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

HIGHLIGHTS

Issued on May 6, 2024
Effective May 6, 2025

Supersedes

Dual Use Research of Concern (DURC Policy) 2012, 2014

Potential Pandemic Pathogen Care and Oversight (P3CO Framework) 2017

This Policy addresses oversight of research on **biological agents** and **toxins** that, when enhanced, have the potential to pose **risks** to **public health**, **agriculture**, **food security**, **economic security**, or **national security**.

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DEFINITIONS

Dual Use Research of Concern (**DURC**)
life sciences research that 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 pandemic potential (**PPP**) - Pathogen that is likely capable of wide and uncontrollable spread in a **human population** and would likely cause **moderate to severe disease** and/or **mortality** in humans.

Pathogen with enhanced pandemic potential (**PEPP**) - Type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility[10] 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. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

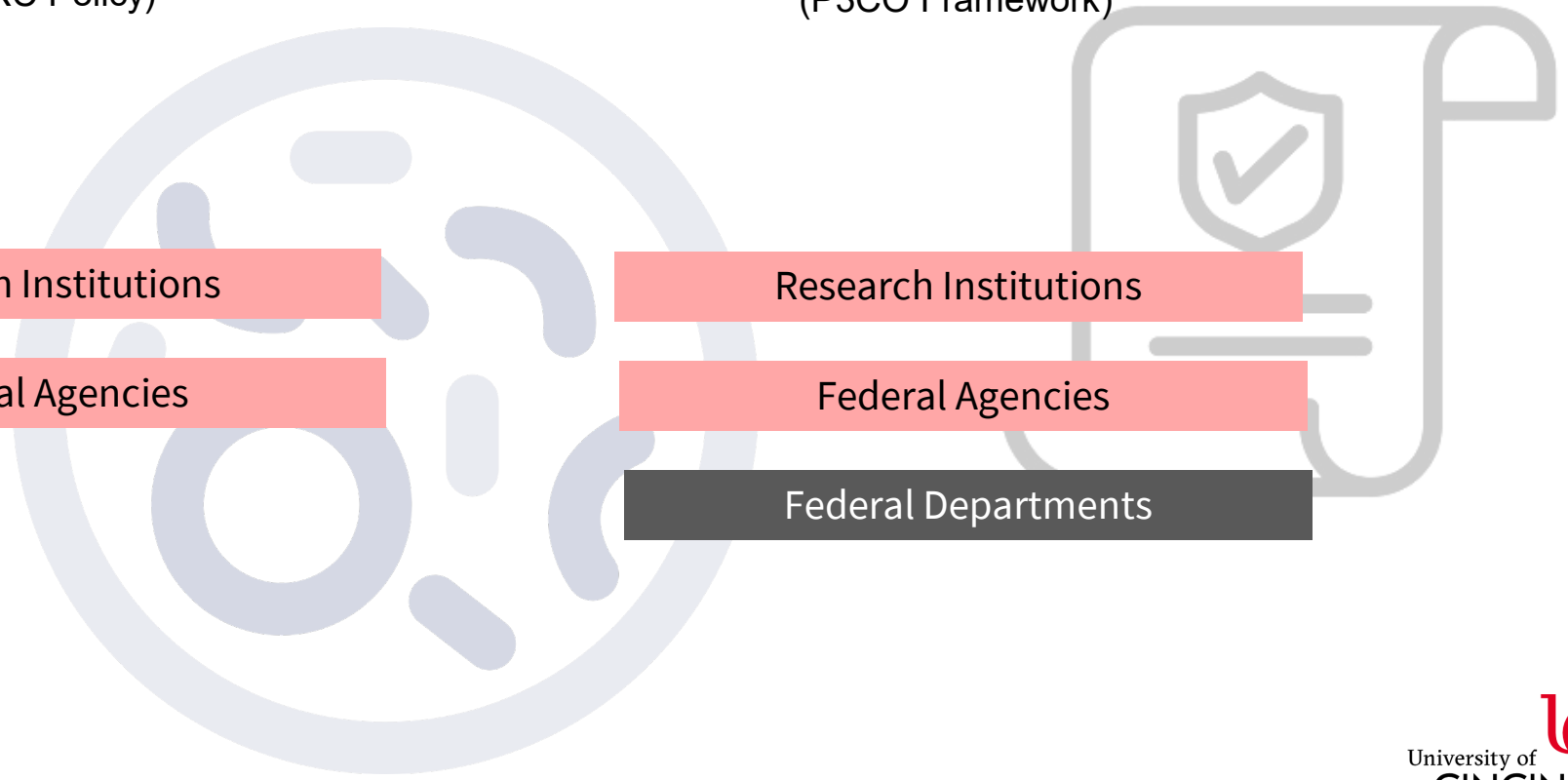
Institutional review entity (**IRE**) **-** Entity established by the research institution to execute the institutional oversight responsibilities.

Type of Research

Category 1	Category 2
(DURC Policy)	(P3CO Framework)

OVERSIGHT

Research Institutions	Research Institutions
Federal Agencies	Federal Agencies
	Federal Departments



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CATEGORY 1 Research

Agents

All Biological Select Agents and Toxins

All Risk Group 4 pathogens in Appendix B of the NIH Guidelines

A subset of **Risk Group 3** *pathogens in Appendix B of the NIH Guidelines

Agents **affecting humans** that are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) per the BMBL

Biological agents added during future updates to the Implementation Guidance

**all RG3 pathogens except HIV, HTLV, SIV, Mtb (including mycobacterium bovis), Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX virus virulence factors, vesicular stomatitis virus, Coccidioides immitis, C. posadasii, Histoplasma capsulatum, and H. capsulatum var. duboisii.*

Experiments

1. Increase transmissibility of a pathogen within or between host species;
2. Increase the virulence of a pathogen or convey virulence to a non-pathogen;
3. Increase the toxicity of a known toxin or produce a novel toxin;
4. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin;
5. Alter the host range or tropism of a pathogen or toxin;
6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; **or**
9. Enhance the susceptibility of a host population to a pathogen or toxin.

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CATEGORY 1 Research

Biological Toxins

Dual Use Research of Concern (DURC Policy) effective until 05/05/2025

→ Botulinum neurotoxin (any quantity)

Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential effective on 05/06/2025

→ **ALL** Select Agents and **Toxins** (9) – above exempt quantities

CATEGORY 2 Research

PPP Agents

no list of PPP agents

- Exhibit sustained human-to-human transmission
- Uncontrollable spread (lack of pre-existing immunity, environmental stability, respiratory transmission, no available vaccine/treatment)
- Likely cause moderate to severe disease and/or mortality in humans

SARS CoV-2 PPP in 2020, not PPP in 2024

When the starting agent is a **PPP** and the research is reasonably anticipated to result in one of the experimental outcomes to produce a **modified** pathogen that meets the definition of a **PEPP**.

When the starting agent is a **not a PPP** and the research is reasonably anticipated to result in one of the experimental outcomes to produce a modified pathogen that meets the definition of a **PEPP**.

When one transfers, generates, uses, or reconstitutes an **extinct or eradicated PPP**, **regardless of whether** the extinct or eradicated pathogen will **be enhanced** relative to its wild-type form.

Research Outside of Policy Scope

Research institutions are encouraged to be mindful that research outside of Category 1 and Category 2 articulated of this Policy may also benefit from the institutional and federal research oversight framework. However, any such expansion would not be subject to oversight requirements as articulated in this Policy.