INSTITUTIONAL REVIEW ENTITY STANDARD OPERATING PROCEDURE		
SOP Title: Institutional Review of Life Sciences Research for Dual Use Potential		
SOP Number: IRE-PP-001	Revision Number: 0	Section: Biosecurity
Author: Patricia Cox		Effective Date: 9/24/2015

1. Purpose

1.1. This procedure refers to IRE reviews only.

1.2. The purpose of this procedure is to describe the process for institutional review of life sciences research for dual use potential.

2. Definitions

2.1. DUR: Dual use research is research conducted for legitimate purposes that generates knowledge, information, technologies and/or products that can be utilized both for benevolent and harmful purposes.

2.2. DURC: Dual use research of concern is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, technologies and/or products 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, material or national security.

2.3. IRE: Institutional Review Entity

2.4. PI: Principal Investigator

2.5. ICDUR: Institutional Contact for Dual Use Research

2.6. USG: United States Government

2.7. IBC: Institutional Biosafety Committee

3. Responsibilities

3.1. PI

3.1.1.1. Notifies the IRE if research will involve one or more of the listed agents or toxins;

3.1.1.2. Notifies the IRE if the material from 3.1.1 can be reasonably anticipated to produce one or more of the listed experimental categories.

3.1.1.3. Works with the IRE to assess the risks and benefits of the DURC and to develop risk mitigation measures;

3.1.1.4. Conducts DURC in accordance with the risk mitigation plan.

3.2. ICDUR

3.2.1.1. Serves as the institutional point of contact for questions about compliance with and implementation of the DURC oversight policies;

3.2.1.2. Serves as the liaison between the institution and the relevant USG funding agency;

3.2.1.3. Consults with the relevant USG funding agency when the institution seeks advice on matters related to DURC.

3.2.1.4. Maintains all records related to the IRE and institutional oversight process.

3.2.1.5. Provides training for IRE members, PIs and research personnel.

3.3. IRE

3.3.1.1. Reviews potential DURC identified by the PI by:

3.3.1.1.1. Verifying that the research involves one or more of the 15 listed agents;

3.3.1.1.2. Reviewing the PI's assessment and determination of one of the listed experimental categories;

3.3.1.1.3. Making the determination as to whether the research meets the definition of DURC.

3.3.1.2. If the research is determined to be DURC, the IRE will:

3.3.1.2.1. Consider the risks and benefits of the research;

3.3.1.2.2. Work with the USG funding agency to develop a risk mitigation plan;

3.3.1.2.3. Review the risk mitigation plan at least annually and modify the plan as needed.

3.4. IRE Chair

3.4.1.1. Manages the IRE.

4. Items Needed

4.1. List of current agents and toxins covered by the USG *DURC Policy*

4.2. List of the categories of experiments covered by the USG *DURC Policy*

4.3. PI Notification form

4.4. IRE DURC Assessment form

4.5. Federal reporting form

5. Procedure

5.1. The PI identifies research that involves any of the USG DURC Policy agents/toxins and experimental categories (if applicable) using the PI Notification form.

5.2. The IRE will review the information to include an assessment to determine if the research is DURC. The review includes:

5.2.1.1. Verification that the research identified by the PI uses one or more of the listed agents/toxins;

5.2.1.2. Review of the PI's assessment as to whether the research produces one or more of the effects listed under experimental categories

5.2.1.3. A final determination as to whether the research is DURC.

5.2.1.4. If it is not DURC, the ICDUR will notify the PI that the research does not fall under DURC and is not subject to additional DURC review or oversight.

5.2.1.5. If the research is determined to be DURC, the IRE will

5.2.1.5.1. Conduct a risk vs. benefit analysis;

5.2.1.5.2. Develop a draft risk mitigation plan in cooperation with the PI and USG funding agency.

5.2.1.6. The USG funding agency finalizes and approves the risk mitigation plan

5.2.1.6.1. Research cannot be conducted until an approved risk mitigation plan is in place.

5.3. The IRE will review all active risk mitigation plans at least annually.

5.3.1.1. Plans should be modified as needed.

5.4. Notification

5.4.1.1. **Within 30 calendar days** of the institutional review of the research for DURC potential, the ICDUR will notify the appropriate USG funding agency of the institutional review findings.

5.4.1.2. For non-USG funded institutional research, notification is made to the NIH.

5.4.1.3. The initial notification contains the following information:

5.4.1.3.1. Grant/contract number

5.4.1.3.2. The name of the PI

5.4.1.3.3. The name(s) of the agent/toxin

5.4.1.3.4. A description as to whether and why the research is deemed to produce one or more of the listed experimental effects.

5.4.1.3.5. For research that is deemed to be DURC, the following additional information should be included:

5.4.1.3.5.1. The name of the investigator (if different from PI) responsible for the performance of the DURC

5.4.1.3.5.2. IRE's basis for DURC determination.

5.4.1.4. **Within 90 calendar days** of an IREs' determination that the research is DURC, the draft mitigation plan must be submitted to the USG funding agency for final review and approval.

5.4.1.4.1. The USG funding agency must provide an initial response within 30 calendar days and should finalize the plan within 60 calendar days of receipt of the draft plan.

5.4.1.5. Notification within 30 calendar days to the USG funding agency or NIH-designated funding agency should be made when:

5.4.1.5.1. Any change in the status of a DURC project including whether the research is determined by the IRE to no longer meet the definition of DURC

5.4.1.5.2. Details of any changes to the risk mitigation plan (such changes need to be approved by the funding agency)

6. Associated SOPs

6.1. IRE Policy Statement on DURC

6.2. IRE Charter

7. Associated Forms

7.1. PI Notification form

7.2. IRE DURC Assessment form

7.3. Federal Reporting form

8. References

8.1. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

9. Revision History

9.1. New Document

10. Approvals

Reviewed by: _____ Date Approved: _____
ICDUR

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IRE Chair

Current List of Agents/Toxins and Categories of Experiments (as of 9.24.15)

Agents and toxins

a) Avian influenza virus (highly pathogenic)
b) *Bacillus anthracis*
c) Botulinum neurotoxin (all quantities)
d) *Burkholderia mallei*
e) *Burkholderia pseudomallei*
f) Ebola virus
g) Foot-and-mouth disease virus
h) *Francisella tularensis*
i) Marburg virus
j) Reconstructed 1918 Influenza virus
k) Rinderpest virus
l) Toxin-producing strains of *Clostridium botulinum*
m) Variola major virus
n) Variola minor virus
o) *Yersinia pestis*

Categories of experiments

a) Enhances the harmful consequences of the agent or toxin
b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
c) 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 current detection methodologies
d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
e) Alters the host range or tropism of the agent or toxin
f) Enhances the susceptibility of a host population to the agent or toxin
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed above