

IBC Policy Number:	101	Version Number:	1.0
Approval Date:	September 18, 2015	Effective Date:	September 24, 2015
Title:	Institutional Oversight of Dual Use Research of Concern (DURC)		

Purpose

The purpose of this Policy is to establish regular review of United States Government-funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) report to federal agencies.

Regulatory Background

The [United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern](#), March 2012, sets forth a process for Federal review of USG-funded or USG-conducted research and requires that those agencies that fund or sponsor life sciences research to identify DURC, to evaluate the research for possible risks, as well as benefits and to ensure that risks are appropriately managed and benefits realized.

All institutions that receive federal funding for any life sciences research and conduct research with the 15 agents and toxins listed below, regardless of funding source, must comply with the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#), effective September 24, 2015.

Scope

Research Subject to Oversight by the DURC Regulations:

All research conducted at the University involving the agents listed below is subject to this policy, regardless of the source of funding.

Agents and toxins of concern:

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (in any quantity)
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot and mouth disease virus
- *Francisella tularensis*
- Marburg Virus

- Reconstructed 1918 influenza virus
- Rinderpest virus
- Toxin producing strains of *Clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

If research with the agents and toxins listed above is anticipated to create any of the effects included within the following categories of concern, it may be considered DURC and will be subject to further review.

Categories of Experimental Effects

- Enhance the harmful consequences of the agent or toxin.
- Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confer to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies.
- Increase the stability, transmissibility or the ability to disseminate the agent or toxin
- Alter the host range or tropism of the agent or toxin.
- Enhance the susceptibility of a host population to the agent or toxin
- Generate or reconstitute an eradicated or extinct agent or toxin listed in the policy.

Responsibility

Institutional Biosafety Committee (IBC): Conducts initial review and refers all research involving agents and toxins of concern to the Ad-Hoc Institutional Review Entity (IRE), which is a sub-committee of the IBC.

Institutional Contact for Dual Use Research (ICDUR): individual designated by the University to be the institutional point of contact for questions relating to compliance with this Policy and to act as the liaison with the relevant USG funding agencies. The Director of Environmental Health and Safety will serve as the ICDUR.

Institutional Review Entity (IRE): An Ad-Hoc subcommittee of the IBC responsible for detailed review of research that may be considered DURC. The IRE reports to the IBC and the Dean for Research.

The IRE will include:

- Chair, IBC (also serves as Chair of the Ad-Hoc IRE)
- Biological Safety Officer

- Director, Environmental Health and Safety
- Director, RIA
- One or more IBC members with subject matter expertise, appointed on an ad-hoc basis by Chair of the IBC
- Faculty members with subject matter expertise, appointed on an ad-hoc basis by Chair of the IBC

Environmental Health and Safety: Administers and documents training and education required by this policy for the PI and all laboratory staff prior to initiation of research and every three years thereafter; conducts regular surveys to document compliance with risk mitigation plans approved by the Ad- Hoc IRE for research that falls under this policy.

Research Integrity and Assurance: Administers the IBC and Ad-Hoc IRE; compiles minutes of IRE deliberations

Principal Investigator

- Registers research with all pathogenic organisms, viruses, biological toxins and recombinant and synthetic nucleic acid molecules using the [IBC Registration Document for Biohazards and Recombinant/Synthetic Nucleic Acid Molecules](#).
- Identifies and refers to the IBC all research involving one or more of the agents or toxins listed in this Policy, along with an assessment of whether the research involves any of the seven experimental effects listed above.
- Participates in the development of risk mitigation plans for DURC. Complies with risk mitigation plans approved by U.S. funding agencies and the Ad-Hoc IRE.
- Participates, with lab staff, in DURC education and training upon initiation of research and every three years thereafter.

Policy

Process

1. PI notifies the IBC of research involving any of the 15 agents or toxins of concern.
2. The IBC will conduct an initial review of research involving any of the 15 agents or toxins to determine if the DURC policy applies.
3. Research involving any of the 15 agents or toxins will be referred to an Ad-Hoc IRE, to be established by the Chair of the IBC.
4. Review by the Ad-Hoc IRE
 - a. The Ad-Hoc IRE will convene and assess:

- The Principal Investigator’s assessment of whether the research produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects of concern.
 - Relevant information, such as the full grant proposal, project reports, similar research in the literature
- b. As needed, ICDUR will consult with the U.S. funding agency.
- c. If the IRE determines that the research **does not** meet the definition of DURC:
- The IRE Chair will notify the Principal Investigator promptly.
 - The ICDUR will notify:
 - Director, Office of Research and Project Administration(ORPA)
 - U.S. Funding Agency in writing, within 30 days of the determination.
For research that is not funded by the U. S. Government, the ICDUR will notify the National Institutes of Health (NIH) Program on Biosecurity and Biosafety Policy.
 - The IRE Chair informs the IBC at next scheduled Committee meeting.
- d. If the IRE determines that the research **does** meet the definition of DURC:
- The IRE Chair will notify the Principal Investigator promptly.
 - The ICDUR will notify:
 - Director of ORPA
 - U.S. Funding Agency or NIH within 30 days.
 - The IRE will identify the risks associated with the potential misuse of the outcome of the research. [The Dual Use Research of Concern Companion Guide](#), particularly section C, provides a helpful framework for review of the research.
 - Request the PI to submit a Draft Risk Mitigation Plan for review and approval. The plan will include the following strategies:
 - Elimination of certain aspects of the research
 - Increasing biosafety levels and biosecurity
 - Medical countermeasures
 - Methods for responsible communication of the research findings
 - Education and training of staff
 - Development of a monitoring plan
 - After review and approval by the IRE, the ICDUR submits the risk mitigation plan to the appropriate U. S. funding agency or the NIH within 90 days of the determination that the research is considered DURC.

- Upon receipt of approval from the U.S. funding agency or NIH, the IRE will notify the Dean for Research. The research may proceed only upon receipt of approved risk mitigation plans and approval by the IBC.
- The IRE will review risk mitigation plans on an annual basis.

References

Princeton University Institutional Biosafety Committee Charter, 2015

Tools for the Identification, Assessment, Management and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern.

<http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>

United States Government Policy for Institutional Oversight of Life Sciences Dual Research of Concern. <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern. <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>

Version History

Version Number	Revision Date	Revisions
1.0	September 16, 2015	Initiation.

Agents and Toxins of Concern:

- Avian influenza virus (high path)
- *Bacillus anthracis*
- Botulinum neurotoxin (in any quantity)
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot and mouth disease virus
- *Francisella tularensis*
- Marburg Virus
- Reconstructed 1918 influenza virus
- Rinderpest virus
- Toxin producing strains of *Clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

Dual Use Research of Concern (DURC) Review Process

Review process begins when a PI registers research with a DURC agent or toxin on an [IBC Registration Document for Biohazards and Recombinant/Synthetic Nucleic Acid Molecules](#).

Ad-Hoc Institutional Review Entity (IRE) is convened by IBC Chair and Dean for Research.

Ad- Hoc IRE meets with PI, reviews pertinent documents and literature and determines if proposed research involves any of the 7 experimental effects of concern.

7 Experimental Effects of Concern:

- Enhances the harmful consequences of the agent or toxin.
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies.
- Increases the stability, transmissibility or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin.
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin listed in the policy.

NO
YES

Ad-Hoc IRE findings are documented and sent to PI, Dean for Research and the U.S. Funding Agency within 30 days.

NO

Ad-Hoc IRE conducts risk assessment to determine if research is DURC.

YES

Recommendations of Ad- Hoc IRE are presented to full IBC at next scheduled meeting.

PI works with Ad-Hoc IRE to develop a draft risk mitigation plan, which is sent to appropriate U.S. funding agency for approval within 90 days of determination that research is considered DURC.

Research may begin only upon receipt of approved risk mitigation plans from U.S. funding agency. EHS administers training for lab staff. Ad-Hoc IRE schedules annual assessment of the mitigation plans.