



**To:** All Faculty and Staff Subscribed to the ERA Listserv

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**Subject:** New DURC Policy

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Dear Colleagues,

The United States Office of Science and Technology Policy (OSTP) issued the [Policy for Oversight of Dual Use Research of Concern \(DURC\) and Pathogens with Enhanced Pandemic Potential \(PEPP\)](#) in May 2024. This document supersedes earlier policies on DURC and applies to research from the proposal stage through funding, experimental activities, and publication. The Policy mandates a unified federal oversight framework for conducting and managing life sciences research on biological agents and toxins that, when enhanced, have potential risk to public health, agriculture, food security, economic security, or national security.

NIH's implementation of this policy **goes into effect May 6, 2025**, and imposes key requirements and responsibilities on researchers and recipient institutions.

To meet these requirements and facilitate compliance, Temple University has developed the following procedures and tools, posted at the [OVPR research compliance website](#):

### **Temple University Guidance**

The [Temple University Guidance on Institutional Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential](#) document includes definitions, investigator responsibilities, and review procedures applicable to all

projects involving life sciences research, regardless of the funding source, that are conducted at Temple University (TU) or one of its affiliated subcontracting institutions.

- Research which falls under this Guidance is divided into two categories: Category 1 (DURC) or/and Category 2 (PEPP) and it is the responsibility of the PI to make the initial assessment as to whether proposed or ongoing life science research may meet the definition of DURC or PEPP, regardless of the source of funding. The "[PI Self-Assessment Form for DURC Determination](#)" is available to aid in this decision.
- A new question had been added to the electronic sponsored project administrative form (eSPAF) to determine if the grant proposal falls under the category of "Life Sciences." If applicable, the PI is responsible for completing and uploading this form in the eSPAF for further reference. The PI must also notify the federal funding agency about this determination.
- If the funding agency is considering funding the proposal it will then contact Temple University and the PI to request the required information consistent with the procedures in the new federal Policy for assessing Category 1 or Category 2 research.
- The Institutional Review Entity (IRE) for DURC at TU will review the PI's initial research category determination, and the funding agency will be advised of its decision.
- Next, if the project is Category 1 or Category 2, the PI develops and submits to the IRE the Risk-Benefit Assessment and Risk Management Plan for review. After IRE review and approval, both documents must be submitted to the funding agency for the final evaluation.
- If identification of potential Category 1 or Category 2 work occurs during the course of experimentation (e.g., new agents and/or experiments are added to the protocol), the PI must halt further work, notify the federal funding agency, and contact the IRE (at [ire1@temple.edu](mailto:ire1@temple.edu)) to conduct the required assessments as noted above.
- Category 1 projects must be reviewed annually; Category 2 projects must be reviewed semiannually.

### **Required Training**

All researchers working with DURC/PEPP materials and IRE members must complete specific training prior to IRE review and approval.

However, we encourage all investigators who currently hold active IBC protocols to complete the training as soon as possible to prepare for upcoming policy changes. Temple University has adopted the CITI "Dual Use Research of Concern (DURC) Training" and PIs are responsible for confirming and verifying all research team members have completed this training.

The training can be completed at [citiprogram.org](https://citiprogram.org). You will have to log in to your CITI Program account and select "Add a Course" under the "My Courses" tab. If you do not have a CITI Program account, click on the "Register" button and follow directions to create your account with Temple University. After that, you will have access to all the courses offered by TU and the option to add and complete the "DURC Training."

### **Upcoming Information Sessions**

OVPR Research Compliance would like to invite all investigators to attend one of the Zoom presentations related to the new DURC/PEPP federal requirements offered on:

- [Thursday, April 24 at 10:30 a.m.](#)
- [Tuesday, April 29 at 10 a.m.](#)
- [Thursday, May 1 at 2:30 p.m.](#)

Please register for your preferred session by clicking the date above.

### **Contact Us**

If you have any questions or concerns regarding new DURC regulations, please contact us at [ire1@temple.edu](mailto:ire1@temple.edu).