

Washington University in St. Louis Policy for Dual Use Research of Concern (DURC)

Overview

This policy has been developed to assist Washington University principal investigators in complying with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. This policy will outline the roles and responsibilities of principal investigators (PIs), the Institutional Review Entity (IRE), and the Institutional Contact for Dual Use Research (ICDUR) in identification, management, and oversight of dual use research of concern (DURC) at Washington University in St. Louis (WU).

Scope

This policy applies to all Washington University principal investigators who work with any quantity of the following agents: avian influenza virus (highly pathogenic), Bacillus anthracis, Botulinum neurotoxin, 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.

Definitions

- Dual use research of concern (DURC): 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.
- Institutional Contact for Dual Use Research (ICDUR): an individual designated by WU to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant US Government funding agency. The Biological & Chemical Safety Officer is WU's ICDUR.
- Institutional Review Entity (IRE): a committee established by WU and empowered to execute the requirements of the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The Institutional Biological & Chemical Safety Committee (IBC) is WU's IRE.

Roles and Responsibilities

Principal Investigators:

- Perform the initial assessment to determine if their research falls under the definition of DURC and report this assessment to the ICDUR. See Appendix A (Dual Use Research of Concern Principal Investigator Questionnaire).
- Provide additional information, as necessary, to the IRE and the ICDUR during verification of the PI's DURC assessment.
- Assist the IRE and ICDUR in developing a Risk Mitigation Plan for any DURC.
- Conduct DURC in accordance with the approved Risk Mitigation Plan.

- Ensure that all members of the PI's lab are familiar with and follow this policy and the approved Risk Mitigation Plan.
- Communicate DURC in a responsible manner.

Institutional Contact for Dual Use Research (ICDUR):

- Act as the liaison between PIs and the IRE to verify the PI's initial DURC assessment.
- Assist the PI and IRE in developing a Risk Mitigation Plan, as necessary.
- Act as the liaison between WU and the US Government funding agency for identified DURC.
- Coordinate the annual review of the Risk Mitigation Plan.
- Maintain records of DURC reviews and Risk Mitigation Plans as required by the US Government Policy.
- Report noncompliance with this policy to the USG funding agency.
- Work with the IRE to develop training on DURC for all individuals conducting life sciences research at WU.
- Consult with the Export Control Manager to ensure compliance with export control regulations.

Institutional Review Entity (IRE)

- Confirm PI's assessment of potential DURC.
- Assist the PI in developing a Risk Mitigation Plan.
- Review annually all active Risk Mitigation Plans.
- Assist the ICDUR in developing training on DURC for all individuals conducting life sciences research at WU.

Sanctions

Violations of this policy may result in University disciplinary action, loss of US Government funding, or regulatory fines and penalties. All penalties and fines are the responsibility of the University department in which the infraction occurred. Grant funding may not be used to pay regulatory fines or penalties.

Additional Resources

- United States Government Policy for Institutional Oversight of Life Sciences Dual Use 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>)
- Dual Use Research of Concern Companion Guide (<http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>)
- NIH Office of Science Policy (<http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern>)
- US Department of Health and Human Services (<http://www.phe.gov/s3/dualuse/Pages/default.aspx>)

Dual Use Research of Concern Principal Investigator Questionnaire

1. Does your work involve any quantity of the following agents?

Agent	Yes	No
Avian influenza virus (highly pathogenic)		
Bacillus anthracis		
Botulinum neurotoxin		
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 you answered “No” in each row above, you do not need to complete the rest of this questionnaire. If you answered “Yes” in one or more row, continue to question #2.

2. Will your work with the agent(s) listed above involve (or potentially involve) any of the following activities?

Activity	Yes	No	Not Sure
Enhance the harmful consequences of the agent or toxin			
Disrupt immunity or the effectiveness of an immunization against the agent or toxin			
Confer to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin			
Facilitate an agent’s or toxin’s 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 above.			

If you answered “No” to all questions above, no further action is necessary. If you answered “Yes” or “Not Sure” to any of the questions above, please contact the University’s Institutional Contact for Dual Use Research (cooks@wusm.wustl.edu, 747-0309) for further direction in developing a risk mitigation plan.