DARTMOUTH
ENVIRONMENTAL HEALTH & SAFETY
Biological Safety Program

Policy 130: Dual Use Research of Concern

I. PURPOSE

This policy outlines the Dartmouth College institutional review and oversight process for research involving certain high-consequence pathogens and toxins to identify the potential for dual use research of concern (DURC) and mitigate the associated risks. Identifying research as DURC should not be seen as a negative categorization, but simply an indication that the research may warrant additional oversight in order to reduce the risks that the knowledge, information, products, or technologies generated could be used in a manner that results in harm. This policy complies with the United States Government (USG) Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. Compliance with this USG Policy is required for institutions within the U.S. that both:

i. Receive USG funds to conduct or sponsor life sciences research; and

ii. Conduct or sponsor research that involves one or more of the 15 agents or toxins listed in Section 6.2.1, even if the research is not supported by USG funds.

Dartmouth is therefore required to comply with the USG Policy. Responsibilities of Principal Investigators (PIs) and the Institutional Review Entity (IRE) are described herein.

II. REGULATORY BACKGROUND

Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for harmful purposes. Such research is called "dual use research". Dual use research of concern is a subset of dual use research that could provide knowledge, information, products, or technologies that could be misapplied to pose a significant risk to public health and safety.

The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern ("March 2012 DURC Policy") is a policy for DURC as applied to a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. The March 2012 DURC Policy established regular review by Federal agencies of USG-funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern. The fundamental aim of this oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

On September 24, 2014, the USG released the Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern ("Policy for Institutional Oversight"). This policy outlines the requirements for institutional oversight of DURC, including the policies, practices, and procedures to ensure DURC is identified and risk-mitigation measures are implemented as necessary. The two polices are complementary, and the goal of oversight is to preserve the benefits of life sciences research while minimizing the risk that knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm.

III. DEFINITIONS

Dual Use Research: Research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.

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, material, or national security.

Institutional Contact for Dual Use Research (ICDUR): An individual designated by the institution to serve as an institutional point of contact for questions regarding compliance with the implementation of the requirements for the oversight of DURC as well as the liaison between the institution and relevant federal funding agencies. At Dartmouth, the Director of Environmental Health & Safety is the ICDUR.

Institutional Review Entity (IRE): A committee established by the institution to review all research with dual use potential. The Dartmouth Institutional Biosafety Committee (IBC) is the IRE for Dartmouth.

Life Sciences: Sciences which pertain to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

Principal Investigator (PI): An individual who is designated by Dartmouth to direct a project or program and who is responsible to the funding agency or the research institution for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project within a single or multiple institutions.

IV. RESPONSIBILITIES

USG agencies that fund life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC and for promoting the responsible conduct and communication of such research.

A. Principal Investigator (PI):

i. Immediately notify the Dartmouth IBC and the Biosafety Officer when:

- Research will involve non-attenuated forms of one or more of the agents listed below (see Section V-A); and/or
- Research with non-attenuated forms of one or more of the agents listed below also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects; and/or
- The PI concludes their research may meet the definition of DURC.

ii. If any of the three above conditions are met, complete the Dual Use Research of Concern survey in the BioRAFT Bio Registration wizard and submit an initial assessment on DURC to the Biosafety

Officer. This information will be reviewed by the IBC for DURC potential.

iii. Work with the IBC/IRE to assess the dual use risks and benefits of the DURC and develop risk mitigation measures.

iv. Conduct DURC in accordance with the approved risk mitigation plan.

v. Be knowledgeable about and comply with all institutional and USG policies and requirements for oversight of DURC.

vi. Ensure that laboratory personnel conducting life sciences research with one or more of the listed agents have received education and training regarding DURC.

vii. Communicate DURC in a responsible manner in accordance with the approved risk mitigation plan.

B. Institutional Review Entity (IRE):

The Dartmouth Institutional Biosafety Committee (IBC) will serve as the Institutional Review Entity in the review of research for DURC potential.

i. Establish and implement internal policies and practices that provide for the identification and oversight of DURC.

ii. When research is identified by a PI as utilizing one of the listed agents or toxins, initiate an institutional review and oversight process that includes the following steps, as applicable.

iii. Verify that the research identified by the PI utilizes one or more of the listed agents or toxins.

iv. Review the PI's assessment of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the listed experimental effects.

v. Determine whether the research meets the DURC definition based on the above and considering the following:

- The *ways* in which the research could be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel or national security;
- The *ease with which* the research might be misused and the feasibility of such misuse; and
- The *magnitude, nature and scope* of the potential consequences of misuse.

vi. Identify the anticipated risks and benefits of the research identified as DURC.

vii. Within 30 calendar days of the institutional review, notify the funding agency of any research that involves one or more of the 15 listed agents and one or more of the seven listed experimental effects, including whether it meets or does not meet the definition of DURC. Information submitted in the notification will comply with the USG Policy for Institutional Oversight and will include a risk mitigation plan drafted in consultation with the PI that will guide the conduct and communication of the DURC.

Note: For non-USG funded research, notification will be made to the National Institutes of Health

Program on Biosecurity and Biosafety Policy at DURC@od.nih.gov.

viii. If the IRE determines that the research does not meet the definition of DURC, the research is not subject to additional institutional DURC oversight. However, if the IRE determines that the research does meet the definition of DURC, the PI will be notified and a draft risk mitigation plan will be prepared.

ix. The USG funding agencies must provide an initial response on the draft risk mitigation plan within 30 calendar days. The IBC/IRE will work with the funding agency and the PI to finalize a risk mitigation plan that must be submitted to the funding agency for approval within 90 days from the initial IBC/IRE determination that the research was DURC.

x. After approval of the risk mitigation plan is received, ensure DURC is conducted according to the risk mitigation plan.

xi. Review plans annually for the duration of the research.

C. Institutional Contact for Dual Use Research (ICDUR):

i. Notify the funding agency, within 30 calendar days, of: 1) any change in the status of a DURC project at the institution (including whether the research is determined by the IBC/IRE to no longer meet the definition of DURC), and 2) details of any changes to risk-mitigation plans (such changes need to be approved by the funding agency). In the case of non-USG funded research, the USG agency designated by NIH should be notified.

ii. Submit the final risk mitigation plan to the funding agency for approval within 90 days of the initial determination for DURC by the IBC/IRE.

iii. Notify the applicable funding agency within 30 calendar days of any change in the status of any DURC, including whether such research has been determined by the IBC/IRE to no longer meet the definition of DURC. The notification should include details of any changes to an approved risk-mitigation plan, which must be approved by the funding agency.

iv. 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.

v. Provide education and training on DURC to individuals conducting life sciences research with any of the agents listed in this policy. Maintain records for 3 years after the completion of the study.

vi. Report non-compliance within 30 calendar days to the funding agency.

V. RESEARCH REQUIRING REVIEW AND OVERSIGHT

Research that directly involves one or more of the following agents or toxins and/or falls into one of the experimental categories listed below must be evaluated for DURC potential.

A. Agents and Toxins Requiring DURC Review

The 15 agents and toxins listed below are subject to the Select Agent Regulations as outlined at http://www.selectagents.gov/. Dartmouth is not part of the Select Agent Program; therefore, only agents and toxins that have been excluded or exempted from the regulations are permitted as per *Select Agents & Toxins* (IBC Policy #120).

Avian influenza virus (highly pathogenic)	Marburg virus
Bacillus anthracis	Reconstructed 1918 influenza virus
Botulinum neurotoxin	Rinderpest virus
Burkholderia mallei	Toxin-producing strains of *Clostridium botulinum*
Burkholderia pseudomallei	Variola major virus
Ebola virus	Variola minor virus
Foot-and-mouth disease virus	*Yersinia pestis*
Francisella tularensis	

For compliance with USG policies on DURC, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.

B. Experimental Categories (Effects)

i. Enhances the harmful consequences of the agent or toxin.

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

iii. 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.

iv. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin.

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

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

vii. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

C. Exclusions

The review and oversight requirements presented in this policy do not apply to research that involves the use of the genes from any of the listed agents, *in silico* experiments (e.g., modeling experiments, bioinformatics, etc.) involving the biology of the listed agents, or research related to the health impact of the listed agents (e.g., modeling the effects of a toxin, developing vaccine delivery, etc.).

VI. COMPLIANCE

Non-compliance with this Policy may result in suspension, limitation, or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Note that if the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* apply, DURC may be considered a "Major Action" (Section III-A) and require notification to the NIH Office of Science Policy (OSP) and approval by the OSP or NIH Director.

VII. RESOURCES

- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. National Institutes of Health Office of Science Policy, 84 FR 17858, 2019 April https://osp.od.nih.gov/biotechnology/nih-guidelines/

- Policy 120: Select Agents & Toxins. Dartmouth IBC 2022 http://www.dartmouth.edu/~ehs/biological/policies_sops.html

- *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern*. National Institutes of Health Office of Science Policy, 2014 September https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/

- *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*. National Institutes of Health Office of Science Policy, 2014 September https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/

- *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*. National Institutes of Health Office of Science Policy, 2012 March https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/