

<b>ENVIRONMENTAL HEALTH AND SAFETY</b>
<b>Title: Institutional Review Entity Charter</b>
<b>Document #: EHS-400-03</b>
<b>Version #: 02</b>
<b>Approved by EHS Date: 29Jan2026</b>

## **I. Purpose**

The existence of an Institutional Review Entity (IRE) is mandated by the U.S. Government (USG) Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC), Pathogens of Enhanced Pandemic Potential (PEPP) and Gain of Function (GOF). At the University of North Texas Health, the IRE is responsible for reviewing research that falls within the scope of this charter. The IRE provides institutional assurance to the Vice President for Research that UNT Health remains in compliance with the USG DURC, PEPP and GOF policies.

The IRE at UNT Health functions as a subset of the Institutional Biosafety Committee (IBC), excluding community members who are required for IBC membership. This structure ensures that DURC, PEPP and GOF oversight remains robust while aligning with existing institutional biosafety frameworks.

## **II. Scope**

This charter establishes the framework for institutional responsibilities, Principal Investigator (PI) obligations, and IRE requirements necessary to ensure compliance with the U.S. Government Policy for Oversight of DURC, PEPP and GOF. The overarching goal is to support the integrity of scientific research while protecting public health, agriculture, national security, and the environment.

## **III. Functions and Responsibilities**

### **a. Institutional Responsibilities**

The Institution is responsible to:

- i. Ensure that an Institutional Review Entity (IRE) is established at UNT Health to establish a comprehensive oversight of DURC, PEPP and GOF research

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- activities. The UNT Health Institutional Biosafety Committee, excluding community members, will serve as the IRE.
- ii. Ensure that all appropriate IRE members are appointed by the Vice President of Research for an annual term renewed each September.
  - iii. Ensure that all PIs and research members are appropriately informed and trained on the DURC, PEPP, and GOF research regulations.
  - iv. Designate the Biosafety Officer as the Institutional Contact for Dual Use Research (ICDUR) to act as an internal resource for monitoring and compliance with the USG Policy and the liaison (as necessary) with the federal funding agency.

The Office of Sponsored Projects is responsible to certify at the time of seeking funding that the institution fully follows the research oversight framework under the USG Policy.

### **b. Institutional Contact for Dual Use Research (ICDUR) Responsibilities**

The Institutional Contact for Dual Use Research (ICDUR) is responsible to:

- i. Serve as the institutional point of contact for questions regarding compliance with and implementation of the requirements of the DURC oversight policies.
- ii. Serve as the liaison between the institution and the relevant USG funding agency.
- iii. Consult with the relevant USG funding agency when the institution seeks advice on matters related to DURC.
- iv. Provide, on an annual basis, formal assurance to the relevant federal funding agencies that the institution is operating consistent with the USG Policy.
- v. Make relevant information available to local authorities on Category 1 and Category 2 research, as appropriate.
- vi. Conduct regular reviews of active Risk Mitigation Plans (RMP) to ensure compliance with protocols and address changes in research scope or risks.
- vii. Communicate findings and progress to relevant federal agencies as required.

### **c. Institutional Review Entity (IRE) Responsibilities**

The Institutional Review Entity (IRE) is responsible to:

- i. Ensure protocols comply with U.S. Government Policy and institutional biosafety standards.
- ii. Review research identified by the principal investigator (PI) or brought forth by the IBC.

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- iii. Review the PI's assessment and make final determination as to whether the research meets any of the definitions of DURC, PEPP or GOF as defined by the regulations.
- iv. Evaluate research proposals submitted to the IRE to identify DURC risks and classify projects as Category 1 or 2 as defined in the regulations.
- v. Review the PI's risk assessment of the project and determine if the research can be safely conducted at UNT Health.
- vi. Establish and maintain policies to evaluate, monitor, and mitigate risks associated with DURC and PEPP research.
- vii. Collaborate with PIs to develop RMPs and oversee federal approval processes.
- viii. Review the risk mitigation plan at least annually and modify the plan as needed.
- ix. Maintain records of IRE reviews and completed RMPs for the term of the research grant, contract, cooperative agreement, or other agreement or transaction, plus three (3) years after its completion.
- x. Report findings and recommendations to the institution and federal oversight bodies as necessary.
  - a. Instances of failure to follow USG Policy will be submitted to the relevant agency within 30 days of the research institution becoming aware or being notified of an occurrence.
- xi. Approve RMPs and ensure they are submitted to the appropriate federal funding agencies and approved before research begins.
- xii. Ensure that biological agents or toxins from Category 1 or Category 2 research are properly accounted for and destroyed when no longer needed.
- xiii. Conduct periodic reviews of ongoing DURC/PEPP research to ensure alignment with approved RMPs and the evolving U.S. Government Policy.

### **d. Principal Investigator Responsibilities**

The Principal Investigator is responsible to:

- i. Assess research at the proposal stage, and continuously throughout the research life cycle to determine if research involves Category 1 or 2 agents or anticipated outcomes of concern.
- ii. Notify the ICDUR immediately if relevant research is identified, or if the PI believes the project should undergo IRE review.
- iii. Submit research project protocol to the IRE prior to commencing work.
- iv. Work closely with the IRE to evaluate risks, develop RMPs and a risk benefit assessment.
- v. Complete all required documentation for submission to the IRE and granting agency.

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- vi. Submit the draft RMP and risk benefits assessment to the federal funding agency for review and approval following scientific merit review.
- vii. Ensure that RMPs receive federal approval before initiating research.
- viii. Follow all approved protocols and RMPs, maintaining strict compliance with biosafety and biosecurity standards.
- ix. Submit amendments to oversight bodies for changes in research scope or identification of new risks.
- x. Provide updates on research progress and compliance with RMPs to institutional and federal oversight bodies for review, evaluation, assessment and, where necessary, clarification or confirmation.
  - a. Annually for Category 1 research
  - b. Semi-annually for Category 2 research.
  - c. As requested by the federal funding agency
- xi. Maintain thorough records of training, assessments, and research activities for periodic review.
- xii. Ensure that all staff are trained and understand the regulations as they apply to DURC, PEPP, and GOF.

### **IV. Collaboration between the IRE and IBC**

The IBC, IRE and PIs must work to:

- i. Ensure comprehensive evaluation and oversight of all DURC/PEPP research.
- ii. Maintain consistent communication to streamline compliance processes.
- iii. Foster a culture of responsible research and mitigate risks effectively.

### **V. Membership**

The IRE is composed of no fewer than five members with knowledge of US government policies and sufficient range of expertise in Biosafety, Biosecurity, DURC, PEPP and GOF conducted at UNT Health.

The IRE may use additional ad hoc members to execute its responsibilities or acquire needed expertise for review of research.

#### **a. Composition**

- a. The IRE is a subset of the Institutional Biosafety Committee (IBC) minus the community members (which are required for the IBC).
- b. The IRE Chair shall be the IBC Chair.
- c. The IRE Vice-Chair shall be the IBC Vice-Chair.
- d. The ICDUR is a permanent member appointed by the Vice President of Research and is the biosafety officer.

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- e. The Research Compliance director is a permanent non-voting member appointed by the Vice President of Research.

### **VI. Procedure**

For research that is determined to be DURC, PEPP or GOF, the IRE will:

- ii. Conduct in-depth reviews of proposed research to identify any experimental outcomes of concern.
- iii. Consider the risks and benefits of conducting the research.
- iv. Work with the appropriate federal funding agency to develop a risk mitigation plan.
- v. Review the risk mitigation plan at least annually and modify the plan as needed.
- vi. Communicate with the appropriate Federal review board for approval of the project.
- vii. When a PI makes an initial assessment that research may constitute Category 1 or Category 2 research, the IRE will assess if research activities involve Category 1 or 2 biological agents or toxins and evaluate potential risks.
  - a. Within 30 calendar days of institutional review, the IRE will notify the federal funding agency of any research with scope, including whether it meets or does not meet the definition of Category 1 or Category 2 research.
- viii. Approve RMPs and ensure they are submitted to the appropriate federal funding agencies and approved before research begins.
  - a. Within 90 calendar days from the time that the IRE determines research to be within the scope of Category 1 or Category 2, ensure the RMP is submitted to the federal funding agency for review.

#### **a. Appeal procedure**

PIs can appeal institutional decisions regarding research that is determined by the IRE to meet the definition of Category 1 or Category 2 research by contacting the ICDUR and providing a written rationale for their appeal. Appeals will be subsequently heard and assessed by the IRE within a time frame that permits the institution to meet reporting timelines. If no resolution can be met the Vice President of Research (VPR) will be notified to provide a final decision.

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### **b. Meetings**

The meeting format should facilitate the taking of minutes. The meetings are not open to the public and meeting minutes are not required to be released for public review. The review process for research subject to the policy may be released per request.

The IRE will conduct meetings as needed for the conduct of business. The IRE meeting will run sequentially with the IBC meeting. A proposed agenda will be developed and distributed before each meeting. Meetings will proceed and official business will be conducted only when a quorum, defined as more than half of the members, is present. All research subject to DURC, PEPP, GOF regulations must be reviewed at a convened meeting of the IRE with a quorum present. Meeting minutes will be taken to accurately reflect the topics of discussion. Minutes will be reviewed, approved by the members and maintained on file.

### **c. Conflicts of Interest**

No member of the IRE may review a project with the following conflicts:

- i. They are listed as a PI, Co-PI or staff on a protocol
- ii. Institutional conflict of interest
- iii. Conflicts of commitment
- iv. Individual conflicts
  - a. Financial
  - b. Competing

### **d. Failure to Follow the Research Oversight Framework**

For PIs and research institutions, failure to follow the research oversight framework under this Policy may result in suspension, limitation, or termination of federal funding and loss of future federal funding opportunities for the research proposal and for other life sciences research at the research institution, as imposed by the federal funding agency. Federal funding agencies will consider relevant statutory and regulatory authorities when considering appropriate actions.

## **VII. References**

- United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential- May2024, <https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf>

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- Implementation Guidance for the United States Government Policy for Oversight of 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>

### **VIII. IRE Charter Approval**

IRE members will review the IRE charter yearly, or when regulatory changes occur.

### **IX. Reference document**

IBC Charter/Principal Investigator's Guide to IBC- EHS400-02

### **X. Version revisions**

Approved August 20, 2025

Revised 29 January 2026 renumbered document