Institutional Discussion on OSTP's Recent Report on DURC – Implications & Implementation

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Speakers









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Presentation Overview

• What's New?: May 2024, U.S. Gov. Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) and Implementation Guidance

• What Changed? Comparison with Current Process for Reviewing **DURC and Enhanced Potential Pandemic Pathogens**

Institutional Concerns Regarding Implementation of the New Policy



U.S. Gov. Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential and Implementation Guidance

• History: RFI about potential changes in Oct 2023; COGR submitted comments.

New Policy:

- **Purpose:** Establish unified federal oversight framework for federally funded research on biological agents & toxins that pose risks to public health or national security
- Supersedes 2012 Policy for Oversight of Life Sciences DURC, 2014 U.S. Government Policy for Institutional Oversight of DURC, and the 2017 Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)
- Complements existing federal regulation, including Select Agent regulations
- Effective date May 6, 2025. Federal agencies must change current policies and guidance to conform by this effective date.



Current vs. New DURC Review Process

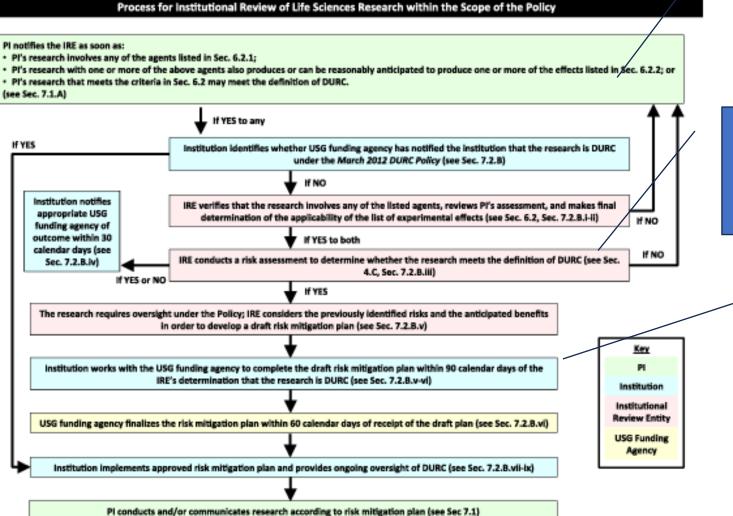
- CURRENT PROCESS HAS MUCH SMALLER SCOPE OF REVIEW
- Current DURC Review Process U.S. Gov. Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
 - SCOPE: Current policy limited to life sciences research that involves 15 named agents and toxins and 7 categories of experiments
- New Policy Scope:
 - DURC research is referred to as Category 1 Research
 - Covers much broader categories of agents and 9 categories of experiments



Current P3CO v. New PEPP Review Process

- CURRENT PROCESS HAS MUCH SMALLER SCOPE OF REVIEW THAN NEW **PROCESS**
- Current P3CO Review Process: Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)
 - SCOPE: Current policy limited to potential pandemic pathogen (PPP) that (a) is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and (b) is likely highly virulent and likely to cause significant morbidity and/or mortality in humans
- New Policy Scope: Any pathogen modified in a way that is "reasonably anticipated" to result in the development, use, or transfer of a PEPP. Includes development of new PPP, enhancement of existing PPP, and eradicated or extinct PPP that may pose significant threat to public health, health system capacity to function, or national security.

Figure 1 provides an overview of the process for institutional review of life sciences research within the scope of the Policy.



PI notifies ONLY the
Institutional Review Entity
(IRE) of possible DURC
research

IRE determines if research is DURC and if so, develops draft risk mitigation plan

Institution communicates with funding agency to finalize acceptable plan

Current DURC Review Process



PI communicates initial assessment to IRE and Agency ♦IRE makes assessment Figure 1. Overview of Review Process for Category 1 or Category 2 Research. Depicts the general workflow for review and assessment of of whether research is research under to the Policy involving PIs (green boxes), research institutions (peach boxes), federal funding agencies (blue boxes), and federal DURC or PEPP, and departments (gray box). federal agency then evaluates this assessment. Research Conduct Risk-Benefit Assessments and Departmental Review of PI Initial Federal Funding Institutional Review Entity and Ongoing Category 2 Research Risk Mitigation Plan Agency Notification Agency Verification ♦Appeals process Assessment and Risk Assessment Oversight Notification required for institutional IRE and PI develop and decisions re. research submit risk-benefit that IRE determines is assessments and risk mitigation plan for Category 1 Category 1 or 2. Does If Category 1 research to federal funding PI assesses whether federal agency have IRE assesses whether proposed or PI and research If considering research meets the Federal Federal department ongoing research ategory 1 research may not institution conduct and ultimate say on three-step criteria for funding may be within funding the begin or continue until federal oversee federally funded multidisciplinary review scope of Category 1 proposed research, Category 1 or agency category? What else can funding agency has approved research in accordance entity to evaluate the or Category 2 based federal funding Category 2 oversight. evaluates and risk mitigation plan. with approved risk be appealed? verifies research including riskon biological agent agency notifies mitigation plan and benefit assessments and or toxin and research institution Research institution research applicable regulations, notifies federal institution's risk mitigation plan and experiment, and if of PI initial policies, and guidelines. so, notifies federal funding agency of its assessment. makes recommendations to assessment inform federal funding funding agency and assessment. IRE. agency funding decisions. If Category 2 Additional federal Agency Category 2 research may IRE and PI develop and submit not begin or continue until departmental level communicates with risk-benefit assessments and federal funding agency has risk mitigation plan for PI and institution review required for approved risk mitigation Category 2 research for plan. department-level review PEPP research = 2 federal reviews If Research Does NOT Meet PI continually assesses research for any changes that may alter an assessment of whether research is Category 1 or Category 2. Category 1 or Category 2 Criteria All other relevant regulations, policies, and guidelines still apply. New DURC and PIs Federal funding agencies Research institutions Federal departments PFPP Review **Process**



Information on NIH Implementation

- May 2025 will be the implementation date for institutions not just the date for NIH to promulgate a policy.
- NIH anticipates increase in number of protocols requiring IRE review will increase from 100s to 1000s because of broader scope of agents and experiments that require review.
- NIH hopes to issue an RFI on its implementation process in the fall.
- NIH is unsure about if/how current amount thresholds for select agents/toxins will come into play under new process.
- NIH expects that there will be some flexibility in how flow charts in OSTP Policy are implemented.





Potential Institutional Concerns/Issues

- Confusing lines of communication communications with agencies were via institution and IRE; now PI is involved.
- Lack of clarity re. who is doing the risk assessment before this was clearly the IRE's job. Now federal agency is involved.
- What changes will be needed to the appeals process? 2014 policy required appeal process for institutional decisions re. research that IRE determines to be DURC v. 2024 policy requirement of institutional appeals process for decisions regarding research that IRE determines meets the definition of Category 1 or Category 2 research?
 - Will appeals be limited to categorization only? Or can other IRE requirements (e.g., risk plan requirements) be appealed?
 - How will the appeals process intersect with agency's categorization of research? Does the agency have the final say on categorization?
 - Will PIs force institutions to go to agencies whenever the PI disagrees with IRE determinations?
- Agencies could extend requirements to non-federally funded Category 1 and Category 2 research.
- Agencies could issue different requirements





Potential Institutional Concerns

- A much larger scope of research will require review there is a much more "open-ended" description of types of agents included in Categories 1 & 2. Do current review committees have the capacity to take on this responsibility?
- Need for additional clarification, assessment tools, and guidance to assist institution in determining what is Category 1 and Category 2 research.
- Increased review time
- Will additional burden cause institutions to withdraw from doing this type of research – particularly with respect to Category 2 research? Or will institutions become more liberal and let the federal agency be the "backstop"?







COGR Point of Contact

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Q & A







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Thank You

