Please email completed, signed 'Form' to ehrsappr@exchange.upenn.edu

DUAL USE RESEARCH OF CONCERN (DURC)

Notifying the Penn Institutional Biosafety Committee (IBC) of Potential Dual Use Research of Concern That May Require Institutional Review

Note on this template: This template is designed to assist principal investigators (PIs) in conducting initial reviews and ongoing assessments of research that may be subject to DURC oversight. This template includes information that may be useful for the institutional review entity (IRE), should it be called upon to review the research.

The use of this template by institutions is optional. Institutions may choose to utilize this template as a starting point for developing their own materials or tools based on the specific issues or needs of the institution.

The *Policy for Institutional DURC Oversight* requires PIs at institutions subject to the Policy[20] to notify the IRE as soon as:[21]

A. The PI's research directly involves nonattenuated[22] forms of one or more of the listed agents; or

B. The PI's research with nonattenuated forms of one or more of the listed agents also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects; or

C. The PI concludes that his or her research with nonattenuated forms of one or more of the listed agents that also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects may meet the definition of DURC and should be considered (or reconsidered) by the IRE for its DURC potential.

This notification must include the PI's assessment of the applicability of any of the seven listed experimental effects. More information on the identification and assessment of research that requires institutional review can be found in **Section B** of the *Companion Guide*.

Each institution is responsible for establishing and implementing its own internal policies and practices that provide for the identification and effective oversight of DURC. This includes establishing a mechanism for the PI to immediately refer a project to the IRE, when applicable. The institution may require the use of a specific form and/or additional supporting documentation (e.g., project proposals, progress reports).

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[20] The *Policy for Institutional DURC Oversight* and its oversight requirements apply to the following institutions: (1) USG departments and agencies that fund or conduct life sciences research, (2) institutions within the United States that receive USG funds to conduct or sponsor life sciences research and conduct or sponsor research, regardless of source of funding, that involves 1 or more of the 15 agents or toxins listed in the Policy, and (3) institutions outside the United States that receive USG funds to conduct or sponsor research that involves 1 or more of the 15 agents or toxins listed in the Policy.

[21] *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, September 24, 2014, http://www.phe.gov/s3/dualuse/Pages/default.aspx, Section 7.1.A.

[22] The 15 agents and toxins listed in this Policy are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of this Policy or the March 2012 DURC Policy.

Notifying the Penn Institutional Biosafety Committee (IBC) of Potential Dual Use Research of Concern That May Require Institutional Review

1. Contact Information

1.1 Principal Investigator (PI)

Name (Last, First, MI):	
Mailing address:	Phone number:
	Fax:
	Email:
Department (if applicable):	

1.2 Person Preparing This Document (If Not the PI)

Name:	Phone number:
Email:	Fax:

2. Project Information

Please identify any life sciences research you conduct at this institution that directly involves nonattenuated forms of one or more of the agents listed below (please use a separate form for each identified project). If none of the agents are identified, your research is *not* subject to institutional DURC oversight. However, PIs should be aware that, if at any time, research is initiated that involves any of the below listed agents, he or she will need to immediately notify the institutional review entity (IRE) (or appropriate institutional authority), per the policy of this institution.

2.1 Project Title(s)

2.2 Agent or Toxin Involved in Project (Check All That Apply)

- ☐ Avian influenza virus (highly pathogenic)
- ☐ *Bacillus anthracis*
- ☐ Botulinum neurotoxin (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*

2.3 Type of Funding Source(s) for This Project

- ☐ Department/institutional funds
- ☐ Foundation
- ☐ Federal funds
- ☐ Business /industry
- ☐ Other

If project is supported with Federal funds, name of funding agency and grant or contract number:

3. Training of Laboratory Personnel

The *Policy for Institutional DURC Oversight* requires that all laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting research with nonattenuated forms of 1 or more of the 15 listed agents have received education and training on DURC. Please indicate below the names of all laboratory personnel involved in this project and include the titles and dates of any DURC training.

Name	Title/Role	Title of DURC Training	Completion Date(s)

(Please insert more rows as necessary.)

4. Assessment by the PI for Experimental Effects

PIs are required to assess whether any research directly involving nonattenuated forms of 1 or more of the 15 listed agents produces, aims to produce, or is reasonably anticipated to produce 1 or more of the experimental effects listed in Section 6.2.2 of the *Policy for Institutional DURC Oversight* (relisted below). Note: the research and this assessment must be submitted to the IRE for review regardless of whether any of the following experimental effects apply.

☐ Enhances the harmful consequences of the agent or toxin.

If checked, please explain below:

☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.

If checked, please explain below:

☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates its ability to evade detection methodologies.

If checked, please explain below:

☐ Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated.

If checked, please explain below:

☐ Alters the host range or tropism of the agent or toxin.

If checked, please explain below:

☐ Enhances the susceptibility of a host population to the agent or toxin.

If checked, please explain below:

☐ Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section 2.2 of this form.

If checked, please explain below:

As a reminder, if there is a change in this research with respect to the applicability of any of the seven experimental effects, or if the PI, for any reason, thinks the research needs to be reconsidered by the IRE for DURC potential, the PI should submit this form again to the IRE with his/her revised assessment.