University of Michigan
Policy for Identification and Oversight of
Life Sciences Dual Use Research of Concern

This policy is established by the University of Michigan (U-M) Vice President for Research in accordance with the United States Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern (hereafter, "USG Policy").

"Dual use research of concern" (DURC) is life sciences 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, or national security (USG Policy, Section 4.C.).

1) The U-M shall comply with all provisions of the USG Policy, effective September 24, 2015.

2) The U-M has designated the Institutional Biosafety Committee (IBC) BSL3 Subcommittee to be the Institutional Review Entity (IRE) fulfilling requirements as specified in Section 7.2.E. of the USG Policy.

3) Principal Investigators at U-M are required to notify the IBC BSL3 Subcommittee as soon as they are aware that any of the three following criteria are met in their research **with one or more of the 15 agents or toxins** (see Box 1) to which the USG Policy applies:

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

   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** (see Box 1) *may* meet the definition of DURC and should be considered (or reconsidered) by the IRE for its DURC potential.

4) All PIs planning to perform research with federally-regulated Select Agents and Toxins must seek advance approval from the IBC BSL3 Subcommittee (i.e., the IRE). The IBC BSL3 Application Form and Annual Progress Report include questions for the PI regarding the DURC potential of their research (i.e., consideration of the agents/toxins and whether the work can be reasonably anticipated to produce one or more of the seven listed experimental effects). [Addresses USG Policy Section 7.2.B and C.]

5) Assistance will be provided, as necessary, by the IRE to PIs conducting life sciences research when questions arise about whether their research may require further review or oversight (USG Policy Section 7.2.I.).

6) Upon notification that a PI's research involves one or more of the listed agents or toxins, and through review of the experiment and the PI's responses to questions about DURC potential, the IRE will determine whether the research meets the definition of DURC, as in Section 4.C. of the USG Policy. The outcome of this institutional review will be conveyed to the appropriate USG funding agency within 30 calendar days of the review. [Addresses USG Policy Section 7.2.B]

7) For research that is identified as DURC, the IRE will work with the PI and the USG funding agency to devise a risk mitigation plan taking into account the anticipated benefits of the research. The risk mitigation plan will be submitted to the USG funding agency for review and approval within 90 calendar days of the IRE's determination that the research is DURC. [Addresses USG Policy Section 7.2.B]

8) The DURC will be conducted in accordance with the risk mitigation plan that is approved by the USG funding agency. [Addresses USG Policy Section 7.2.B]

9) The IRE will review, at least annually, all active risk mitigation plans for DURC, and modify the plans as needed. The USG funding agency must be notified within 30 calendar days of changes in status of DURC projects, and changes to risk mitigation plans. [Addresses USG Policy Section 7.2.B]

10) The U-M will maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation (USG Policy Section 7.2.F.).

11) The U-M will provide education and training on DURC for individuals conducting life sciences research with one or more of the agents listed in Section 6.2.1 of the USG Policy, and maintain records of such education and training for the term of the research grant or contract plus three years after its completion (USG Policy Section 7.2.G.).

12) The U-M will ensure compliance with the USG Policy and with approved risk mitigation plans. The U-M will report instances of non-compliance with the USG Policy, as well as mitigation measures undertaken by the institution to prevent recurrences of similar non-compliance, within 30 calendar days to the USG funding agency. (USG Policy Section 7.2.H.)

13) PIs may appeal in writing to the Vice President for Research institutional decisions regarding research that is determined by the IRE to meet the definition of DURC (USG Policy Section 7.2.J.)

14) The U-M will make available, upon request, information about the process for review of research subject to the USG Policy, as consistent with applicable law (USG Policy Section 7.2.K.)

15) The U-M will certify, when applying for or accepting USG funds for life sciences research, as applicable, that the institution is in compliance with all aspects of the USG Policy (USG Policy Section 7.2.L.)

Box 1. Reference information for the *USG Policy for Institutional Oversight of Life Sciences DURC*

Agents and toxins subject to the Policy

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

Categories of experimental effects

1. Enhances the harmful consequences of the agent or toxin;
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
3. Confers to the agent or toxin resistance to clinically 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; or
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

Definition of dual use research of concern

Life sciences 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, or national security.

Box 1 illustration from: *Implementation of the U.S. Government Policy on Institutional Oversight of Life Sciences DURC, Case Studies*; NIH, September 2014.

Further reading: *A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern: Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern*, NIH, September 2014.

Approved,

S. Hu 9/22/2015

S. Jack Hu, Interim Vice President for Research *Date*