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

June 6, 2024

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Speakers

Moderator:
Kris West
COGR *Director for REC*

Ara Tahmassian
Chief Research Compliance Officer
Harvard University

Stacy Pritt
Assoc. Vice Chancellor, Research & Chief Research Compliance Officer
Texas A&M University System

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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**

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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.

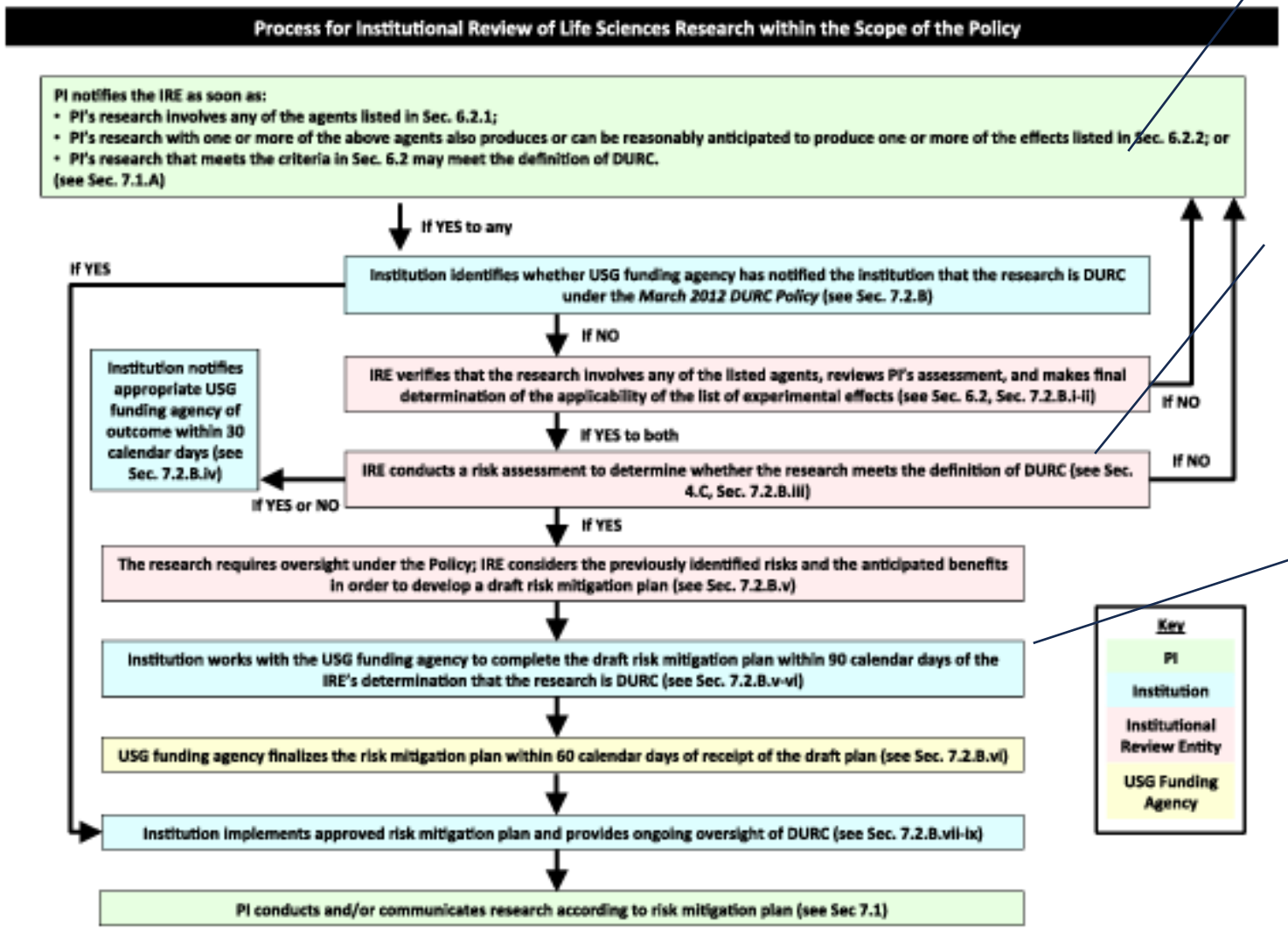
Current vs. New DURC Review Process

- **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

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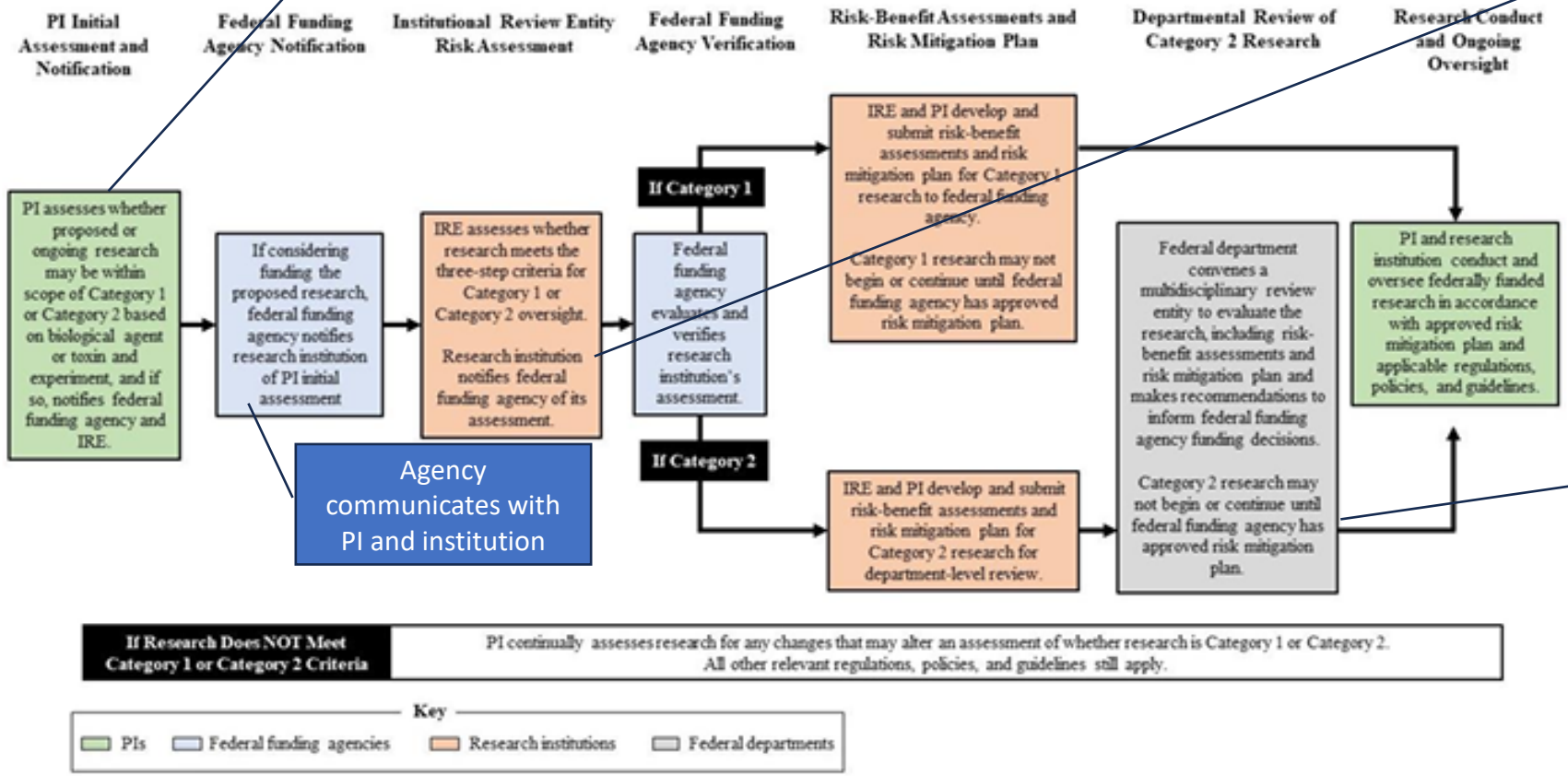
PI communicates initial assessment to IRE and Agency

Figure 1. Overview of Review Process for Category 1 or Category 2 Research. Depicts the general workflow for review and assessment of research under to the Policy involving PIs (green boxes), research institutions (peach boxes), federal funding agencies (blue boxes), and federal departments (gray box).



Agency communicates with PI and institution

♦IRE makes assessment of whether research is DURC or PEPP, and federal agency then evaluates this assessment.
♦Appeals process required for institutional decisions re. research that IRE determines is Category 1 or 2. Does federal agency have ultimate say on category? What else can be appealed?

Additional federal departmental level review required for PEPP research = 2 federal reviews

New DURC and PEPP Review Process

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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"?

#COGROct23

COGR Point of Contact

Kris West, Director, kwest@cogr.edu
Research Ethics & Compliance Committee

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Q & A

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