The University of Texas Health Science Center at Houston (UTHealth Houston)
Institutional Biosafety Committee (IBC)

**Title:** Institutional Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

**Section:** Biological Safety

**IBC Approval Date:** February 2016

**Revision Date:** April 10, 2025

On May 6, 2024, the United States Government (USG) issued the USG Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf The effective date of this policy is May 6, 2025.

**This policy supersedes:**

- USG Policy for Oversight of Life Sciences DURC, issued 2012, http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf ,
- USG Policy for Institutional Oversight of Life Sciences DURC, issued 2014, https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO Framework), July 2017

  https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf

This policy is a unified federal oversight framework for certain types of federally funded life sciences research on biological agents and toxins that, when enhanced, have the potential to pose risks to public health, agriculture, food security, economic security, or national security. An Implementation Guidance is provided by USG to assist with implementation of this policy https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf

**This policy applies to:**

- Federal departments and agencies that fund or sponsor intramural or extramural research at research institutions in the United States and internationally with biological agents or toxins where the research is within Category 1 or 2 under this policy.
- Research funded or sponsored by grants, contracts, cooperative agreements, and other agreements and transactions issued on or after the effective date of this policy.
- Research proposal stage and full life cycle of the research is covered in this policy.
- Non-federally funded research at institutions that receive federal funding
- Research that is outside the scope of this Policy but may benefit from the voluntary risk assessment and mitigation

**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 research that 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, the environment, material, or national security.

*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.

*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.

*Institutional Contact for Dual Use Research (ICDUR)* is the official designated by the research institution to serve as an internal resource for the application of this Policy, as well as the liaison (as necessary) between the institution and the relevant federal funding agency.

This policy categorizes the research previously overseen by the 2012 Federal DURC, the 2014 Institutional DURC, and the 2017 P3CO Framework policies into Category 1 and Category 2 research. This policy expands the scope previously overseen by those policies.

**Category 1 research meets the all of the following three criteria**

i. Involves one or more of the listed biological agents and toxins
    a) All listed in 9 CFR 121.3-121.4, 42 CFR73.3-73.4, and 7 CFR 331.2, and regulated by USDA and/or HHS
    b) All Risk Group 4 Pathogens listed in Appendix B of the NIH Guidelines
    c) A subset of Risk Group 3 Pathogens listed in Appendix B of the NIH Guidelines
    d) Biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines or BMBL
    e) Biological agents added during future updates

ii. It is reasonably anticipated to result, or does result, in one of the listed experimental outcomes
    i. Increase transmissibility of a pathogen within or between host species
    ii. Increase the virulence of a pathogen or convey virulence to a non-pathogen
    iii. Increase the toxicity of a known toxin or produce a novel toxin
    iv. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin
    v. Alter the host range or tropism of a pathogen or toxin
    vi. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods
    vii. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions
    viii. 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
    ix. Enhance the susceptibility of a host population to a pathogen or toxin

iii. Based on current understanding, the institution or funding agency classifies the work as DURC
    i. Based on current understanding, the research can be reasonably anticipated to provide, or does 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, material, or national security.

**Category 2 research meets all of the following three criteria**

i. It involves, or is reasonably anticipated to result in a PPP
    i. A PPP, or any pathogen that will be modified in such a way that is reasonably anticipated to result in a PPP.

ii. It is reasonably anticipated to result, or does result, in one of the following experimental outcomes or actions
    i. Enhance transmissibility of the pathogen in humans
    ii. Enhance the virulence of the pathogen in humans
    iii. Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunizations or natural infection
    iv. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

iii. The research can be reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security.

**Oversight Framework for Category 1 and Category 2 Research Associated with this Policy**

1. The Principal Investigator (PI) makes the initial assessment of whether their proposed or ongoing research may be within the scope of this policy.
2. The PI and/or UTHealth Houston Sponsored Projects Administration (SPA) will notify the UTHealth Houston Environmental Health and Safety (EHS), Biological Safety Program.
    a. Notification via a statement on START/AURA form.
3. The UTHealth Houston Environmental Health and Safety (EHS), Biological Safety Program will notify the Senior Vice President, Academic and Faculty Affairs (SVP AFA) to evaluate the research to be conducted at UTHealth Houston. If the SVP AFA declines, the SVP AFA will notify the PI, SPA, and EHS. If approval is granted, the PI may proceed.
4. The PI simultaneously submits a UTHealth Houston Institutional Biosafety Committee (IBC) protocol and the research proposal to the federal funding agency, including notification that the research may be within the scope of this policy.

5. When the federal funding agency has completed a merit review of the proposed research, and if it is considering funding the proposed research, the federal funding agency notifies UTHealth Houston.
6. UTHealth Houston, through the IBC, reviews the PI's initial assessment and confirms whether the proposed or ongoing research is within the scope of this policy. As per UTHealth Houston IBC policy, an ad-hoc member may be added to the protocol review as a subject matter expert.
7. UTHealth Houston, through the IBC, notifies the federal funding agency of the results of the Category 1 or 2 research determination.
8. The federal funding agency evaluates and verifies UTHealth Houston's assessment.
9. UTHealth Houston conducts a risk-benefit assessment and develops a draft risk mitigation plan. The PI and UTHealth Houston IBC submit the assessment and draft risk mitigation plan to the federal funding agency.
10. The federal funding agency will review all documents for approval.

**The PI has the following responsibilities:**

- Initial assessment of whether their proposed or ongoing research may be within the scope of this policy.
- Submitting the research proposal to the federal funding agency, including notification that the research may be within the scope of this policy.
- Working with UTHealth Houston's IBC to develop a risk mitigation plan
- Conducting approved work associated with this policy only after approval by the federal funding agency, the IBC, and in accordance with the risk mitigation plan
- Being knowledgeable about this policy and educating lab personnel accordingly
- Providing annual progress reports for Category 1 and semiannual progress reports for Category 2 to the federal funding agency for review, evaluation, assessment, clarification, or confirmation.
- Communicating the research and research findings associated with this policy in a responsible manner.

**UTHealth Houston has the following responsibilities:**

- Establishing and implementing internal policies and practices for research under this policy.
- Providing PIs education and training to report on their research regarding this policy.
- Establish an Institutional Review Entity (IRE)
    - UTHealth Houston's IBC will fulfill the role of the IRE.
- Engaging in an ongoing dialogue with the PI of the research in question when conducting a risk-benefit assessment and developing appropriate risk mitigation plans for research that may apply to this policy.
- Establishing a mechanism to ensure that the resulting biological agent or toxin from Category 1 and Category 2 research are properly accounted for and destroyed when no longer needed if not already required to do so by existing law and regulation
- Evaluating the risk mitigation plans at least annually
- Ensuring that the federal funding agency is notified and a risk mitigation plan is reviewed, approved, and implemented before the initiation of the proposed Category 1 or Category 2 research
    - Within 30 calendar days of the institutional review, notifying the federal funding agency of the review and determination of research meeting the criteria listed in the policy

    - Within 90 calendar days, providing a copy of the risk mitigation plan to the federal funding agency for review.
- Maintaining records of institutional Category 1 and Category 2 research reviews and completed risk mitigation plans for at least three years after the completion of the funded project unless a longer period is required by law or regulation.
- Reporting instances of failure to follow this Policy, as well as mitigation measures undertaken by UTHealth Houston to prevent recurrences of similar failures, within 30 calendar days of UTHealth Houston's awareness or receipt of notification of a failure to the federal funding agency
- Establishing an internal mechanism for PIs to appeal the institutional decisions regarding research that the IBC determines to meet the definition of Category 1 or Category 2 research.
- Certifying at the time of seeking funding (e.g., by signing the face page of a grant application) that UTHealth Houston fully follows the research oversight framework under this Policy
- On an annual basis, providing a formal assurance to relevant federal funding agencies that UTHealth Houston is operating consistent with this Policy.

**The Federal Funding Agency has the following responsibilities:**

- Completing a merit review of the proposed research and if it is considering funding the proposed research, notifying UTHealth Houston.
- Reviewing and approving UTHealth Houston risk-benefit assessments and risk mitigation plans and notifying UTHealth Houston of any concerns, disagreements, or proposed modifications with the assessments or plans
- Determining that the potential benefits of the research justify the potential risks and approve the risk mitigation plan before notifying UTHealth Houston and PI that the experiments identified as Category 1 or Category 2 may proceed
- Before reaching the final determination to fund, or continue to fund the research, consult with UTHealth Houston to address any disagreements identified.

**The Institutional Contact for Dual Use Research (ICDUR)**

- Official designated by UTHealth Houston to serve as an internal resource for the application of this Policy as well as the liaison (as necessary) between UTHealth Houston and the relevant federal funding
- The Senior Vice President, Academic and Faculty Affairs, Dr. Keven Morano, has been designated the ICDUR.

The effective date of implementation is May 6, 2025.

The Biological Safety Officer (BSO) will oversee the implementation process and ensure that all required components are in place in advance of May 6, 2025.

This policy has been reviewed and approved by the Institutional Biosafety Committee.

4-14-2025

UTHealth Houston Institutional Biosafety Committee Chair

**Appendix A:** Category 1 Biological Agents and Toxins

| HHS Select Agents and Toxins | | | |
|---|---|---|---|
| ☐ | Abrin | ☐ | Severe acute respiratory coronavirus (SARS-CoV) |
| ☐ | *Bacillus cereus Biovar anthracis* | ☐ | SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors |
| ☐ | Botulinum neurotoxins | ☐ | Saxitoxin |
| ☐ | *Clostridium botulinum* and neurotoxin-producing species of *Clostridia* | ☐ | Chapare virus |
| ☐ | Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7) | ☐ | Guanarito virus |
| ☐ | *Coxiella burnetii* | ☐ | Junín virus |
| ☐ | Crimean-Congo hemorrhagic fever virus | ☐ | Machupo virus |
| ☐ | Diacetoxyscirpenol | ☐ | Sabía virus |
| ☐ | Eastern equine encephalitis virus | ☐ | Staphylococcal enterotoxins (subtypes A, B, C, D, E) |
| ☐ | *Ebolavirus* | ☐ | T-2 toxin |
| ☐ | *Francisella tularensis* | ☐ | Tetrodotoxin |
| ☐ | Lassa fever virus | ☐ | Tick-borne encephalitis complex virus: Far Eastern subtype |
| ☐ | Lujo virus | ☐ | Tick-borne encephalitis complex virus: Siberian subtype |
| ☐ | Marburg virus | ☐ | Kyasanur Forest disease virus |
| ☐ | Mpox virus Clade I | ☐ | Omsk hemorrhagic fever virus |
| ☐ | 1918-1919 H1N1 including reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus) | ☐ | Variola major virus (Smallpox virus) |
| ☐ | Ricin | ☐ | Variola minor virus (Alastrim) |
| ☐ | *Rickettsia prowazekii* | ☐ | Yersinia pestis |
| Overlap Select Agents and Toxins | | | |
| ☐ | *Bacillus anthracis* | ☐ | Hendra virus |
| ☐ | *Bacillus anthracis Pasteur strain* | ☐ | Nipah virus |
| ☐ | *Burkholderia mallei* | ☐ | Rift Valley fever virus |
| ☐ | Burkholderia pseudomallei | ☐ | Venezuelan equine encephalitis virus |

| | | | |
|---|---|---|---|
| USDA Veterinary Services (VS) Select Agents and Toxins | | | |
| ☐ | African swine fever virus | ☐ | *Mycoplasma mycoides* |
| ☐ | Avian influenza virus [this is included here as a veterinary select agent in 9 CFR 121.3. Low pathogenicity strains are excluded.] | ☐ | Newcastle disease virus |
| ☐ | Classical swine fever virus | ☐ | Peste des petits ruminants virus |
| ☐ | Foot-and-mouth disease virus | ☐ | Rinderpest virus |
| ☐ | Goat pox virus | ☐ | Sheep pox virus |
| ☐ | Lumpy skin disease virus | ☐ | Swine vesicular disease virus |
| ☐ | *Mycoplasma capricolum* | | |
| USDA Plant Protection and Quarantine PPQ) Select Agents and Toxins | | | |
| ☐ | *Coniothyrium glycines* | ☐ | *Sclerophthora rayssiae* |
| ☐ | *Ralstonia solanacearum* | ☐ | *Synchytrium endobioticum* |
| ☐ | *Rathayibacter toxicus* | ☐ | *Xanthomonas oryzae* |
| Other Risk Group 4 Pathogens | | | |
| ☐ | Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, and Kumlinge | ☐ | Hemorrhagic fever agents and viruses as yet undefined |
| ☐ | Herpesvirus simiae (herpes B or monkey B virus) | | |
| Other Risk Group 3 Pathogens | | | |
| ☐ | *Bartonella* | ☐ | Hantaviruses, including Hantaan virus |
| ☐ | Brucella | ☐ | Middle East respiratory syndrome coronavirus (MERS-CoV) |
| ☐ | *Orientia tsutsugamushi* | ☐ | Severe acute respiratory coronavirus 2 (SARS-CoV-2) |
| ☐ | *Pasteurella multocida* type B -"buffalo" and other virulent strains | ☐ | Japanese encephalitis virus except strain SA 14-14-2 |
| ☐ | *Rickettsia akari, R. australis, R. canada, R. conorii, R. rickettsii, R, siberica, R. typhi (R. mooseri)* | ☐ | Yellow fever virus |
| ☐ | Chikungunya virus except the vaccine strain 181/25 | ☐ | Human influenza A virus H2N2 (1957-1968) |
| ☐ | Semliki Forest virus | ☐ | Highly pathogenic avian influenza A virus H5Nx strains within the Goose/Guangdong/96-like H5 lineage (e.g., H5N1, H5N6, H5N8 etc.) |
| ☐ | Flexal virus | ☐ | Transmissible spongiform encephalopathy (TSE) agents (e.g., Creutzfeldt-Jacob disease and kuru agents) |
| ☐ | Lymphocytic choriomeningitis virus (LCM) (neurotropic strains) | | |

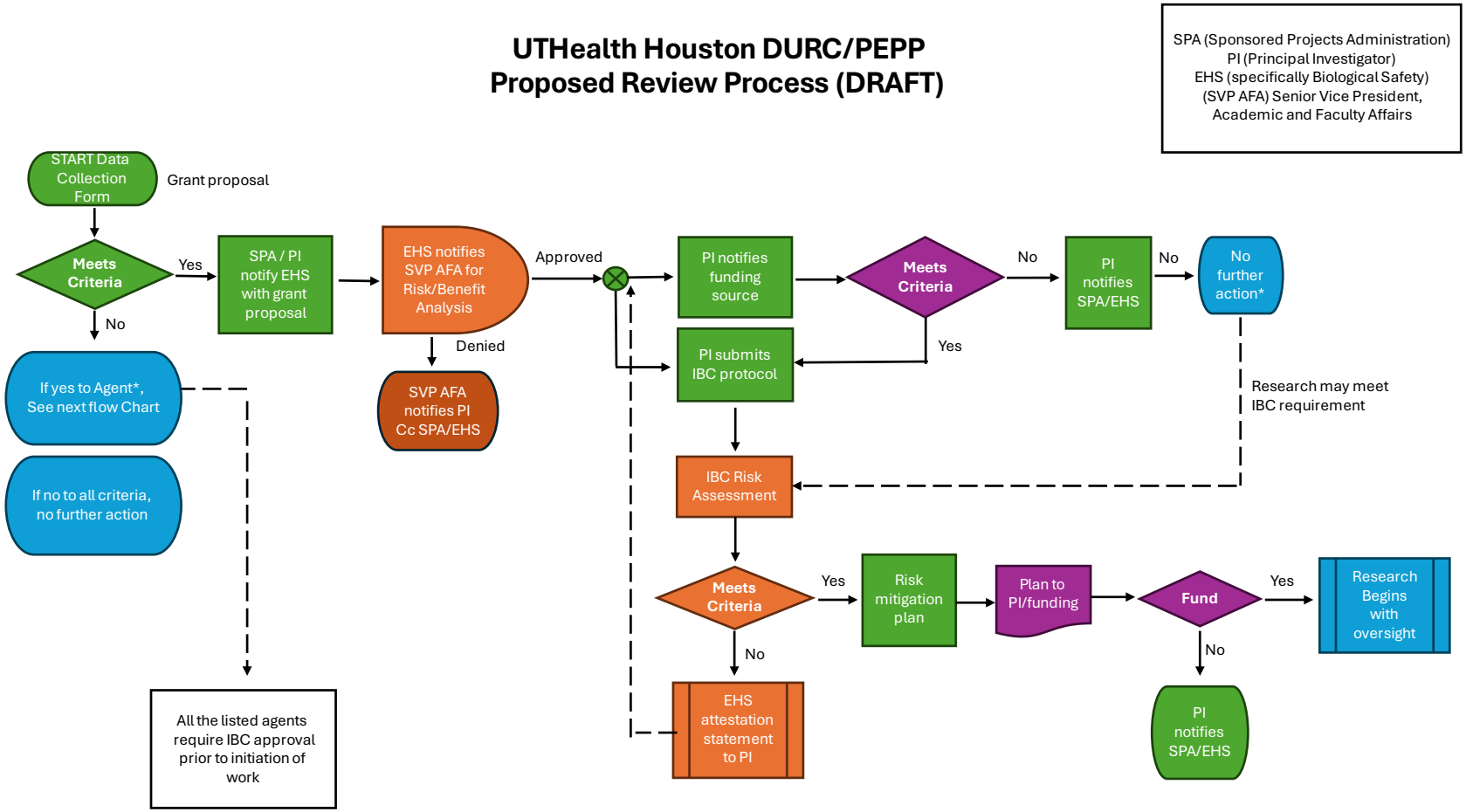
| Other | | | |
|---|---|---|---|
| ☐ | Any attenuated pathogen or vaccine strain that is currently excluded from the Select Agent Regulations that exhibits the recovery of virulence at or near the wild-type | ☐ | Mpox virus clade I/II chimeric viruses resulting from any deliberate manipulation of clade II to incorporate nucleic acids coding for clade I virulence factors |

Biological agents and toxins listed in this part of the list are controlled by Select Agent Regulations, please refer to the Select Agents and Toxins list for any relevant strain exclusions.

Please refer to the NIH Guidelines for any relevant strain exclusions

There is no exemption for research involving quantities of toxins that are otherwise excluded from oversight by the Select Agent Program.

**Appendix B:** UTHealth Houston DURC/PEPP Review Process



# UTHealth Houston DURC/PEPP
# Proposed Review Process (DRAFT)

SPA (Sponsored Projects Administration)
PI (Principal Investigator)
EHS (specifically Biological Safety)
(SVP AFA) Senior Vice President, Academic and Faculty Affairs