



VCU

Dual Use Research of Concern in the Life Sciences (DURC)

Policy Type: Administrative

Responsible Office: Office of Research and Innovation

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Policy Statement and Purpose

This Policy is to establish VCU's review and oversight of all research (regardless of the source of funding) that may qualify as Dual Use Research of Concern (DURC). DURC is defined by the United States Government (USG) Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern as "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[sic], or national security." The fundamental aim of DURC review is to preserve the benefits of life sciences research while mitigating the risk of misuse of the knowledge, information, products, or technologies provided by such research where appropriate and as required by federal regulation.

In order to meet the requirements of the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, VCU has established an Institutional Review Entity (IRE) and appointed an Institutional Contact for Dual Use Research (ICDUR). The IRE will function as a separate committee and has the responsibility and authority to review all research projects involving the agents and toxins identified by the USG to have DURC potential and to direct the ICDUR to report those projects to the USG. The IRE in collaboration with the USG has the authority to establish ongoing review procedures and may place certain restrictions, up to and including a moratorium (when required by the USG), on research found to be DURC.

In addition to the institutional review and oversight detailed in this policy, each Principal Investigator whose research may qualify as DURC is required to communicate with the IRE and comply with the procedures set forth in this Policy as well as any additional procedures established by VCU's IRE or the USG.

Noncompliance with this policy may result in disciplinary action up to and including termination of employment. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

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Who Should Know This Policy

All university faculty and staff conducting or overseeing research that may be qualified as DURC are responsible for knowing this policy and familiarizing themselves with its contents and provisions. Deans, Department Chairs / Directors / Managers, Principal Investigators (PIs), Laboratory Managers, and those with supervisory authority are ultimately responsible for ensuring that work or research is conducted within the requirements of this policy.

Definitions

Dual Use Research

As defined by the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, "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

As defined by the USG Policy for Institutional Oversight of Life Sciences 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[sic], or national security."

Institutional Contact for Dual Use Research (ICDUR)

The individual designated by the University to be the institutional point of contact for questions relating to compliance with this Policy and the liaison with the relevant USG funding agencies. The Senior Associate Vice President for Research Compliance and Administration will serve as VCU's ICDUR.

Institutional Review Entity (IRE)

The committee established by this policy and drawing its membership from practicing scientists, safety and research experts, VCU's attending veterinarian, and other experts, which meets on an as needed basis and is the final authority on the risk analysis of potential DURC and any relevant Risk Mitigation Plans.

Life sciences

As defined by the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, A field of study that "pertains 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, synthetic 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 for understanding life at the level of ecosystems, organisms, organs, tissues, cells, and molecules."

Principal Investigator (PI)

As defined by the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, "an individual who is designated by the research institution 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."

Risk Mitigation Plan

A written plan developed by the PI, the IRE, and the USG to mitigate any DURC-related risk.

Contacts

The Office of Research and Innovation officially interprets this policy. Office of Research and Innovation is responsible for obtaining approval for any revisions as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Please direct policy questions to the Office of Research and Innovation.

Policy Specifics and Procedures

Investigator Responsibilities:

- 1. Initial Assessment of Potential DURC:** Before commencing research activities, any person employed by VCU that is conducting research with one or more potential DURC agents or toxins must complete an initial assessment to determine whether any such agent or toxin produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern list of Categories of Experiments. For convenience, both lists are included below, but persons responsible for complying with this policy should consult the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern directly for the most accurate information.

Potential DURC Agents and Toxins (USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern § 6.2.1):

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (in 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 Experiments (USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern § 6.2.2):

- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against the agent or toxins or facilitates their ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin previously listed above

2. IRE Notification of Potential DURC: The PI must submit the IRE Review Form along with the PI's initial assessment to the IRE at least 10 business days before initiating any research that may be qualified as DURC. If research is already underway at the time this policy is implemented, the PI must submit the IRE Review Form to the IRE immediately.

- The IRE can be reached through
 - Susan Robb, Senior Associate Vice President for Research Compliance and Administration
 - 804-827-0479 or exportctrl@vcu.edu

3. Risk Mitigation: If the IRE determines that the proposed research is DURC, the PI is expected to:

- a. Collaborate with the IRE to develop a Risk Mitigation Plan;
- b. Conduct research in accordance with the Risk Mitigation Plan;
- c. Notify the IRE of any substantive change in the ongoing conduct of the research;

- d. Ensure that all laboratory personnel conducting research with one or more of the listed agents or toxins has received and documented education and training on DURC and any relevant Risk Mitigation Plan.
- e. Communicate DURC in a responsible manner and ensure that communication is in compliance with the approved Risk Mitigation Plan.

4. Ongoing review:

- a. The PI shall assess his or her research for DURC potential on an ongoing basis (i.e., throughout the research process from project conception through application for funding, submission of progress reports, and communication of the research findings) and notify the VCU IRE if any DURC concerns arise or if the PI feels that the research should no longer be considered DURC, and request a review of the Risk Mitigation Plan.

5. Annual Report:

- a. A PI with a DURC Risk Mitigation Plan in place should submit an updated IRE Review Submission Form annually to the IRE.

Institutional Responsibilities:

1. IRE Verification of DURC:

- a. The IRE will review the PI's initial assessment to verify any determination of DURC and conduct appropriate risk assessment.

2. Risk Mitigation Plan Development and Implementation: Upon completion of the risk assessment (whether or not anticipated research is determined to be DURC), the IRE will coordinate through the ICDUR with the PI, and the USG to develop and implement an appropriate Risk Mitigation Plan according to the source of research funding as set forth below.

a. IRE Procedures for USG Funded Research

- i. The IRE will direct the ICDUR to notify the appropriate USG funding agency of the outcome of the review within 30 calendar days.
- ii. If the research requires DURC oversight, the IRE considers the previously identified risks and the anticipated benefits in order to develop a draft Risk Mitigation Plan.
- iii. The IRE works with the USG funding agency, through the ICDUR, toward completing the draft Risk Mitigation Plan within 90 calendar days of the IRE's determination that the research is DURC.
- iv. Once the USG funding agency finalizes the Risk Mitigation Plan (generally within 60 calendar days of receipt of the draft plan), the PI and the IRE implement the approved Risk Mitigation Plan and provide ongoing oversight of DURC.
- v. Risk Mitigation Plans must include a requirement for the PI to submit an annual update via an IRE Review Submission Form.

b. IRE Procedures for Non-USG Funded Research

- i. The IRE will direct the ICDUR to notify the NIH Program on Biosecurity and Biosafety Policy within 30 days of identifying any non-USG funded research as

DURC. The NIH will provide the ICDUR with further direction on the appropriate government agency to collaborate with on developing a Risk Mitigation Plan.

- ii. Risk Mitigation Plans must include a requirement for the PI to submit an annual update via an IRE Review Submission Form.
- iii. Contact information for NIH:
 - Program on Biosecurity and Biosafety Policy
 - Office of the director
 - National Institute of Health
 - Phone: 301-496-9838
 - Email: DURC@od.nih.gov

3. ICDUR Responsibilities:

- a. Ensure that the USG is appropriately notified of IRE reviews per this policy
- b. Ensure that the IRE is informed of any USG requests or orders made to the IRE or the PI
- c. Ensure the PI receives the appropriate education and training as outlined by the IRE and USG in a Risk Mitigation Plan
- d. Maintain records of institutional DURC reviews, established risk mitigation plans, and follow up DURC reviews
- e. Notify the USG within 30 calendar days of any change in the status of any DURC project including a determination by the IRE that the project is no longer DURC. Notification must include any changes to an approved Risk Mitigation Plan.
- f. Ensure that any changes to an approved Risk Mitigation Plan are approved by the USG.
- g. Report within 30 calendar days to USG any issues of noncompliance identified by VCU's IRE.

4. Ongoing DURC Review:

- a. The IRE shall review each DURC Mitigation Plan annually by comparing the original Plan with any changes in the PI's updated IRE Review Submission Form. If the research has changed and the Risk Mitigation Plan must be updated the IRE must direct the ICDUR to notify the USG of the Plan changes and receive approval from the USG.

5. Training and Communication:

- a. The IRE will ensure that education and training approved as part of the Risk Mitigation Plan is available and will direct the ICDUR to monitor training and retain records for individuals who are conducting research with one or more DURC Agents.
- b. If the IRE receives notification from the USG it will direct the ICDUR to notify the PI if the USG requests voluntary redaction of research publications, classifies the research or terminates funding.

Forms

1. [Internal DURC Report Form](#)

Related Documents

1. [VCU IRE Procedures for Dual Use Research of Concern Experiments](#)
2. [Companion Guide to the US Government Policies for the Oversight of Life Sciences Dual Use Research of Concern](#)
3. [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern \(USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern\)](#)
4. [Safety training modules](#)

Revision History

09/17/2015	<i>Dual Use Research of Concern (DURC) – Interim</i>
04/12/2017	<i>Dual Use Research of Concern (DURC) (minor revision to remove “interim” from initial approval date)</i>

FAQ

1. What if I have questions about DURC or this policy?

Answer: Contact the Office of Research and Innovation at exportctrl@vcu.edu.

2. What forms must be submitted to the Office of Research and Innovation prior to beginning a research project involving agents or toxins of dual use concern?

Answer: Prior to beginning any potential DURC research, the Principal Investigators must submit a completed IRE Review Form to the Office of Research and Innovation (exportctrl@vcu.edu).

3. Does the designation of DURC mean the research should not be published or conducted?

Answer: No. A determination that research is DURC, in and of itself, does not mean that the research should not be published or conducted. Research that is categorized as DURC is often vitally important to science, public health, and agriculture, and its findings contribute to the broader base of knowledge that advances science and public health objectives. Upon identifying research as DURC, institutions should give careful thought to the ways in which the research or its results might be misused and the mitigation measures that can be put in place to minimize the possibility of misuse.

4. Where can institutions and investigators find more information about DURC and the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern?

Answer: Information about dual use research in the life sciences in general, as well as specific details on the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, is available on the USG Science, Safety, Security (S3) website:

<http://www.phe.gov/s3/dualuse/Pages/default.aspx>