restrictions.
  - f. The Information Protection Plan will ensure the Recipient identifies, secures, and prohibits public disclosure of "sensitive or CUI or classified information." Recipient maintains responsibility for their due diligence in identifying and properly marking any information governed by U.S. export controls regulations. For further information on applicable export controls, please see Article II., Section H. of this award.
  - g. Required Notifications to DHS.
    - (i) If Recipient determines that research under this Award involved, used, or generated sensitive, CUI or classified information, it agrees to secure the information in accordance with its Information Protection Plan and notify the DHS Program Officer immediately.
    - (ii) For remediation, the Recipient shall inform the DHS Program Officer in writing within **24 hours** of the Recipient becoming aware of any potential security lapses or breaches

involving either: the handling requirements for sensitive, CUI, classified or privacy information; or material failure of individuals to follow the Information Protection Plan.

- h. Flowdown Requirements. The Recipient shall include the substance of this section in all sub-awards/contracts at any tier where the sub-Recipient may use, generate, or have access to government facilities and sensitive, CUI or classified information.
- i. Definitions. For purposes of this section.
- (i) **Controlled Unclassified Information (CUI).** Any information the Government creates or possesses, or an entity creates or possesses for or on behalf of the Government (other than classified information) that a law, regulation, or Governmentwide policy requires or permits an agency to handle using safeguarding or dissemination controls. This definition includes the following CUI categories and subcategories of information:
- (ii) **Sensitive Information. General Definition.** Any information, the loss, misuse, disclosure, or unauthorized access to or modification of which could adversely affect the national or homeland security interest, or the conduct of federal programs, or the privacy to which individuals are entitled under Section 552a of title 5, United States Code (the Privacy Act), but which has not been specifically authorized under criteria established by an Executive Order or an Act of Congress to be kept secret in the interest of national defense, homeland security or foreign policy.
- (iii) This definition includes the following categories of information:
- Protected Critical Infrastructure Information (PCII) as set out in the Critical Infrastructure Information Act of 2002 (Title II, Subtitle B, of the Homeland Security Act, Public Law 107-296, 196 Stat. 2135), as amended, the implementing regulations thereto (Title 6, Code of Federal Regulations, Part 29) as amended, and any supplementary guidance officially communicated in writing by an authorized official of the Department of Homeland Security (including the PCII Program Officer or his/her designee);
  - Information designated as “For Official Use Only,” which is unclassified information of a sensitive nature and the unauthorized disclosure of which could adversely impact a person’s privacy or welfare, the conduct of federal programs, or other programs or operations essential to the national or homeland security interest; and
  - Personally Identifiable Information (PII). Any information that permits the identity of an individual to be directly or indirectly inferred, including any information that is linked or linkable to that individual, regardless of whether the individual is a U.S. citizen, legal permanent resident, visitor to the U.S., or employee or contractor to the Department.
  - Sensitive PII is PII which if lost, compromised, or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual.
- (iv) **Classified Information.** Defined as information designated in accordance with Executive Order 12958.

## 12. Data Acquisition and Management Plan

- a. Within thirty (30) calendar days of initiating work on any research project that requires access to third party data the Recipient must provide a Data Acquisition and Management Plan (DAMP). The term “third party data” means data that has been sourced from other than the subject of the research, including data provided by DHS Component agencies. DHS will review the plan and notify the Recipient of any concerns that may be identified. The Recipient

shall review the DAMPs at least annually, if the project continues, and identify or update, as necessary, any new areas of research that require access to third party data.

- b. The plan must include the following information for each project (see Article II., Section J, Item 3.b.(iii) for data definitions):
  - (i) The purpose for collecting the data and characteristics of the data. If the data is deemed privacy sensitive, the Recipient must comply with the applicable federal, state, and local privacy laws, as well as DHS and university/research institute policies regarding the collection and use of PII.
  - (ii) The uses of the data.
  - (iii) The conditions under which the data will be collected and provided to those on the research team.
  - (iv) A plan for the disposal or retention of the data after the research ends.
  - (v) All plans must contain a signature page indicating document concurrence by the Principal Investigator, and a representative from the University's Sponsored Research Office.
- c. Information collection activities performed under this award are the responsibility of the awardee, and DHS support of the project does not constitute agency approval of the survey design, questionnaire content or information collection procedures. The awardee shall not represent to respondents that such information is being collected for or in association with the DHS or any other Government agency without the specific written approval of such information collection plan or device by the agency. This requirement, however, is not intended to preclude mention of DHS support of the project in response to an inquiry or acknowledgment of such support in any publication of this information.
- d. Flowdown Requirements. The Recipient shall include the substance of this section in all sub-awards/contracts at any tier where the sub-Recipient may use, generate, or have access to government facilities and CUI or classified information.

### 13. Information Technology Security

As a condition of access to this COE, DHS agrees not to provide the Recipient any data or information that is CUI, i.e., information or data that would not be released completely in response to a request under the Freedom of Information Act, 5 U.S.C. § 552. Should the Recipient receive any data or information from DHS that the Recipient has reason to believe may be CUI or classified, within 24 hours, the Recipient shall (1) notify the DHS Grants Management Specialist named in the award documents; (2) notify Program Manager (3) shall erase or otherwise destroy any vestige of such data in accordance with the processes outlined within Information Protection Plan or information in its records and computer systems; and (4) shall notify the Grants Management Specialist of the means and time of such destruction.

### 14. Foreign Participation Reporting Instructions

- a. The admittance of foreign detailees, scientists, and students into DHS sponsored/funded academic and other programs may result in continuous exposure of DHS information, personnel, IT systems, technologies, facilities, resources, and programs by non-U.S. citizens. In order to mitigate this potential security risk, DHS Management Policy 121-08 stipulates all foreign detailees, scientist, professors, principal investigators, and student nominees involved in long-term (greater than 30 days) DHS sponsored/funded academic or other DHS programs must submit a DHS Form 11055, to the DHS Office of Chief Security Officer: [Chief Security Office | Federal Law Enforcement Training Centers](#) (please see Item 14.c. below for instructions on how to submit this form). The University is required to ensure all foreign investigators and students working on DHS sponsored/funded research or receiving tuition or

travel support of any kind through this award, complete DHS Form 11055, to report all foreign national students/teaching assistants. Within the Form, Section I (Foreign National Information), Section II (Foreign National Information-Passport/Visa), and Section III (Foreign National Information (Employer Information) must be completed.

- b. Sponsor information will be completed internally at S&T.
- c. Please complete, save, and return Form 11055 by email to [Rebecca.Medina@hq.dhs.gov](mailto:Rebecca.Medina@hq.dhs.gov). **Do Not Use the “Submit” button on the form.** Form 11055 shall be submitted within 30 calendar days from either project kick-off or from new foreign participants joining the project. For individual engagements with Foreign Nationals, Recipient will submit Form 11055 at least 30 calendar days prior to the activity in which the foreign national participates.
- d. Please indicate your COE affiliation and position title in the email.

15. Intellectual Property Management

- a. It is vitally important that both Parties understand their respective intellectual property rights and applicable obligations under this Award.
- b. Recipients should refer to 2 C.F.R. § 200.448 for a complete summary of their rights and responsibilities.
- c. Flowdown Requirements: The Recipient shall include the substance of this section in all sub-awards/contracts at any tier where the sub-Recipient may use, generate or have access to government facilities and CUI or classified information.

16. Research Safety Plan

- a. DHS COE research addresses issues of importance to intelligence and counter-terrorism agencies, law enforcement, or emergency responders, all of which involve inherent risks. To ensure that researchers and research facilities funded through this Award meet the highest safety standards possible, DHS requires every Recipient of a COE award to develop a Research Safety Plan. The Recipient shall review the Research Safety Plan at least annually and identify or update, as necessary, any new areas of research or sub-Recipients conducting research activities under this plan. This review will also ensure that all sub-Recipients conducting research covered by this plan have developed and implemented appropriate safety plans and periodic safety training in accordance with their institutional policies and procedures.
- b. Recipient will submit any updates to the Research Safety Plan to the DHS Program Officer for review and comment.
- c. The Research Safety Plan must include, at a minimum, the following:
  - (i) Identification of possible research hazards associated with the types of research to be conducted under this Award;
  - (ii) Research protocols or practices that conform to generally accepted safety principles applicable to the nature of the research;
  - (iii) The Recipient’s processes and procedures to ensure compliance with the applicable protocols and standards;
  - (iv) The Recipient’s processes and procedures to ensure the prevention of unauthorized activities conducted in association with this Award;
  - (v) Faculty oversight of student researchers;
  - (vi) Research safety education and training to develop a culture of safety;
  - (vii) Access control, where applicable;
  - (viii) Independent review by subject matter experts of the safety protocols and practices; and

- (ix) Demonstrated adherence to all safety-related terms and conditions contained elsewhere in this Award.
- d. Flowdown Requirements. The Recipient shall include the substance of this section in all sub-awards/contracts at any tier where the sub-Recipient may conduct research where safety protocols are necessary to conduct safe research.

## **B. DHS PROGRAMMATIC INVOLVEMENT**

DHS staff are not meant to play a dominant role nor assume direction or primary responsibility for awardee activities. However, in addition to the usual monitoring and technical assistance, the following identifies DHS responsibilities under this Award:

1. DHS shall determine if a kickoff meeting is required for proposed projects or proposed continuations of existing projects. DHS shall coordinate with appropriate DHS staff, Center staff and Center researchers prior to project initiation.
2. DHS shall approve or disapprove annual workplans and any modifications to the workplans for this Award (See Article I., Section A.).
3. DHS shall conduct ongoing monitoring of the activities of Recipient's workplan, and activities funded through this Award through face-to-face and/or telephone meetings and review of progress reports.
4. DHS shall coordinate biennial reviews in cooperation with the Recipient during the Project Period to provide guidance on how the research and education programs need to evolve to align with the needs of the Homeland Security Enterprise consistent with the COE mission. The biennial review evaluates the Center's long-term strategy, relevance of the research and education to DHS mission needs and technology gaps, stakeholder engagement, research quality, outreach efforts and management of the activities funded under this Award. The DHS Program Officer will select a review panel of subject matter experts representing government, industry, and academia for the biennial review.
5. DHS coordination with the Recipient will include, but is not limited to:
  - a. Providing strategic input as necessary on an ongoing basis;
  - b. Coordinating research and development activities that support the national research agenda; and
  - c. Creating awareness and visibility for this program.
6. DHS may modify this Award to support additional research projects funded by DHS or other sources provided that these projects meet three conditions:
  - a. Are research for a public purpose that addresses homeland security research priorities;
  - b. Fall within scope of the grant or cooperative agreement; and
  - c. Conform to federal assistance agreements (grant and cooperative agreement) guidelines.
7. DHS employees may co-author publications with COE researchers. Any publication co-authored by DHS staff will be subject to DHS's publications approval process prior to dissemination of the publication as required under Article I., Section A., Item 9.
8. DHS shall review and provide comments on the Recipient's Information Protection Plan as required under Article I., Section A., Item 11.
9. DHS shall review and provide comments on the Recipient's Research Safety Plan as required under, Article I., Section A., Item 16.
10. DHS may create a Board of Directors that provides guidance on research relevance to the DHS Program Officer regarding the Recipient's research plan.

11. DHS may invite subject matter experts, customers, or stakeholders to assist in evaluating the Center's annual workplan, annual meetings, or other events for the purpose of reviewing project quality and/or providing relevant operational perspectives.
12. DHS shall facilitate initial engagement with Homeland Security Enterprise stakeholders, but Recipient is expected to maintain ongoing engagement for research areas of interest to the stakeholders.
13. DHS shall ensure adherence to DHS privacy policies and requirements and include that Recipients perform work in a manner consistent with DHS authorities.

## C. AMENDMENTS AND REVISIONS

1. Budget Revisions.
  - a. Transfers of funds between direct cost categories in the approved budget when such cumulative transfers among those direct cost categories exceed ten percent of the total budget approved in this Award require prior written approval by the DHS Grants Officer.
  - b. The Recipient shall obtain prior written approval from the DHS Grants Officer for any budget revision that would result in the need for additional resources/funds.
  - c. The Recipient is not authorized at any time to transfer amounts budgeted for direct costs to the indirect costs line item or vice versa, without prior written approval of the DHS Grants Officer.
2. Extension Request.
  - a. Extensions to the Period of Performance can only be authorized in writing by the DHS Grants Officer.
  - b. The extension request shall be submitted to the DHS Grants Officer sixty (60) days prior to the expiration date of the performance period.
  - c. Requests for time extensions to the Period of Performance will be considered, but will not be granted automatically, and must be supported by adequate justification to be processed. The justification is a written explanation of the reason or reasons for the delay; an outline of remaining resources/funds available to support the extended Period of Performance; and a description of performance measures necessary to complete the project. Without current performance and financial status reports and justification submitted, extension requests shall not be processed.
  - d. DHS has no obligation to provide additional resources/funding as a result of an extension.

## D. EQUIPMENT

1. Prior to the purchase of Equipment in the amount of \$5,000 or more per unit cost, the Recipient must obtain the written approval from DHS.
2. For equipment purchased with Award funds having a \$5,000 or more per unit cost, the Recipient shall submit an inventory that will include a description of the property; manufacturer model number, serial number or other identification number; the source of property; name on title; acquisition date; and cost of the unit; the address of use; operational condition of the property; and, disposition data, if applicable. This report will be submitted with the Final Progress Report, which is due 90 days after the expiration of the project period. GrantSolutions submission guidance may be found here: <https://home.grantsolutions.gov/home/wp-content/uploads/2021/04/Grant-Recipient-Process-Performance-Progress-Report.pdf>

## E. FINANCIAL REPORTS

1. Annual Federal Financial Reports. The Recipient shall submit a Federal Financial Report (SF425) to the DHS Grants Officer no later than sixty (60) calendar days after the end of the budget period end date. The report shall be submitted via GrantSolutions using the guidance found here: <https://home.grantsolutions.gov/home/wp-content/uploads/2021/04/Grant-Recipient-Process-Federal-Financial-Report.pdf>
2. Final Federal Financial Report. The Recipient shall submit the final Federal Financial Report (SF425) to the DHS Grants Officer no later than 120 calendar days after the end of the Project Period end date. The report shall be submitted via GrantSolutions using the guidance found here: <https://home.grantsolutions.gov/home/wp-content/uploads/2021/04/Grant-Recipient-Process-Federal-Financial-Report.pdf>

## F. PAYMENT

1. The Recipient shall be paid in advance using the U.S. Department of Health and Human Services/Payment Management System, provided it maintains or demonstrates the willingness and ability to maintain written procedures to minimize the time elapsing between the transfer of the funds from the DHS and expenditure disbursement by the Recipient. When these requirements are not met, the Recipient will be required to be on a reimbursement for costs incurred method.
2. Any overpayment of funds must be coordinated with the U.S. Department of Health and Human Services/Payment Management System.

## G. PERFORMANCE REPORTS

The Recipient shall submit performance reports to the DHS Grants Officer for review and acceptance by DHS as a condition for receiving further annual funding increments. The reports shall be submitted via GrantSolutions using the guidance found here <https://home.grantsolutions.gov/home/wp-content/uploads/2021/04/Grant-Recipient-Process-Performance-Progress-Report.pdf>

Semi-Annual Report. The Semi-Annual performance report shall describe project progress from July 1 through January 31 of the budget period and is due no later than March 1.

1. Annual Report. The Annual performance report must provide a summary of the activities conducted during the full budget year (July 1 – June 30) and is due no later than August 31.
2. Performance reports must provide information on the overall progress of the Center based on the activities discussed in the corresponding workplan. These reports should map workplan activities (activities planned) to those activities performed during the year to include:
  - a. Summary reports on the Center’s strategic vision and support justification
  - b. Summary of Center communication and transition activities;
  - c. Summary of Center management efforts including decision making apparatus;
  - d. Performance reports on each Center Project should include:
    - Explanation of any changes from the initially approved workplan
    - Objective/Purpose
    - Baseline
    - Methodology
    - Project milestones to include progress met against them
    - Performance metrics used to evaluate progress and assessments of current concept of operations and baselines/state of the art in use

- Transition plans to include development steps, intellectual property management plans, and market specific considerations
  - Stakeholder engagement
  - Potential programmatic risks to completion
  - Progress against each milestone outcomes and outputs and explanation of why any items were not reached
  - Unanticipated problems and plans for addressing them; and
  - Information supported by data on how project outcomes will advance or impact current technologies or capabilities.
- e. Budget information and expenditure (narrative and figures) categorized by both object class and project as described in Article I., Section A., Item 4.a.(v).
  - f. If applicable, include a certification that no patentable inventions were created during the budget period.
  - g. Updates to the Center’s Information Protection Plan and Researcher Safety Plan as needed.
3. If the performance report contains any information that is deemed proprietary, the Recipient will denote the beginning and ending of such information with the following heading:  
\*\*\*\*\*PROPRIETARY INFORMATION\*\*\*\*\*
  4. Final Performance Report. The Recipient shall submit the Final COE Performance Report to the DHS Grants Officer and DHS Program Officer no later than 120 calendar days after the expiration of the Project Period (See Article I., Section H.). The report shall be submitted via GrantSolutions using the guidance found here: <https://home.grantsolutions.gov/home/wp-content/uploads/2021/04/Grant-Recipient-Process-Performance-Progress-Report.pdf>
  5. The Final COE Performance Report shall include:
    - a. An executive summary and final summary abstracts for each sub-project across all years of the period of performance
    - b. Address the areas identified above in the annual report section.

## H. PERIOD OF PERFORMANCE

The Period of Performance is the Project Period approved for the supported activity and is comprised of one or more Budget Periods as reflected on the Notice of Award cover page.

1. Project Period. The Project Period is referenced in the original award letter. All COE annual performance periods shall run from July 1 to June 30 of the following year. An exception is made for the first performance period, which will run from the date of award to June 30 of the following year. Subsequent years’ funding is contingent on acceptable performance, as determined by the DHS’s acceptance and approval of each non-competing continuation application, and the availability of the next year’s annual DHS appropriations. The Recipient shall only incur costs or obligate funds within the Project Period for approved activities.
2. Budget Period.
  - a. The Budget Period shall be for a period of 12 months, from July 1 through June 30 of the following year.
  - b. Additional funding will be provided for subsequent Budget Periods of the project, contingent on all of the following:
    - (i) Acceptable performance of the project as determined by the DHS under this Award;
    - (ii) Acceptance and approval by the DHS of each noncompeting continuation application;
    - (iii) Acceptance and approval by the DHS of each previous Annual Performance Report; and

- (iv) Subject to the availability of appropriated funds.
- 3. Non-Competing Continuation Requirements.
  - a. Ninety (90) calendar days prior to the expiration date of each budget period, the Grants Officer will request submission of the annual incremental funding request details via Grants.gov website.
  - b. The Recipient shall submit a non-competing continuation application to request the next Budget Period's incremental funding and a separate request for any possible carryover of prior year funds. The non-competing continuation application shall include:
    - (i) An annual project workplan as described in Article I., Section A., Item 4;
    - (ii) **Carryover of Funds.** Recipients are required to submit a separate Carryover Application for the unobligated balances remaining from funds awarded in one budget period to be carried over to the next succeeding budget period. This submission is due to the DHS Grants Officer and DHS Program Manager 90 calendar days prior to budget period expiration (e.g., March 31 unless otherwise notified by DHS Grants and Financial Assistance Officers) and is a best estimate at the budget period expiration from the Recipient (lead university and all sub-Recipients). The Program Officer will review the Carryover justification, in consultation with the DHS Grants Officer, and provide input to the Grants Officer that the justification is reasonable, and the carryover funds should be used to complete any objectives which remain unmet from the prior budget period. Requests for carryover of funds from one Budget Period to the next Budget Period shall be submitted separately via email to the DHS Grants Officer with an SF 424 (R&R) face page and shall include:
      - (1) A brief description of the projects or activities and milestones to be carried forward;
      - (2) The amount of funds to be carried over and a revised Center budget consistent with Article I., Section A., Item 4.;
      - (3) The reason the projects or activities were not completed in accordance with the project timeline; and
      - (4) The impact on any future funding for the projects or activities.
    - (iii) The DHS Program Officer will review the continuation application submission and provide input to the Grants Officer as to whether the Continuation Application is consistent with the approved workplan.

## **I. PRIOR APPROVAL REQUIRED**

The Recipient shall not, without the prior written approval of the DHS, request reimbursement, incur costs or obligate funds for any purpose pertaining to the operation of the project, program, or activities prior to the approved Budget Period.

## **ARTICLE II. GENERAL TERMS AND CONDITIONS**

### **A. ACCESS AND RETENTION TO RECORDS**

Pursuant to 2 C.F.R. § 200.334, the Recipient shall retain financial records, supporting documents, statistical records, and all other records pertinent to this Award for a period of 3 years from the date of submission of the final expenditure report. The only exceptions to the aforementioned record retention requirements are the following:

1. If any litigation, dispute, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, dispute or audit findings involving the records have been resolved and final action taken.
2. Records for real property and equipment acquired with federal funds shall be retained for 3 years after final disposition.
3. The DHS Grants Officer may direct the Recipient to transfer certain records to DHS custody when he or she determines that the records possess long term retention value. However, in order to avoid duplicate recordkeeping, the DHS Grants Officer may make arrangements for the Recipient to retain any records that are continuously needed for joint use.

In accordance with 2 C.F.R. § 200.337, DHS, the Inspector General, Comptroller General of the United States, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of the Recipient that are pertinent to this Award, in order to make audits, examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to Recipient's personnel for the purpose of interview and discussion related to such documents. The rights of access in this award term are not limited to the required retention period but shall last as long as records are retained.

With respect to sub-Recipients, DHS shall retain the right to conduct a financial review, require an audit, or otherwise ensure adequate accountability of organizations expending DHS funds.

Recipient agrees to include in any sub-award made under this Agreement the requirements of this award term (Access to Records).

## **B. COMPLIANCE ASSURANCE PROGRAM OFFICE**

The Compliance Assurance Program Office (CAPO) is comprised of the DHS Treaty Compliance Group (TCG), DHS Export Controls Group (ECG), and the DHS Regulatory Compliance Group (RCG). The Under Secretary of Science and Technology (USST) is the DHS official responsible for the various portfolios under CAPO's purview and for implementing procedures to ensure that the Recipient and any Recipient institutions/collaborators under this Award comply with international treaties, federal regulations, and DHS policies for Arms Control Agreements, Biosafety, Select Agent and Toxin Security, Animal Care and Use, the Protection of Human Subjects in Research, Life Sciences Dual Use Research of Concern, and Export Controls.

CAPO collects and reviews relevant documentation pertaining to this Award on behalf of the USST. Additional guidance regarding the review process is provided in the following sections, along with contact information. This guidance applies to the Recipient and any/all Recipient institutions involved in the performance of work under this Award. The Recipient is responsible for ensuring that any/all Recipient institutions and collaborators comply with all requirements and submit relevant documentation, as outlined in sections C – G below, for work being performed under this Award.

## **C. TREATY COMPLIANCE FOR BIOLOGICAL AND CHEMICAL DEFENSE EFFORTS**

The Recipient and any Recipient institution shall conduct all biological and chemical defense research, development, testing, evaluation, and acquisition projects in compliance with all arms control agreements of the U.S., including the Chemical Weapons Convention and the Biological Weapons Convention. DHS Directive 041-01, *Arms Control Compliance for Chemical and Biological Defense Activities*, requires review of all such projects, including classified projects; projects involving biological and/or chemical agents, surrogates, or simulants; and non-laboratory activities related to biological and/or chemical agents (e.g., literature reviews, simulations, and/or modeling

activities) to be systematically evaluated for compliance at inception, prior to funding approval, whenever there are any project changes, and whenever in the course of project execution an issue potentially raises a compliance concern.

1. Requirements for Initial Treaty Compliance Review. To ensure compliance with DHS Directive 041-01, for each biological and/or chemical defense-related effort (including non-laboratory activities related to biological and/or chemical agents) to be conducted under this Award, **the Recipient must submit the following documentation for compliance review and certification prior to funding approval:** a completed Treaty Compliance Form (TCF) and a Statement of Work (or workplan). The Recipient should contact the DHS Program Manager to engage CAPO regarding Treaty compliance issues. The DHS Program Manager should help them obtain the TCF, submit the completed TCF, and/or request additional guidance regarding treaty compliance documentation and review requirements. The CAPO will review all submitted materials and provide written confirmation of approval to the Recipient once the treaty compliance certification process is complete. **The Recipient and any Recipient institution shall not initiate any new activities, or execute modifications to approved activities, prior to receipt of this written confirmation.**
2. Requirements for Ongoing Treaty Compliance Review. To ensure ongoing treaty compliance for approved biological and/or chemical defense-related efforts funded through this Award, **the Recipient, working with the DHS PM must notify CAPO of changes** to include – but are not limited to—the addition of biological or chemical agents (including any additional strains/isolates of biological material, simulants, or surrogates), a change in performers or sub-performer(s), modifications to the scope of work, and/or changes to the technical approach **per DHS Directive 041-01.**

#### **D. REGULATORY COMPLIANCE FOR BIOLOGICAL LABORATORY WORK**

The Recipient and any Recipient institution shall conduct all biological laboratory work in compliance with applicable federal regulations; the latest edition of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) *Biosafety in Microbiological and Biomedical Laboratories* and *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NSC, 2024)*; DHS Directive 066-02, *Biosafety*; DHS Instruction 066-02-001, *Instruction for Ensuring Biosafety Compliance*; and any local institutional policies that may apply for Recipient institution facilities performing work under this Award. The CAPO will review the submitted TCF for planned work under this Award to determine the applicability of the requirements outlined in this section. **The Recipient must engage the DHS Program Manager who will facilitate engagement with CAPO for guidance on the requirements, and then submit all required documentation based on CAPO guidance, prior to the initiation of any biological laboratory work under this Award.**

1. Requirements for All Biological Laboratory Work. Biological laboratory work includes, but not limited to, laboratory activities involving: (1) recombinant or synthetic nucleic acid molecules (DNA, RNA); (2) Biological Select Agents and Toxins or ‘BSAT’; or (3) biological agents, toxins, surrogates, or other biological materials that are not recombinant, synthetic, or BSAT. **Each Recipient and any Recipient institution to be conducting biological laboratory work under this Award must submit copies of the following documentation, as required by the CAPO after review of the TCF(s), for review prior to the initiation of such work:**
  - a. Research protocol(s), research or project plan(s), standard operating procedures(s), or other detailed description of the biological laboratory work to be conducted;
  - b. Documentation of project-specific biosafety review for biological laboratory work subject to

- such review in accordance with institutional policy;
- c. Institutional or laboratory biosafety manual (may be a related plan or program manual) for each facility/laboratory to be involved in the biological laboratory work;
  - d. Biosafety training program description (should be provided as available in existing policies, plans, and/or manuals for all relevant facilities/laboratories) where work is conducted;
  - e. Documentation of the most recent safety/biosafety inspection(s) for each facility/laboratory where the biological laboratory work will be conducted;
  - f. Exposure Control Plan, as applicable;
  - g. Documentation from the most recent Occupational Safety and Health Administration (OSHA) or State Occupational Safety and Health Agency inspection report; a copy of the OSHA Form 300 Summary of Work-Related Injuries and Illnesses or equivalent, for the most recent calendar year; and documentation of any OSHA citations or notices of violation received in the past five (5) years; and
  - h. Documentation from the most recent U.S. Department of Transportation (DOT) inspection report; and documentation of any DOT citations or notices of violation received in the past 5 years.
2. Requirements for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Laboratory activities involving the use and procurement of recombinant or synthetic nucleic acid molecules research are defined by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, “*NIH Guidelines*” and the *U.S. Government Framework for Nucleic Acid Synthesis Screening (NSC, 2024; referred to as the “Framework” herein)*. Each Recipient and any Recipient institution shall conduct all such work in compliance with the NIH Guidelines. In addition to the documentation referenced above, **each facility conducting research activities involving recombinant or synthetic nucleic acid molecules under this Award must submit copies of the following documentation to the CAPO for review prior to the initiation of such activities:**
- a. Institutional Biosafety Committee (IBC) Charter, and/or other available documentation of IBC policies and procedures;
  - b. Most recent Office of Biotechnology Activities (OBA) acknowledgement letter of the annual IBC Report;
  - c. IBC-approved recombinant or synthetic nucleic acid molecules research protocol(s); and
  - d. Documentation of final IBC approval for each recombinant or synthetic nucleic acid molecules research protocol and all subsequent renewals and amendments as they occur.
3. Requirements for Activities Involving Synthetic Nucleic Acids and Devices Capable of Synthesizing Nucleic Acids. **Beginning on April 26, 2025, the Performer (or Recipient of award) may procure synthetic nucleic acids and benchtop nucleic acid synthesis equipment, as defined in the 2024 OSTP Framework for Nucleic Acid Synthesis Screening (Framework), only from providers or manufacturers that attest to adhering to the Framework. The attestation may be posted on a public website or provided directly to the Performer (or Recipient of award) upon request. The Performer (or Recipient of award) shall include this requirement in all lower tier agreements.**
4. Requirements for Activities Involving Biological Select Agents and Toxins (BSAT). **Planned activities involving the possession transfer, and/or use of BSAT must be reviewed by the CAPO prior to initiation.** This requirement also applies to activities involving select toxins that fall below the Permissible Toxin Limits, both at facilities registered with the National Select

Agent Program and at unregistered facilities. Each Recipient and any Recipient institution shall conduct all BSAT work in compliance with all applicable regulations, including 42 C.F.R. § 73, 7 C.F.R. § 331, and 9 C.F.R. § 121, related entity- and laboratory-specific policies and procedures, and DHS Directive 026-03, Rev 01, *Safeguarding Select Agents and Toxins*; and DHS Instruction 026-03-001, *Safeguarding Select Agents and Toxins*. **In addition to the documentation referenced in Article II, Section D, Item 1 above, each facility conducting activities involving BSAT under this Award must submit copies of the following documentation to the CAPO for review prior to the initiation of such activities:**

- a. Current Animal and Plant Health Inspection Service (APHIS)/CDC Certificate of Registration;
- b. Current versions of the Biosafety, Security, and Incident Response Plans required and reviewed under the Select Agent Regulations; and
- c. Documentation of the most recent annual BSAT facility inspection, as required of the Responsible Official under the Select Agent Regulations.

The Recipient should contact the DHS Program Manager who will work with CAPO to obtain the CAPO Documentation Request Checklist, submit documentation, or request more information regarding the DHS CAPO documentation and compliance review requirements. The CAPO will provide written confirmation of receipt of all required documentation to the designated Point(s) of Contact. The CAPO will evaluate the submitted materials, along with available documentation from any previous reviews for related work at the Recipient and Recipient institution. Additional documentation may be required in some cases and must be submitted upon request. The CAPO will review all submitted materials and provide written confirmation to the Recipient once all requirements have been met.

CAPO review of submitted materials may determine the need for further compliance review requirements, which may include documentation-based and on-site components. The Recipient, and any Recipient institutions conducting biological laboratory work under this Award, must also comply with ongoing CAPO compliance assurance and review requirements, which may include but are not limited to initial and periodic documentation requests, program reviews, site visits, and facility inspections.

The Recipient must promptly report the following to the CAPO, along with any corrective actions taken: (1) any serious or continuing biosafety or BSAT program issues as identified by the APHIS/CDC National Select Agent Program, other compliance oversight authorities, or institutional-level reviews (e.g., IBC or equivalent, laboratory safety/biosafety inspections); (2) any suspension or revocation of the APHIS/CDC Certificate of Registration; and (3) any for-cause suspension or termination of biological, rDNA, or BSAT activities at the laboratories/facilities where DHS-sponsored work is conducted.

Foreign Contractors/Collaborators and U.S. Institutions with Foreign Subcomponents. Foreign organizations (including direct Contractors, Subcontractors, Grant Recipients, sub-Recipients, and subcomponents or collaborating partners to U.S. Recipients) are subject to applicable DHS requirements for biological laboratory activities. All entities involved in activities under this Award must comply with applicable national and regional/local regulations, and standards and guidelines equivalent to those described for U.S. institutions (e.g., *BMBL and NIH Guidelines*). The Recipient must provide the CAPO with documentation sufficient to illustrate this compliance. The CAPO will evaluate compliance measures for these institutions on a case-by-case basis. The Recipient must not initiate work nor provide funds for the conduct of biological laboratory work under this Award without CAPO's formal written approval.

## E. REGULATORY REQUIREMENTS FOR RESEARCH INVOLVING ANIMALS

The Recipient and any Recipient institution shall conduct all research involving animals under this Award in compliance with the requirements set forth in the Animal Welfare Act of 1966 (P.L. 89-544), as amended, and the associated regulations in 9 C.F.R., Chapter 1, Subchapter A; the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (which adopts the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training”, 50 FR 20864, May 20, 1985); the National Research Council (NRC) Guide for the Care and Use of Laboratory Animals; the Federation of Animal Science Societies (FASS) Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching; any additional requirements set forth in the DHS Directive 026-01, *Care, Use, and Transportation of Animals in Research*; and DHS Instruction 026-01-001, *Care, Use, and Transportation of Animals in Research*. **Each Recipient and any Recipient institution planning to perform research involving animals under this Award must comply with the requirements and submit the documentation outlined in this section.**

1. Requirements for Initial Review of Research Involving Animals. Research Involving Animals includes any research, experimentation, biological testing, and other related activities involving live, vertebrate animals, including any training for such activities. Each facility conducting research involving animals under this Award must submit copies of the following documentation to the CAPO for review **prior to the initiation of such research**:
  - a. Institutional Animal Care and Use Committee (IACUC)-approved animal research protocol(s), including documentation of IACUC approval, any protocol amendments, related standard operating procedure(s), and related approval notifications;
  - b. Public Health Service (PHS) Animal Welfare Assurance, including any programmatic amendments, and the most recent NIH Office of Laboratory Animal Welfare (OLAW) approval letter for each Recipient and Recipient institution; or DHS Animal Welfare Assurance, if the Recipient is not funded by the PHS and does not have a PHS Assurance on file with OLAW. Any affiliated IACUCs must be established under the same requirements as set forth in the PHS Policy;
  - c. Most recent IACUC semiannual program review and facility inspection reports covering all relevant species facilities/laboratories involved in DHS-funded work;
  - d. Most recent U.S. Department of Agriculture (USDA) Inspection report covering all relevant species, facilities/laboratories involved in DHS-funded work; and
  - e. Most recent Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation letter for AAALAC-accredited institution(s) housing and/or performing work involving animals under this Award.

All documentation, as well as any questions or concerns regarding the requirements referenced above, should be submitted to the DHS Program Manager who will facilitate engagement with CAPO. Additional documentation may be required in some cases and must be submitted upon request. The CAPO will review all submitted materials and provide written confirmation to the Recipient once all documentation requirements have been met. Upon receipt of this written confirmation, the Recipient may initiate approved animal research projects under this Award but must address any potential compliance issues or concerns identified by the CAPO. **Research involving the use of nonhuman primates or international collaborations involving animal research will require more extensive review prior to approval and must not begin under this Award without first obtaining a formal certification letter from the CAPO.**

The Recipient, as well as any Recipient institution and partner institutions conducting animal research

under this Award, shall also comply with ongoing CAPO compliance assurance functions, which may include but are not limited to periodic site visits, program reviews, and facility inspections.

2. Requirements for Review of Research Involving Nonhuman Primates. For research activities involving any nonhuman primates, each Recipient and any Recipient institutions will be further reviewed by the Veterinary Medical Officer and CAPO prior to the initiation of work.
3. Requirements for Ongoing Review of Research Involving Animals. For ongoing animal research activities, each Recipient and any Recipient institutions must submit updates to the CAPO regarding any amendments or changes to (including expiration, renewal, or completion of) ongoing animal protocols as they occur and may be required to submit annual updates regarding the Animal Care and Use program at Recipient and Recipient institutions. Annual updates may include, but are not limited to, the IACUC semiannual (program review and facility inspection) reports, the USDA inspection report, and the most recent AAALAC accreditation letter, as applicable.

The Recipient must promptly report the following to the CAPO, along with any corrective actions taken: (1) any serious or continuing noncompliance with animal care and use regulations and policies adopted by DHS (as referenced above); (2) any change in AAALAC accreditation status; (3) any USDA Notice of Violation; and (4) IACUC suspension of any animal research activity conducted under this Award.

4. Foreign Contractors/Collaborators and U.S. Institutions with Foreign Subcomponents. Foreign organizations (including direct Contractors, Subcontractors, Grant Recipients, Sub-recipients, and subcomponents or collaborating partners to U.S. Recipients) are subject to DHS approval for work involving animals. All entities involved in activities under this Award must comply with their own applicable national and regional/local regulations, standards and guidelines. The Recipient must provide CAPO documentation sufficient to illustrate this compliance. The CAPO will evaluate compliance measures for these institutions on a case-by-case basis to determine their sufficiency. The Recipient must not initiate nor provide funds for the conduct of work involving animals at foreign institutions under this Award without formal written approval from the CAPO.

#### **F. COMPLIANCE WITH THE UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF DUAL USE RESEARCH OF CONCERN AND PATHOGENS WITH ENHANCED PANDEMIC POTENTIAL (DURC/PEPP)**

1. As a condition of this award and as a condition of receipt of any funding from the Department of Homeland Security (DHS), any research institution conducting, or planning to conduct, life sciences research that meets the definition of Category 1 research or Category 2 research, as defined by Sections 4.1 and 4.2, respectively, of the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, issued in May 2024, (DURC/PEPP Policy) must comply with the DURC/PEPP Policy.
2. If a research institution is conducting, or planning to conduct, life sciences research hereunder, the research institution is directed to expend special attention to Section 5 (Oversight Framework for Category 1 and Category 2 Research that is Subject to this Policy) with particular emphasis on Section 5.1 (Responsibilities of Principal Investigators); Section 5.2 (Responsibilities of Research Institutions); and a research institution's collaboration and information sharing requirements, including but not limited to the provision of risk-benefit assessments and risk mitigation plans, with a federal funding agency as set forth in Section 5.3 (Responsibilities of Federal Funding Agencies) so that DHS may meet its obligations under the DURC/PEPP Policy.
3. It is the responsibility of any research institution receiving life sciences research funding from DHS

to educate its principal investigators on their responsibilities under the DURC/PEPP Policy, including how to identify research that may fall into Category 1 research, Category 2 research, the role of the institutional review entity at the research institution, the preparation of risk-benefit assessments, the preparation of risk mitigation plans, and any other information required to be evaluated by the principal investigator, the research institution, and/or the funding agency in accordance with the DURC/PEPP Policy. Research institutions and principal investigators are responsible for remaining up to date on any changes that may be made to the DURC/PEPP Policy.

4. As a condition of award, DHS may share information relating to the facts and circumstances about the life sciences research conducted, or planned to be conducted, hereunder with other USG agencies in accordance with applicable laws, policies, and regulations. Information that DHS may share may include research objectives, agents involved in the study, whether the project has been determined to be Category 1 research or Category 2 research, the geographic location of the research, and the names of research institutions and principal investigators carrying out the research.

## **G. REGULATORY REQUIREMENTS FOR RESEARCH INVOLVING HUMAN SUBJECTS**

The Recipient and any Recipient institutions shall conduct all Research Involving Human Subjects in compliance with the requirements set forth in 6 C.F.R. 46 and 45 C.F.R. 46, Subparts B-E, DHS Directive 026-04, *Protection of Human Subjects*, and DHS Instruction 026-04-001, *Ensuring Human Subjects Research Compliance*, prior to initiating any work with human subjects under this Award. Each Recipient and any Recipient institutions planning to perform research involving human subjects under this Award must submit, through the DHS Program Manager, the documentation outlined in this section for CAPO review.

1. Requirements for Research Involving Human Subjects. Each Center conducting research involving human subjects under this Award is required to have a project-specific Certification Letter, a determination memo, or a memo of concurrence with an IRB's research or exemption determination issued by the CAPO. Each Recipient must submit the following documentation to the CAPO for compliance review and clearance **prior to initiating research involving human subjects under this Award**:
  - a. Research protocol, as approved by an Institutional Review Board (IRB), for any human subjects research work to be conducted under this Award;
  - b. IRB approval letter or notification of exemption (see additional information below on exemption determinations), for any human subjects research work to be conducted under this Award.
  - c. IRB-approved informed consent document(s) or IRB acknowledgement of a waiver or alteration of informed consent for projects involving human subjects research under this Award;
  - d. Any applicable IRB-approved surveys/questionnaires and recruitment materials;
  - e. Federal-wide Assurance (FWA) number from the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) for all Recipient institutions (including sub-Recipients) engaged in human subjects research under this Award;
  - f. IRB registry number for the IRB of Record (IRB0000XXXX) and the IRB Panel Number (if reviewed by the full board);
  - g. The DHS-approved Statement of Work or workplan; and
  - h. DHS CAPO's Cover Sheet and Document Checklist.

2. Exemptions for Research Involving Human Subjects. Exemption determinations for human subject research to be conducted under this Award should only be made by authorized representatives of (1) an OHRP-registered IRB, or equivalent, or (2) DHS CAPO. Exemption determinations made by an OHRP-registered IRB, or equivalent, should be submitted by the Recipient to the DHS Program Manager who will provide to CAPO per DHS Directive 026-04. Program managers, principal investigators, research staff, and other DHS or institutional personnel should not independently make exemption determinations in the absence of an IRB or CAPO review. Those without access to an IRB seeking an exemption determination from the CAPO should submit a request to the DHS Program Manager to be provided to CAPO and it should include the following:
  - a. Research protocol or detailed description of planned activities to be conducted under this Award;
  - b. A complete CAPO Human Subjects Research Determination Request Form (HDRF);
  - c. The DHS-approved Statement of Work or workplan;
  - d. Any applicable informed consent document(s);
  - e. Any applicable surveys/questionnaires and recruitment materials; and
  - f. Identification of the exemption category that applies to the project(s) to be conducted under this Award and explanation of why the proposed research meets the requirements for that category of exemption.

All documentation, as well as any questions or concerns regarding the requirements referenced above, should be submitted through the DHS Program Manager to the CAPO. The submitted documentation will be retained by the CAPO and used to conduct a regulatory compliance assessment. Additional documentation and/or information may be required in some cases to complete this assessment. The Recipient must provide this documentation and information upon request. All compliance issues or concerns raised by the CAPO must be addressed in writing and resolved before a certification letter, determination memo, or memo of concurrence is issued and prior to initiation of any activities involving human volunteers under this Award. The CAPO will review all submitted materials and provide written confirmation to the DHS Program Manager and the Recipient once all documentation requirements have been met.

The Recipient and any Recipient institution shall submit updated documentation regarding ongoing research involving human subjects, as available and **prior to the expiration of previous approvals**. Such documentation includes protocol modifications, IRB renewals for ongoing research protocols (“Continuing Reviews”), reportable events, and notifications of study completion.

The Recipient must promptly report the following to the CAPO, along with any corrective actions taken: (1) any serious or continuing noncompliance with human subjects research regulations and policies adopted by DHS (as referenced above); and (2) suspension, termination, or revocation of IRB approval of any human subjects research activities conducted under this Award.

3. Foreign Contractors/Collaborators and U.S. Institutions with Foreign Subcomponents. Foreign organizations (including direct Contractors, Subcontractors, Grant Recipients, sub-Recipients, and subcomponents or collaborating partners to U.S. Recipients) are subject to all DHS and CAPO requirements for research involving human subjects. All entities involved in activities under this Award must comply with applicable national and regional/local regulations, and standards and guidelines equivalent to those described for U.S. institutions; e.g., 6 C.F.R 46 and 45 C.F.R. § 46, Subparts B-E, as applicable. The CAPO will evaluate compliance measures for these institutions on a case-by-case basis to determine their sufficiency. The Recipient must not initiate nor provide funds for the conduct of work involving human subjects at foreign institutions under this Contract

without formal written approval from the CAPO.

## H. COMPLIANCE WITH U.S. EXPORT CONTROLS

Activities performed by the Recipient and any Recipient institution under this Award may or may not be subject to U.S. export control regulations. The Recipient and any Recipient institution shall conduct all such activities, to include any and all DHS-funded research and development, acquisitions, and collaborations in full compliance with all U.S. export controls — to include but not limited to the Export Administration Regulations (EAR), the International Traffic in Arms Regulations (ITAR), and the Office of Foreign Assets Control (OFAC) Regulations. The Recipient and any Recipient institution will ensure that all legal requirements for compliance with U.S. export controls are met prior to transferring commodities, technologies, technical data, or other controlled information to a non-U.S. person or entity.

## I. CONTROLLED UNCLASSIFIED INFORMATION

The parties understand that information and materials provided pursuant to or resulting from this Award may be export controlled, sensitive, for official use only, CUI, or otherwise protected by law, executive order, or regulation. The Recipient is responsible for compliance with all applicable laws and regulations. Nothing in this Award shall be construed to permit any disclosure in violation of those restrictions.

Awards are intended for unclassified, publicly releasable research. The awardee will not be granted access to classified information. DHS does not expect that the results of the research project will involve classified information.

## J. INTELLECTUAL PROPERTY, PATENT, AND DATA RIGHTS

1. Patent rights. The Recipient is subject to applicable regulations governing patents and inventions, including government-wide regulations, 37 CFR Part 401, “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements.”
2. Invention Disclosure and Related Requirements. The clause at 37 CFR 401.14, “Standard Patent Rights Clauses,” is incorporated by reference herein. 37 CFR 401.14(c)(1) requires the disclosure of each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. Under 35 U.S.C. 201(d), an invention means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the U.S. Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act. Invention disclosure statements shall be made by creating an invention record using the Interagency Edison system website at: <http://www.iedison.gov>.
3. Data rights.
  - a. General Requirements. The Recipient grants the Government a royalty-free, nonexclusive and irrevocable license to reproduce, display, distribute copies, perform, disseminate, or prepare derivative works, and to authorize others to do so, for Government purposes in:
    - (i) Any data that is first produced under this Award and provided to the Government;
    - (ii) Any data owned by third parties that contributed in the data provided to the Government under this Award; or
    - (iii) Any data requested in paragraph 2 below, if incorporated in the Award.

“Data” means recorded information, regardless of form or the media on which it may be

recorded.

b. Additional requirement for this Award.

- (i) **Requirement:** If the Government believes that it needs additional research data that was produced under this Award, the Government may request the research data and the Recipient agrees to provide the research data within a reasonable time.
- (ii) **Applicability:** The requirement in Item b.(i) of this section applies to any research data that are:
  - (1) Produced under this Award, either as a Recipient or sub-Recipient;
  - (2) Used by the Government in developing an agency action that has the force and effect of law; and
  - (3) Published, which occurs either when:
    - The research data is published in a peer-reviewed scientific or technical journal; or
    - DHS publicly and officially cites the research data in support of an agency action that has the force and effect of law.
- (iii) **Definition of “research data.”** For the purposes of this section, “research data:”
  - (1) Means the recorded factual material (excluding physical objects, such as laboratory samples) commonly accepted in the scientific community as necessary to validate research findings.
  - (2) Excludes:
    - Preliminary analyses;
    - Drafts of scientific papers;
    - Plans for future research;
    - Peer reviews;
    - Communications with colleagues;
    - Trade secrets;
    - Commercial information;
    - Materials necessary that a researcher must hold confidential until they are published, or similar information which is protected under law; and
    - Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.
- (iv) **Requirements for sub-awards.** The Recipient agrees to include in any sub-award made under this Agreement the requirements of this award term (Patent Rights and Data Rights) and **DHS Standard Terms and Conditions award term (Copyright).**

## K. PROGRAM INCOME

Post-award program income. In the event program income becomes available to the Recipient post-award, it is the Recipient’s responsibility to notify the DHS Grants Officer to explain how that development occurred, as part of their request for guidance and/or approval. The Grants Officer will review approval requests for program income on a case-by-case basis; approval is not automatic. Consistent with the requirements outlined in 2 C.F.R. § 200.307(e), pertinent guidance and options, as determined by the type of Recipient and circumstances involved, approval may be approved by the

Grant Officer. If approval is granted, an award modification will be issued with an explanatory note in the remarks section of the face page, concerning guidance and/or options pertaining to the Recipient's approved request. All instances of program income shall be listed in the progress and financial reports.

## L. PUBLICATIONS

1. Publications. All publications produced as a result of this funding which are submitted for publication in any magazine, journal, or trade paper shall carry the following:
  - a. **Acknowledgement**: "This material is based upon work supported by the U.S. Department of Homeland Security under Grant Award Number **as outlined in Item 4 on the Notice of Award**."
  - b. **Disclaimer**: "The views and conclusions contained in this document are those of the authors and should not be interpreted as necessarily representing the official policies, either expressed or implied, of the U.S. Department of Homeland Security."

Recipient agrees to include in any sub-award made under this Agreement the requirements of this award term (Publications).

2. Use of DHS Seal and DHS S&T Logo. Recipient shall not use the DHS seal. Recipient shall acquire DHS's approval prior to using the DHS S&T logo.
3. Enhancing Public Access to Publications. DHS requires that the Recipient shall forward one electronic (PDF) copy of all peer-reviewed publications generated under this award to the **Program Officer** at the time of publication. The COE will make all peer-reviewed publications publicly available via the DHS Storefront in PubMed Central (PMC): [DHS in PMC](#) in a manner consistent with copyright law prior to or at the official date of publication. DHS Policy explicitly recognizes and upholds the principles of copyright. Authors and journals can continue to assert copyright in publications that include research findings from DHS-funded activities, in accordance with current practice. While individual copyright arrangements can take many forms, DHS encourages investigators to sign agreements that specifically allow the manuscript or software to be deposited with DHS for U.S. Government use after journal publication. Institutions and investigators may wish to develop particular contract terms in consultation with their own legal counsel, as appropriate. But, as an example, the kind of language that an author or institution might add to a copyright agreement includes the following: "Journal (or Software Recipient) acknowledges that the Author retains the right to provide a final copy of the final manuscript or software application to DHS upon acceptance for Journal publication or thereafter, for public access purposes through DHS's websites or for public archiving purposes."

## M. SITE VISITS

DHS, through authorized representatives, has the right, at all reasonable times, to make site visits to review project accomplishments and management control systems and to provide such technical assistance as may be required. If any site visit is made by the DHS on the premises of the Recipient, or a contractor under this Award, the Recipient shall provide and shall require its contractors to provide all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All site visits and evaluations shall be performed in such a manner that will not unduly delay the work.

## N. TERMINATION

1. By DHS. DHS may terminate a federal award, in whole or in part, for the following reasons:
  - a. If the Recipient fails to comply with the terms and conditions of the federal award;
  - b. With the consent of the Recipient, in which case the parties must agree upon the termination conditions, including the effective date, and in the case of partial termination, the portion to be terminated; or
  - c. Pursuant to the terms and conditions of the federal award, including, to the extent authorized by law, if the federal award no longer effectuates the program goals or agency priorities.
2. By the Recipient. The Recipient may terminate the federal award, in whole or in part, by sending written notification to the DHS Grants Officer stating the reasons for such termination, the effective date, and in the case of partial termination, the portion to be terminated. However, if DHS determines that the remaining portion of the federal award will not accomplish the purposes for which the federal award was made, DHS may terminate the federal award in its entirety.
3. Notice. Either party will provide written notice of intent to terminate for any reason to the other party no less than 30 calendar days prior to the effective date of the termination.
4. Costs. The Recipient's authority to incur new costs will be terminated upon arrival of the date of receipt of the written notice of intent to terminate or the date set forth in the notice. Any costs incurred up to the earlier of the date of the receipt of the notice or the date of termination set forth in the notice will be negotiated for final payment.
5. Compliance with Closeout Requirements for Terminated Awards. The Recipient must continue to comply with closeout requirements in 2 C.F.R. §§ 200.344-200.345 after an award is terminated.

## O. TRAVEL

Travel required in the performance this Award must comply with 2 C.F.R. Part 200.475.

***Foreign travel must be approved by DHS in advance and in writing.*** Requests for foreign travel identifying the traveler, the purpose, the destination, and the estimated travel costs must be submitted to the DHS Grants Officer 60 days prior to the commencement of travel.

## P. CLASSIFIED SECURITY CONDITION

1. "Classified national security information," as defined in Executive Order (EO) 12958, as amended, means information that has been determined pursuant to EO 12958 or any predecessor order to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form.
2. No funding under this award shall be used to support a contract, sub-award, or other agreement for goods or services that will include access to classified national security information if the Recipient itself has not been approved for and has access to such information.
3. Where an Recipient has been approved for and has access to classified national security information, no funding under this award shall be used to support a contract, sub-award, or other agreement for goods or services that will include access to classified national security information by the contractor, sub-awardee or other entity without prior written approval from the DBS Office of Security, Industrial Security Program Branch (ISPB), or, an appropriate official within the Federal department or agency with whom the classified effort will be performed.
4. Such contracts, sub-awards, or other agreements shall be processed and administered in accordance with the DHS "Standard Operating Procedures, Classified Contracting by State and Local Entities," dated July 7, 2008; EOs 12829, 12958, 12968, as amended; the National Industrial

Security Program Operating Manual (NISPOM); and/or other applicable implementing directives or instructions.

5. Immediately upon determination by the Recipient that funding under this award will be used to support such a contract, sub-award, or other agreement, and prior to execution of any actions to facilitate the acquisition of such a contract, sub-award, or other agreement, the Recipient shall contact ISPB, or the applicable Federal department or agency, for approval and processing instructions.

DHS Office of Security ISPB contact information:

Telephone: 202-447-5346

Email: [DD254AdministrativeSecurity@hq.dhs.gov](mailto:DD254AdministrativeSecurity@hq.dhs.gov)

Mail: Department of Homeland Security

Office of the Chief Security Officer

ATTN: ASD/Industrial Security Program Branch

Washington, D.C. 20528