SOP Number:	OBS-IBC-005	Revision Number:	04	Effective Date:	5/06/2025
Title:	**Institutional Review of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)**				

1. PURPOSE

1.1. This Standard Operating Procedure (SOP) describes the review and approval process that will be followed by the Institutional Review Entity (IRE) for Dual Use Research of Concern (**DURC**) and Pathogens with Enhanced Pandemic Potential (**PEPP**).

2. TRAINING

2.1. IRE Members are required to review this SOP.

3. DEFINITIONS:

3.1. The following terms are defined in the United States Government Policy for Oversight of DURC and PEPP (May 2024) ("Policy")

3.1.1. DURC: Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

3.1.2. Pathogen with Pandemic Potential (PPP): A pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans.

3.1.3. PEPP: A type of PPP resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

3.1.4. Category 1 Research meets 3 criteria: (1) involves one or more of the biological agents and toxins specified in Section 4.1.1 of the Policy; (2) it is reasonably anticipated to result, or does result, in one of the experimental outcomes specified in Section 4.1.2 of the Policy; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC as specified in Section 4.1.3 of the Policy.

3.1.4.1. Category 1 research is subject to oversight by research institutions and federal funding agencies.

3.1.5. Category 2 Research meets 3 criteria: (1) it involves, or is reasonably anticipated to result in, a PPP as specified in Section 4.2.1 of the Policy; (2) it is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified in Section 4.2.2 of the Policy; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP[1] that may pose a significant threat to public health, the capacity of health

[1] Current eradicated and extinct pathogens include Variola major, Variola minor, and 1918 H1N1 Influenza virus

systems to function, or national security as specified in Section 4.2.3 of the Policy.

3.1.5.1. Category 2 research is subject to oversight by research institutions, federal funding agencies, and their federal department if applicable, due to heightened potential for biosafety and biosecurity risks.

3.1.5.2. Any research that meets the definition of both Category 1 and Category 2 research is designated as Category 2 research.

4. SCOPE

4.1. Category 1 Biological Agents and Toxins.

4.1.1. All research involving the agents and toxins described below that may produce, aim to produce, or can be reasonably anticipated to produce one or more of the experimental effects ("Experimental Effects") listed in Sections 4.3.1 through 4.3.9 is subject to additional review and oversight by the IRE as potential DURC.

4.1.1.1. All Select Agents and Toxins listed in the Select Agent Regulations.

4.1.1.2. All Risk Group 4 pathogens and a subset of Risk Group 3 pathogens listed in Appendix B of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ("*NIH Guidelines*").

4.1.1.3. Biological agents that have not been assigned a Risk Group in the *NIH Guidelines* but that the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommends being handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4).

4.1.1.4. Biological agents for which no risk group or biosafety level has been assigned, and the Institutional Biosafety Committee (IBC) identifies as needing BSL-3 or BSL-4 containment based on a risk assessment.

4.1.1.5. Biological agents added during future updates to the DURC/PEPP Implementation Guidance.

4.2. Category 2 Biological Agents

4.2.1. All research involving a PPP as defined in Section 3.1.2 of this SOP, or any pathogen expected to be modified in a way that could result in a PPP and aims to produce or is reasonably anticipated to produce one or more of the experimental effects underlined in Section 4.3 below, is subject to additional review and oversight by the IRE as potential PEPP.

4.3. Experimental Effects (Category 1 and Category 2 outcomes combined):

4.3.1. Increase transmissibility of a pathogen within or between host species, including enhancing the transmissibility of the pathogen in humans

4.3.2. Increase the virulence (i.e.., the ability of a pathogen to cause disease) of a pathogen or convey virulence to a non-pathogen, including enhancing the virulence of the pathogen in humans

4.3.3. Increase the toxicity of a known toxin or produce a novel toxin

4.3.4. Increase the stability of a pathogen or toxin in the environment or increase the ability to disseminate a pathogen or toxin (e.g., improving characteristics of the pathogen or toxin such as environmental stability and aerosolubility)

4.3.5. Alter the host range or tropism of a pathogen or toxin

4.3.6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods

4.3.7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or

therapeutic interventions (e.g., antimicrobials, antivirals, antitoxins, vaccines)

4.3.8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin, including enhancing the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection

4.3.9. Enhance the susceptibility of a host population to a pathogen or toxin

4.3.10. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

5. RESPONSIBILITIES

5.1. PIs must fulfill their responsibilities in accordance with *The United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and University Rule 15.99.06.M1.

5.2. Per TAMU Rule 15.99.06.M1 TAMU's Institutional Biosafety Committee (IBC) serves as TAMU's Institutional Review Entity (IRE).

5.2.1. The IRE may utilize ad hoc reviewers as needed to ensure the IRE has the appropriate expertise to review the proposed research.

5.3. TAMU's Vice President for Research (VPR) designated the Responsible Official (RO) to serve as the Institutional Contact for Dual Use Research (ICDUR). The ICDUR serves as TAMU's internal resource for issues regarding compliance with and implementation of the requirements for oversight of DURC. The ICDUR shall also serve as the point of contact for Authorized Organizational Representatives (AORs), who are responsible for liaising between the University and relevant funding agencies.

5.4. Annually, the ICDUR is responsible for reviewing this SOP and other institutional policies and procedures to ensure they align with the Policy. AORs are responsible for providing relevant funding agencies with a formal assurance to this effect.

6. PROCESS FOR INSTITUTIONAL REVIEW OF LIFE SCIENCES RESEARCH FOR DURC/PEPP

6.1. Research involving potential DURC/PEPP will be reviewed by the IRE when identified as such per Sections 6.1.1 through 6.1.5.

6.1.1. PI notifies the IBC/IRE as soon as their initial assessment of the potential for their biohazard-related activities to generate knowledge, information, products (including pathogens or toxins), or technology that meets the criteria for Category 1 or Category 2 research involving biohazardous materials.

6.1.2. PI's proposed research involves any of the agents listed in Section 4.1 or 4.2 of this SOP.

6.1.3. PI's proposed research with one or more of the agents in Section 4.1 or 4.2 may produce, aim to produce or can be reasonably anticipated to produce one or more of the Experimental Effects listed in Section 4.3 of this SOP; or

6.1.4. PI's research that is within the scope of Section 4 may meet the definition of DURC/PEPP.

6.1.5. TAMU, through The Office of Biosafety, receives notice from the funding agency that a proposed research/study may fall within the scope of Section 4 of this SOP.

7. IRE REVIEW

7.1. The IRE verifies that the proposed research involves any of the agents listed in Section 4.1 or 4.2, reviews the PI's assessment of whether the research produces, aims to produce, or is

reasonably anticipated to produce one or more of the Experimental Effects, and makes a final determination of their applicability.

7.2. The results of the IRE's determination will be communicated to the PI and the federal funding agency per Section 8 below.

7.2.1. If the IRE determines that the research does not meet the definition of Category 1 or Category 2 research, the research is not subject to additional review or oversight by the IRE unless the funding agency, while reviewing the IRE's determination, determines otherwise.

7.2.1.1. In such cases, the research will undergo continuous assessment throughout its lifecycle for potential Category 1 or Category 2 research.

7.2.2. The communication to the PI will inform the PI of his or her option to appeal the determination of the IRE by writing to the Chair of the IRE, within 10 calendar days of the date of the communication, detailing the basis of the appeal and requesting a meeting with the IRE.

7.3. If the IRE determines that the research does meet the definition of Category 1 or Category 2 research, a risk mitigation plan will be developed in collaboration with the PI and the funding agency, as appropriate.

7.4. The risk mitigation plan will include a risk-benefit assessment. The risk-benefit assessment will be conducted by the IRE in collaboration with the PI during the Category 1 or Category 2 research determination and in development of the risk mitigation plan.

7.5. In conducting the risk assessment, the risks and benefits of the project, including how research methodologies may generate risk and/or whether open access to the knowledge, information, products or technologies generates risk should be considered.

7.6. The risk mitigation plan may include, but is not limited to, the following risk mitigation measures:

7.6.1. Modifying the design or conduct of the research.

7.6.2. Applying specific or enhanced biosecurity or biosafety measures.

7.6.3. Evaluating existing evidence of medical countermeasures (MCM) efficacy or conducting experiments to determine MCM efficacy against agents or toxins resulting from DURC, and where effective MCM exist, including that information in publications.

7.6.4. Requesting that the PI notify the IRE and Office of Biosafety if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed.

7.6.5. Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.

7.6.6. If the risks cannot be adequately managed, not approve the research.

7.7. The funding agency will require documentation confirming the IRE's review and determination of the proposed research. This includes the risk-benefit assessment and a draft risk mitigation plan (if the research falls under Category 1 or Category 2), as outlined in Section 8 below. Once approved, the risk mitigation plan will be implemented, and the research must be conducted in accordance with the approved plan.

7.8. The risk mitigation plan will be subject to ongoing review and modification, as necessary. At a minimum, risk mitigation plans for Category 1 research must be evaluated annually, while those for Category 2 research must be evaluated semi-annually.

7.9. Any changes in the status of a Category 1 or Category 2 research project (including whether the research is determined to no longer meet the definition of Category 1 or Category 2 research) or proposed changes to the risk mitigation plan, must be communicated to the funding agency per Section 8 below. Changes in the risk mitigation plan require approval from the funding agency.

8. NOTIFICATIONS/REPORTS

8.1. Within 30 calendar days of the IRE's determination of whether the research meets the criteria for Category 1 or Category 2, the ICDUR, acting on behalf of the IRE, will coordinate with the AOR to ensure that the appropriate federal funding agency is notified of the review outcome.

8.1.1. In collaborations involving multiple institutions through a subaward, the primary institution must notify the federal funding agency of any research classified as Category 1 or Category 2. This includes providing copies of each institution's risk mitigation plan or a consolidated plan with relevant components.

8.1.2. Initial notification should include: the grant or contract number related to the research; the name(s) of the PI(s); identification of the agent(s); a description of why the research is deemed to produce one or more of the Experimental Effects.

8.2. Within 90 calendar days of the IRE's determination that the research is Category 1 or Category 2 research, the AOR, on behalf of the institution, will submit to the federal funding agency the following documentation, as applicable:

8.2.1. Confirmation of IRE review and category determination

8.2.2. Documentation of the risk-benefit assessment and the draft risk mitigation plan described in Section 7.3 through 7.6 above

8.3. Annual and semi-annual reports on the evaluations of risk mitigation plans are required for Category 1 and Category 2 research, respectively.

8.4. Instances of noncompliance with the Policy, as well as mitigation measures undertaken to prevent recurrences of similar noncompliance will be reported by the AOR on behalf of the institution, within 30 calendar days to the federal funding agency, as appropriate.

8.5. Records of Category 1 or Category 2 research reviews and completed risk mitigation plans will be maintained for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

9. REFERENCE DOCUMENTS AND FORMS

9.1. Tools for the identification, assessment, management, and responsible communication of dual use research of concern: A Companion Guide to the USG Policies for Oversight of Life Sciences Dual Use Research of Concern: http://www.phe.gov/s3/dualuse/documents/durc-companion-guide.pdf

9.2. USG Policy for Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (May 2024): https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf

9.3. Implementation Guidance for the USG Policy for Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential: https://aspr.hhs.gov/S3/Documents/USG-DURC-PEPP-Implementation-Guidance-May2024-508.pdf

9.4. Biosafety in Microbiological and Biomedical Laboratories https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

9.5. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

9.6. Proposed Biosecurity Oversight Framework for the Future of Science (March 2023): https://aspr.hhs.gov/S3/Documents/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf

9.7. Select Agent Regulations: 9 CFR 121.3–121.4, 42 CFR 73.3–73.4, and 7 CFR 331.3

https://www.selectagents.gov/sat/list.htm

9.8. Texas A&M University Rule: 15.99.06.M1. *Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern*

10. REVISION HISTORY

03 Reclassified as an IBC document, minor edits to clarify the role of the ICDUR and the AOR. Additional revisions made to reflect the new DURC/PEPP policy.

04 Major revisions to align with the USG Policy for Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (May 2024).