Policy DURC/PEPP Policy	Author: Institutional Contact for Dual Use Research (ICDUR)	Owner: OESO Biological Safety
Approved By: Duke University Safety Committee (DUSC)		Date Effective: 6 May 2025

REVISIONS:

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4/24/2025	New Policy	AV, AS

SUMMARY
Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) refer to categories of life sciences research that could be misapplied to pose significant threats to public health, agriculture, or national security. Duke University has established this policy to outline the institutional procedures and responsibilities for identifying and overseeing such research. The policy defines expectations and requirements for individuals and committees involved in ensuring Duke's compliance with federal requirements related to DURC and PEPP.

PURPOSE
Life sciences research offers significant benefits to society through scientific discovery and innovation. However, a subset of this research carries the potential for misuse, which could pose threats to public health and safety, agriculture, animals, the environment, or national security. To address these concerns, the United States Government issued the 2024 Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)[1], which calls for rigorous risk assessment and oversight by both institutional committees and federal funding agencies.

Duke University adheres to the 2024 USG Policy, promoting responsible conduct and oversight of research that may carry dual use or pandemic potential risks. Although the federal policy formally applies to departments and agencies that fund or sponsor research, institutions are recognized as essential stakeholders and are expected to implement similar oversight for research regardless of funding source.

The Duke DURC-PEPP Policy outlines the institutional practices and procedures necessary to ensure full compliance with the federal framework. It establishes clear responsibilities for identifying and managing research that falls within the scope of the 2024 USG Policy.

All research conducted at Duke University that is classified as Category 1 or Category 2 (as defined below) is subject to this policy—regardless of the source of funding.

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DEFINITIONS

Dual use research is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

Dual use research of concern (DURC) is 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.

Federal Funding Agency (FFA) is a federal department, agency, institute, center, or office that funds or sponsors intramural or extramural research at research institutions in the United States or internationally, with biological agents or toxins where the research is within Category 1 or Category 2 under the 2024 USG Policy.

Institutional Contact for Dual Use Research (ICDUR) is the official designated by the research institution to serve as an internal resource for application of the 2024 USG Policy as well as the liaison (as necessary) between the institution and the relevant federal funding agency. Here at Duke University, the ICDUR is the Director of the Biological Safety Division in the Occupational and Environmental Safety Office.

Institutional review entity (IRE) is the entity established by the research institution to execute the institutional oversight responsibilities described the 2024 USG Policy. At Duke University, the Institutional Biosafety Review Committee (IBRC) will serve as the IRE.

Occupational and Environmental Safety Office (OESO) exists to support Duke University's mission of excellence and leadership in education, medical teaching, and research with specific responsibility for providing expertise in safety and health in order to promote a safe environment.

Pathogen with enhanced pandemic potential (PEPP) is a type of pathogen with pandemic potential (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.

Pathogen with pandemic potential (PPP) is 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.

Principal investigator (PI) is the senior/key person seeking or receiving federal research and development funding (i.e., extramural funding). This includes researchers at federal agency laboratories and facilities, as well as researchers at government-owned, contractor operated laboratories and facilities (i.e., intramural researchers, whether or not federally employed). There may be more than one PI on a research grant or project within a single or multiple institution(s).

Risk Mitigation Plan (RMP) is developed by the IRE in partnership with the PI, and describes measures to be instituted for the conduct and communication of Category 1 and Category 2 research. The RMP will include details of the risks identified by the IRE in its review of the research, and an explanation of the risk mitigation strategy or strategies that are being implemented to address those risks.

Reasonably anticipated describes an assessment of an outcome such that, generally, individuals with scientific expertise relevant to the research in question would expect this outcome to occur with a non-trivial likelihood. It does not require high confidence that the outcome will definitely occur but excludes experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely.

APPLICABILITY

This policy and its oversight requirements apply to all life sciences and related research being performed at Duke University, regardless of funding sources. Non-compliance with this Policy may result in suspension, limitation, or termination of research at the institution.

ORGANIZATIONAL FRAMEWORK FOR OVERSIGHT OF DURC/PEPP

1. **Principal Investigator (PI) Self-Assessment**
   At the time of proposal development and throughout the research lifecycle, the PI is responsible for identifying whether their research may fall under DURC or PEPP oversight and for completing a self-assessment accordingly.

2. **Institutional Review of Self-Assessment**

Upon submission of the PI's self-assessment, the institution reviews the research to determine whether it meets the criteria for Category 1 (DURC) or Category 2 (PEPP) under the 2024 USG Policy.

3. **Submission to Federal Funding Agency (FFA)**
   The research proposal is submitted to the appropriate FFA following that agency's established processes. If the FFA determines the research meets the criteria for Category 1 or 2, it will request supporting documentation from the institution in accordance with the policy.

4. **Risk/Benefit Assessment and Risk Mitigation Plan Development**
   While the proposal is under review by the FFA, the Institutional Contact for Dual Use Research (ICDUR) and the Institutional Review Entity (IRE) works with the PI to develop a Risk/Benefit Assessment (RBA) and a Risk Mitigation Plan (RMP) to ensure the safe and secure conduct of the proposed research.

5. **Institutional Submission of Required Materials**
   Upon request from the FFA, the ICDUR—or another institutional representative designated by the FFA—submits the RMP and any other required documentation.

6. **Approval and Implementation of the RMP**
   The FFA reviews and approves the RMP. Once approved, the PI is required to adhere to all provisions outlined in the RMP for the lifecycle of the research.

7. **Ongoing Compliance and Documentation**
   If the project is funded, the PI must coordinate with the ICDUR and relevant research support offices to provide required documentation throughout the award period, consistent with the frequencies and formats specified by the FFA.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS

PIs are expected to take an active role in the identification, oversight, and responsible conduct of research with dual use or enhanced pandemic potential. Specifically, PIs must:

1. **Evaluate Research During Proposal Development**
   Review proposed research during the grant writing stage for potential applicability under the 2024 USG DURC/PEPP Policy and complete the PI Self-Assessment to notify the Institutional Contact for Dual Use Research (ICDUR) of any concerns.

2. **Maintain Ongoing Risk Awareness**
   Continuously assess all research activities for DURC/PEPP potential and notify the ICDUR promptly if any new concerns arise during the project.

3. **Collaborate on Institutional Review and Documentation**
   If the ICDUR and Institutional Review Entity (IRE) concur with the PI's assessment that the research may fall under Category 1 (DURC) or Category 2 (PEPP), the PI must work with institutional officials to develop all required documentation.

4. **Support Regulatory Submissions**
   Prepare and submit the Risk-Benefit Assessment, Risk Mitigation Plan (RMP), and required progress reports—annually for Category 1 and every 6 months for Category 2 research—to the Federal Funding Agency (FFA), in coordination with the ICDUR, IRE, and appropriate research support offices.

5. **Conduct Research in Compliance with Approved Plans**
   Carry out Category 1 and Category 2 research in full accordance with the approved RMP and institutional oversight protocols. When research is categorized as both Category 1 and Category 2 research, the research will be treated as Category 2 research.

6. **Ensure Policy Compliance**
   Stay informed about and comply with all applicable institutional and federal policies and requirements regarding DURC and PEPP oversight.

7. **Train and Monitor Laboratory Personnel**
   Ensure that all laboratory personnel (e.g., graduate students, postdoctoral fellows, technicians, staff, and visiting scientists) are properly trained in relevant oversight policies and procedures and can demonstrate competency in their application.

RESPONSIBILITIES OF DUKE UNIVERSITY

To ensure institutional compliance with the 2024 U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, Duke University will:

1. **Implement Institutional Oversight Infrastructure**
   Establish and maintain internal policies and procedures for the identification and effective oversight of Category 1 (DURC) and Category 2 (PEPP) research. A chapter on DURC/PEPP has been added to the Duke University Laboratory Safety Manual (Section 2: Biological Safety).

2. **Designate an Institutional Contact**
   Appoint the Director of the Biological Safety Division of OESO as Duke's Institutional Contact for Dual Use Research (ICDUR) to serve as the primary institutional resource on the 2024 USG Policy.

3. **Support Principal Investigators (PIs)**
   Ensure appropriate resources are available to assist PIs in identifying research requiring further review or oversight.

4. **Maintain an Institutional Review Entity (IRE)**
   Establish and sustain the Institutional Review Entity in alignment with the requirements stated in the 2024 USG Policy. The Duke Institutional Biosafety Review Committee (IBRC) will serve as the IRE.

5. **Initiate Institutional Review When Required**
   Begin the oversight process when research is identified as potentially falling under Category 1 or 2, following the institutional procedures described above.

6. **Enable Project Referral and Appeals**
   Provide mechanisms for PIs to refer research projects to the ICDUR for DURC/PEPP review or to appeal determinations made by the IRE regarding Category 1 or 2 designations.

7. **Deliver Targeted Training**
   Provide education and training on research oversight to PIs and personnel whose work may fall within the scope of the 2024 USG Policy.

8. **Track and Manage Biological Materials**
   Establish systems to track and manage the inventory and disposal of biological agents or toxins resulting from Category 1 or 2 research when no longer needed.

9. **Maintain Oversight Records**
   Retain documentation of personnel training, IRE reviews, and approved Risk Mitigation Plans (RMPs) for at least three years after project completion.

10. **Report Noncompliance**
    Report any noncompliance with the Policy—and the corrective actions taken to prevent recurrence—to the relevant Federal Funding Agency (FFA) within **30 calendar days** of discovery or notification.

11. **Inform Local Authorities When Appropriate**
    Make relevant information about Category 1 and Category 2 research available to local authorities, when applicable.

12. **Submit Annual Assurances**
    Provide annual formal assurances to relevant FFAs confirming that Duke University is in full compliance with the 2024 USG Policy.

13. **Responsibilities When Acting as Primary Institution**
    If designated as the primary institution on a grant with subawardees, notify the FFA of any Category 1 or 2 research at subawardee institutions and submit all relevant RMPs (either individually or as a single integrated plan).

14. **Responsibilities When Acting as Subawardee**
    If Duke is a subawardee, collaborate with the primary institution to ensure full compliance with the 2024 USG Policy and institutional oversight requirements.

RESPONSIBILITIES OF THE INSTITUTIONAL BIOSAFETY REVIEW COMMITTEE (IBRC) AS THE IRE

At Duke University, the Institutional Biosafety Review Committee (IBRC) serves as the Institutional Review Entity (IRE) as defined in the 2024 U.S. Government Policy for Oversight of DURC and PEPP. In this role, the IBRC will:

1. **Assess Scope of Research**
   Evaluate whether proposed research meets the definitions of Category 1 (DURC) or Category 2 (PEPP) under the 2024 USG Policy.

2. **Support Risk-Benefit and Mitigation Planning**
   Collaborate with the Principal Investigator (PI) to conduct a Risk-Benefit Assessment and develop a Risk Mitigation Plan (RMP).

3. **Ensure Agency Notification**
   Ensure that the relevant Federal Funding Agency (FFA) is appropriately notified when research is determined to fall under Category 1 or Category 2.

4. **Review and Approve RMPs**
   Review, approve, and implement the RMP prior to the initiation of any Category 1 or Category 2 research.

5. **Conduct Annual RMP Reviews**
   Reevaluate RMPs at least annually to determine whether updates or additional mitigation strategies are necessary.

6. **Submit Determinations to FFA**
   Notify the FFA within 30 calendar days of its request regarding the committee's determination of whether the proposed research qualifies as Category 1, Category 2, or neither.

7. **Submit RMPs to FFA**
   Provide the completed RMP to the FFA within 90 calendar days of its request for any research determined to be Category 1 or Category 2.

Committee Structure and Administration

IBRC membership shall consist of members with sufficient breadth of expertise to assess the range of biological materials and projects subject to the review of the IBRC, along with individuals who have knowledge and understanding of biosafety, biosecurity, risk assessment and risk management considerations. Ad hoc members may be called upon as needed, determined by the IBRC co-chairs.

The administrative functions of the IBRC shall be performed by the OESO Biological Safety Division. Further information about the committee's structure, responsibilities, and operations is outlined in the Duke University Institutional Review Committee (IBRC) Charter.

COMPLIANCE WITH THIS POLICY

Failure to comply with this policy subjects the individual to potential civil penalties as well as University sanctions. Violations also subject the University to potentially serious sanctions, including suspension,

limitation, or termination of federal funding and loss of future federal funding and monetary penalties. The Duke Office of Research and Innovation will facilitate compliance through management and administration of standard operation procedures drafted and approved by the IBRC.

APPENDIX

List of Biological Agents and Toxins within the scope of Category 1 and Category 2 Research
(Please note: this is *not* a comprehensive list of biological agents and toxins. Other biological agents and toxins maybe be applicable based on updates to sources listed in the USG DURC/PEPP Policy)

Bacteria

1. *Bacillus anthracis*
2. *Bacillus anthracis* Pasteur strain
3. *Bacillus cereus* Biovar *anthracis*
4. *Bartonella*
5. Botulinum neurotoxin producing species of *Clostridium*
6. *Brucella abortus*
7. *Brucella melitensis*
8. *Brucella suis*
9. *Burkholderia mallei*
10. *Burkholderia pseudomallei*
11. *Coxiella burnetii*
12. *Francisella tularensis*
13. *Mycoplasma capricolum*
14. *Mycoplasma mycoides*
15. *Orientia tsutsugamushi*
16. *Pasteurella multocida* type B
17. *Ralstonia solanacearum*
18. *Rickettsia prowazekii*
19. *Rickettsia spp.*
    a) *Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R, siberica, R. typhi (R. mooseri)*
20. *Yersinia pestis*

Fungi

1. *Coniothyrium glycines*
2. *Ralstonia solanacearum*
3. *Rathayibacter toxicus*
4. *Sclerophthora rayssiae*
5. *Synchytrium endobioticum*
6. *Xanthomonas oryzae*

Prions

1. Transmissible spongiform encephalopathies (TSE) agents (e.g., Creutzfeldt-Jacob disease, kuru agents)

Toxins

1. Abrin
2. Botulinum neurotoxins
3. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)
4. Diacetoxyscirpenol (DAS)
5. Ricin
6. Saxitoxin
7. Staphylococcal enterotoxins (subtypes A,B,C,D,E)
8. T-2 toxin
9. Tetrodotoxin

Viruses

1. African swine fever virus
2. Araguari virus
3. Arenaviruses
    a) Allpahuayo, Bear Canyon, Big Brushy Tank, Cupixi, Gairo, Loei River, Luna, Lunk, Mariental, Merino Walk, Mobala, Mopeia, Morogoro, Okahandja, Oliveros, Pirital, Solwezi, Wēnzhōu, and Whitewater Arroyo
4. Avian influenza virus
    a) Low-pathogenic
    b) High-pathogenic
5. Bovine ephemeral fever virus
6. Chapare virus
7. Chikungunya virus (except the vaccine strain 181/25)
8. Classical swine fever virus
9. Crimean-Congo hemorrhagic fever virus
10. Eastern equine encephalitis virus
11. Ebolavirus
12. Flexal virus
13. Foot-and-mouth disease virus
14. Goat pox virus
15. Guanarito virus
16. Hemorrhagic fever agents undefined
17. Hendra virus
18. Hantaviruses
19. Herpesvirus simiae

20. Influenza A H1N1 (1918-1919)
21. Influenza A H2N2 (1957–1968)
22. Influenza A H5Nx (e.g., H5N1), Highly Pathogenic Avian Influenza (HPAI)
23. Japanese encephalitis virus (except strain SA 14-14-2)
24. Junín virus (except candid #1 vaccine strain)
25. Kyasanur Forest disease virus
26. Lassa fever virus
27. Lujo virus
28. Lumpy skin disease virus
29. Lymphocytic choriomeningitis virus (neurotropic strains)
30. MERS-CoV
31. Machupo virus
32. Marburg virus
33. Mpox virus Clade I (Monkeypox virus)
34. Mpox virus clade I/II chimeric viruses (Monkeypox virus)
35. Newcastle disease virus
36. Nipah virus
37. Omsk hemorrhagic fever virus
38. Orthobunyaviruses
    a) Akabane, Douglas, Ngaric, and Xingu
39. Orthonairoviruses
    a) Artashat, Dugbe, Issyk-Kul, Kupe, Nairobi sheep disease
40. Peste des petits ruminants virus
41. Phleboviruses
    a) Bhanja, Escharte, Heartland, Hunter Island, Malsoor, Morolillo, Salobo, Severe fever with thrombocytopenia syndrome
42. Reoviruses
    a) African horse sickness, Banna, Bluetongue (exotic serotypes), Peruvian horse sickness, Yunnan orbivirus
43. Rift Valley fever virus
44. Rinderpest virus
45. Severe acute respiratory syndrome coronavirus (SARS-CoV)
46. SARS-CoV-2
47. SARS-CoV/SARS-CoV-2 chimeric viruses
48. Sabía virus
49. Semliki Forest virus
50. Sheep pox virus
51. Somone virus
52. South Bay virus
53. Sripur virus

54. Swine vesicular disease virus
55. Tick-borne encephalitis virus complex
    a) Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, and Russian spring-summer encephalitis viruses
56. Tick-borne encephalitis virus complex: Far Eastern subtype
57. Tick-borne encephalitis virus complex: Siberian subtype
58. Vaccine strains with recovered virulence
59. Variola major virus
60. Variola minor virus
61. Venezuelan equine encephalitis virus (except the vaccine strains TC-83 & V3526)
62. Yellow fever virus

Other

1. Any attenuated pathogen or vaccine strain that is currently excluded from the Select Agent Regulations that exhibits the recovery of virulence at or near the wild-type
2. Agents added during future updates to the USG DURC-PEPP policy
3. Biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines but are agents recommended to be handled at BSL3 or BSL4 per the guidance in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*

REFERENCES

1. National Science and Technology Council. (2024). *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*. Executive Office of the President of the United States. https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf