Institutional Biosafety Committee (IBC)
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IBC Policy – Oversight of Life Sciences Dual Use Research of Concern

Policy Statement and Purpose
As outlined in OHSU Policy 04-06-001, the OHSU Institutional Biosafety Committee (IBC) is the designated institutional review entity for the identification, assessment and mitigation of risk, and reporting relating to the conduct of life sciences dual use research of concern (DURC).

This policy establishes procedures by which DURC is identified and reviewed by the IBC as defined by the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

I. Identification of Dual Use Research of Concern

DURC is defined as research that based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel[1] or national security.

Research that is to be identified, assessed and managed as DURC by the IBC involves one of 15 agents or toxins *and* involves one of the seven categories of experiments that are listed below:

Agents and toxins*

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin
4. *Burkolderia mallei*
5. *Burkolderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

*The DURC policy follows the Federal Select Agent Program exclusion criteria, with the exception of Botulinum neurotoxin. Research involving any amount of botulinum neurotoxin is subject to this policy.

Categories of experiments

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity of the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
3. 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
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alters the host range or tropism of the agent or toxin
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above

II. Responsibilities

A. Principal Investigators

The PI is to inform the IBC if they plan to conduct research involving one of the agents listed above in Section I. The PI is to include an assessment of whether the research involving these agents is reasonably anticipated to fall into one of the seven categories of research. Research may not begin until the IBC approval is received and determination under this policy is complete.

For ongoing research involving one of these agents, the PI must also immediately notify the IBC should their research aims change such that a new assessment of DURC is needed.

B. Institutional Review Entity

The Institutional Biosafety Committee (IBC) will serve as the Institutional Review Entity for all research involving one of the 15 listed agents and the PI's assessment of whether the research constitutes DURC.

When performing DURC assessments, this activity of the IBC will be treated as a separate and distinct meeting for this purpose. Minutes will remain separate and are not subject to public accessibility requirements outlined by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

IV. Risk Assessment and Mitigation

Should the research meet the definition of DURC, the IBC will coordinate with the PI to assess the risk associated with the project and develop a risk mitigation plan as needed. The mitigation plan may address, but is not limited to:

- Modification of design or conduct of research
- Application of specific or enhanced biosecurity or biosafety measures
- Evaluation of currently available therapeutics and their continued efficacy in the context of the DURC research
- Additional education or training for research personnel
- Continued review of emerging research findings
- Determining if there are restrictions on dissemination of findings

V. Federal Reporting Requirements

A. Initial Notification

Within 30 days of the IBC review of research that involves one of the 15 listed agents that is determined to fall under one or more of the experimental categories listed in Section I above, the IBC will submit an initial notification of review to either the Federal funding agency or to NIH Program on Biosecurity and Biosafety Policy, as appropriate. The initial notification of DURC review is to include:

- The grant or contract number, if the research is funded by a Federal agency.
- The names of the principal investigators on the grant.
- Identify which of the 15 agents are used in the research and provide of description of why the research is deemed to fit in one of the seven categories of experimental effects, as defined in Section I.

- Whether or not the IBC deems the research to meet the definition of DURC.

B. Submission of Risk Mitigation Plan

For research determined to qualify as DURC, within 90 calendar days from the IBC determination, the IBC will submit a copy of a draft risk mitigation plan to the federal funding agency or to the NIH Program on Biosecurity and Biosafety Policy, as appropriate.

VI. Training Requirements

All researchers conducting research or receiving funding supporting research that involves an agent on the list are to complete DURC training in the manner specified by the IBC.

VII. References

- National Science Advisory Board for Biosecurity (NSABB)
- United States Government Policy for Institutional Oversight of Life Sciences Dual Use research of Concern
- Federal Select Agent Program, Select Agents and Toxins Exclusions
- U.S. Government Science, Safety, Security (S3) website

VIII. Footnotes

1. Materiel includes food, water, equipment, supplies, or materials of any kind