United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

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Agenda

- Definitions
- What's New
- What's Changed
- Implementation

Definitions

- **Dual Use Research of Concern (DURC)**
  - Life Sciences research that, based on current understanding, 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, animals, the environment, materiel, or national security.
- **Pathogen with Enhanced Pandemic Potential (PEPP)**
  - 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.
- **Institutional Review Entity (IRE)**
  - Committee responsible for executing institutional oversight responsibilities described in the USG Policy (e.g., risk-benefit assessment, risk mitigation plan, continued oversight)

What's New: USG Policy on DURC & PEPP (May 2024)

Acknowledges that research with biological agents and toxins is essential to scientific advancements that improve health and safety of the public, ag crops, animals, and the environment.

Establishes unified federal oversight framework for federally funded research on biological agents and toxins that, when enhanced, may pose risks to public health or national security.

Supersedes 2012, 2014, and 2015 policies on oversight of dual use research of concern and potential pandemic pathogens.

Complements existing federal regulation, including Select Agent regulations.

Effective date = May 6, 2025

What's Changed: USG Policy Scope

CURRENT POLICY (2014)

- Covers life sciences research with 15 named agents/toxins and 7 categories of research
- IRE required to assess whether research that uses one or more of the DURC Agents also produces, aims to produce, or is reasonably anticipated to produce one or more of the Experimental Effects of Concern.

NEW POLICY (2024)

- Divides research into two categories
- Category 1 covers ~90 agents and toxins (all SA/ST, RG4, and many RG3 agents) + nine (9) categories of experiments
- Category 2 involves or is reasonably anticipated to result in a PPP + four (4) experimental outcomes or actions

What's Changed: Process

- Everything starts with the PI
- When preparing proposal to federal funding agency, PI evaluates whether research may fall under Category 1 or Category 2
  - PI self-assessment tool will be available
  - Certification of institutional compliance required with proposal submission
- If FFA is considering funding, agency notifies UCLA, prompting IRE review
  - Research is considered within the scope of Category 1 or Category 2:
    - IRE performs risk-benefit assessment, develops draft risk mitigation plan (RMP)
    - FFA must review risk-benefit assessment and approve RMP
    - PI submits annual or semiannual progress reports to FFA (frequency based on Category)
  - Research not within the scope of Category 1 or 2 → inform FFA, PI monitor research for changes
- We are expected to oversee research that does not receive federal funding

Implementation

Effective Date: May 6, 2024

- UCOP revision to systemwide policy on Dual Use Research of Concern
- UCLA revision to Policy 995 (DURC)
- RPC website + CITI training updates
- Coordination with OCGA for institutional certification (EPASS updates?)
- PI education
- PI self-assessment form
- Updates to IBC online system SafetyNet
- Committee review combined with IBC process

Any Questions?

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