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**.

University of CINCINNATI
BIOSAFETY OFFICE

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.

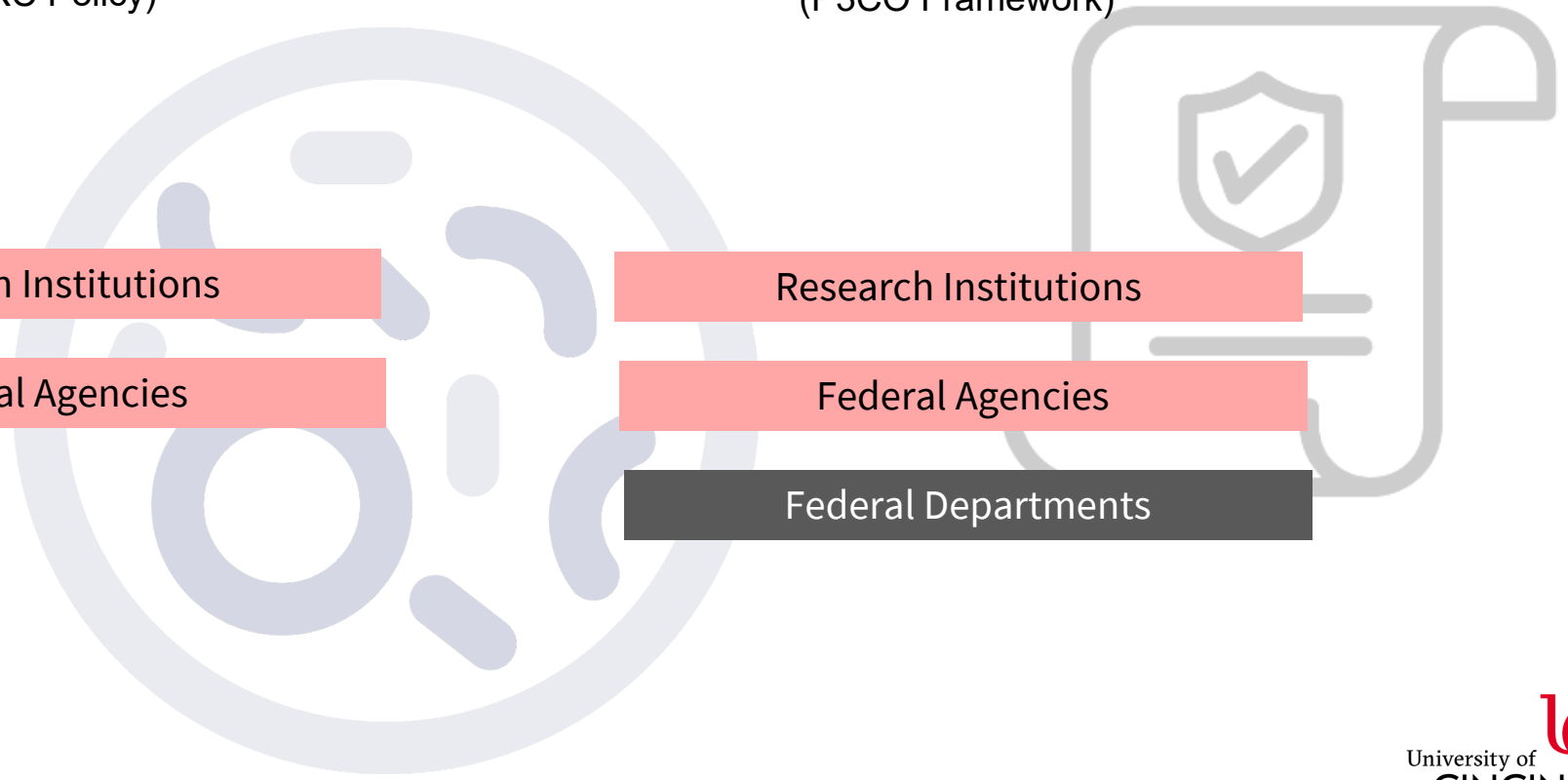
Institutional review entity (**IRE**) **-** Entity established by the research institution to execute the institutional oversight responsibilities.

Type of Research

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

OVERSIGHT

Research Institutions	Research Institutions
Federal Agencies	Federal Agencies
	Federal Departments



University of CINCINNATI
BIOSAFETY OFFICE

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.

CATEGORY 1 Research

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

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

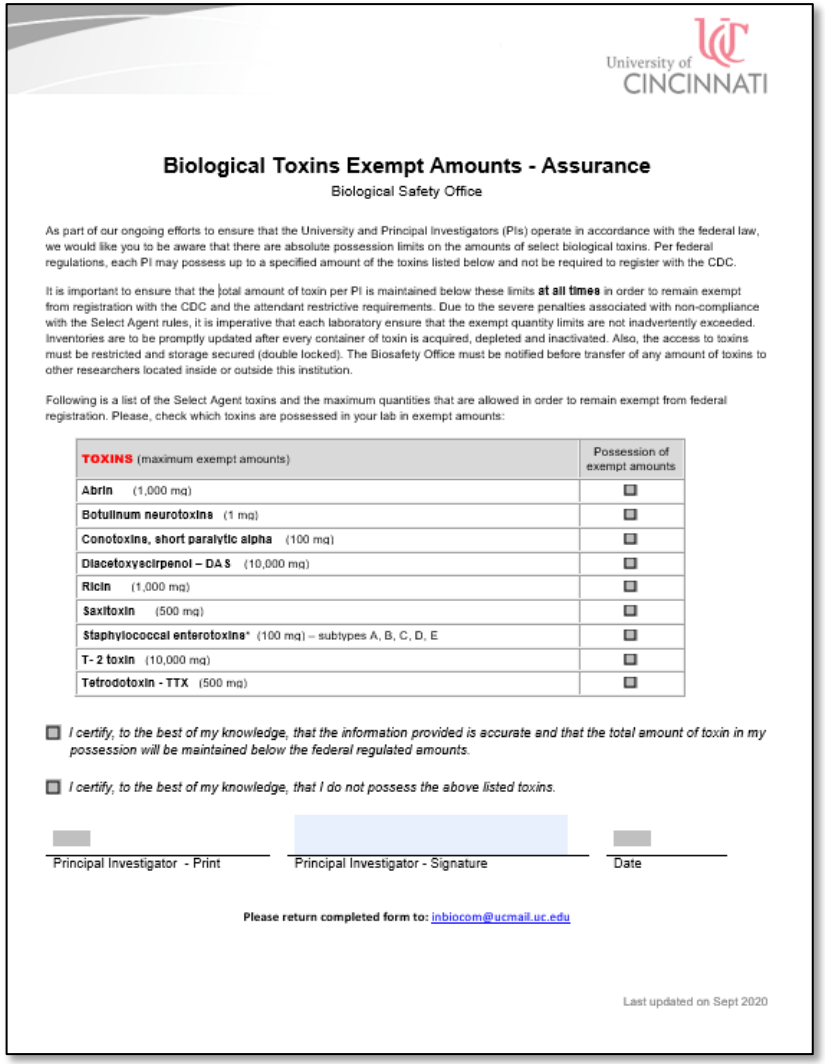
Biological Toxins

Botulinum neurotoxin (any quantity)

ALL Select Agents and **Toxins** (9) in **ANY QUANTITIES!!**

University of CINCINNATI
BIOSAFETY OFFICE

IMPACT at UC



University of CINCINNATI

Biological Toxins Exempt Amounts - Assurance

Biological Safety Office

As part of our ongoing efforts to ensure that the University and Principal Investigators (PIs) operate in accordance with the federal law, we would like you to be aware that there are absolute possession limits on the amounts of select biological toxins. Per federal regulations, each PI may possess up to a specified amount of the toxins listed below and not be required to register with the CDC.

It is important to ensure that the total amount of toxin per PI is maintained below these limits **at all times** in order to remain exempt from registration with the CDC and the attendant restrictive requirements. Due to the severe penalties associated with non-compliance with the Select Agent rules, it is imperative that each laboratory ensure that the exempt quantity limits are not inadvertently exceeded. Inventories are to be promptly updated after every container of toxin is acquired, depleted and inactivated. Also, the access to toxins must be restricted and storage secured (double locked). The Biosafety Office must be notified before transfer of any amount of toxins to other researchers located inside or outside this institution.

Following is a list of the Select Agent toxins and the maximum quantities that are allowed in order to remain exempt from federal registration. Please, check which toxins are possessed in your lab in exempt amounts:

TOXINS (maximum exempt amounts)	Possession of exempt amounts
Abrin (1,000 mg)	☐
Botulinum neurotoxins (1 mg)	☐
Conotoxins, short paralytic alpha (100 mg)	☐
Diacetoxyscirpenol – DAS (10,000 mg)	☐
Ricin (1,000 mg)	☐
Saxitoxin (500 mg)	☐
Staphylococcal enterotoxins* (100 mg) – subtypes A, B, C, D, E	☐
T- 2 toxin (10,000 mg)	☐
Tetrodotoxin - TTX (500 mg)	☐

☐ *I certify, to the best of my knowledge, that the information provided is accurate and that the total amount of toxin in my possession will be maintained below the federal regulated amounts.*

☐ *I certify, to the best of my knowledge, that I do not possess the above listed toxins.*

Principal Investigator - Print _____ Principal Investigator - Signature _____ Date _____

Please return completed form to: inbiocom@ucmail.uc.edu

Last updated on Sept 2020

TOXINS (maximum exempt amounts)	7 UC PIs total
Abrin (1,000 mg)	
Botulinum neurotoxins (1 mg)	1
Conotoxins, short paralytic alpha (100 mg)	
Diacetoxyscirpenol – DAS (10,000 mg)	
Ricin (1,000 mg)	
Saxitoxin (500 mg)	1
Staphylococcal enterotoxins* (100 mg) subtypes A, B, C, D, E	2
T-2 toxin (10,000 mg)	
Tetrodotoxin – TTX (500 mg)	5

University of CINCINNATI

BIOSAFETY OFFICE

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.