Virginia Tech Dual Use Research of Concern Policy

No. 13050

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Policy Owner:
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Affected Parties:
Undergraduate
Graduate
Faculty
Staff
Other

1.0 Purpose

This policy establishes requirements for the identification and oversight of Dual Use Research of Concern (DURC) within the Life Sciences research conducted at Virginia Tech. This policy is in accordance with the requirements outlined in the "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern". This policy outlines the roles and responsibilities of Virginia Tech, investigators, the Institutional Review Entity (IRE), the DURC contact and the Federal funding agencies.

2.0 Policy and Principles

Virginia Tech is actively committed to complying with Federal regulations regarding the use of dual use research of concern. The *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, as well as its amendments and additions, applies to all university personnel (faculty, staff, and students), as well as visitors, engaged in Life Sciences research and/or instructional activities.

Non-compliance with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* 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 Virginia Tech, consistent with existing regulations and policies governing USG funded research, and may subject Virginia Tech to other potential penalties under applicable laws and regulations.

2.1 Scope

Research that uses one or more of the agents/toxins listed in Section 2.1.1, and produces, aims to produce or can be reasonably anticipated to produce one or more of the effects listed in Section 2.1.2 will need to follow the procedures listed in Section 3.0.

For the purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.

Although the agents and toxins listed in Sections 2.1.1 and 2.1.2 are also subject to the select agent regulations, any research meeting the criteria of this policy must follow the procedures listed in Section 3.0 because the Federal Select Agent Program does not oversee implementation of the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.*

2.1.1 Agents and Toxins

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

2.1.2 Categories of Experiments

a. Enhances the harmful consequences of the agent or toxin
b. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
c. 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
d. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
e. Alters the host range or tropism of the agent or toxin
f. Enhances the susceptibility of a host population to the agent or toxin
g. Generates or reconstitutes an eradicated or extinct agent or toxin listed in 2.1.1, above

2.2 Compliance and Responsibilities

To ensure compliance with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,* Virginia Tech has designated the Institutional Contact for DURC and the Institutional Review Entity (IRE) as the institutional bodies that will oversee the review and mitigation of DURC-related research.

2.2.1 Virginia Tech, "The Institution"

Virginia Tech will ensure compliance with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,* and with approved risk mitigation plans.

Virginia Tech will ensure that internal policies establish a mechanism for the principal investigator (PI) to immediately refer a project to the IRE as soon as: (i) The PI's research involves one or more of the agents/toxins listed in Section 2.1.1; (ii) The PI's research involves, or can be reasonably anticipated to include, one or more of the agents/toxins listed in Section 2.1.1 and one or more of the effects listed in Section 1.2.2; and/or (3) The PI's research falls within the scope of Section 6.2 of the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.*

2.2.2 Institutional Contact for Dual Use Research (ICDUR)

The Associate Vice President for Scholarly Integrity and Research Compliance (SIRC)will serve as the IDURC for Virginia Tech, serving as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of Section 2.1 and/or meets the definition of DURC.

If questions arise regarding compliance, implementation of this Policy, or when guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the institution and the relevant program officers at the USG funding agencies, or for non-USG funded research, between the institution and the National Institutes of Health (NIH) (or the USG agency to which NIH refers the institution). The ICDUR, with the help of the Institutional Review Entity (IRE), will ensure compliance with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,* and with approved risk mitigation plans.

The ICDUR will report instances of noncompliance with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, as well as mitigation measures undertaken by Virginia Tech to prevent recurrences of similar noncompliance, within 30 calendar days to the USG funding agency. In the case of non-USG funded research, reports should be made to the USG agency designated by NIH.

2.2.3 Institutional Review Entity (IRE)

The Virginia Tech Institutional Biosafety Committee (IBC) has been appointed as the IRE for Virginia Tech. The IRE is responsible for reviewing life sciences research for the potential for DURC, and to execute the process described in Section 3.0. The IBC will maintain a record of all DURC reviews within the IBC Meeting Minutes. All IBC and IRE meetings will be independent meetings.

DURC training will be required as part of the required IBC member training.

The IRE, with the ICDUR, will ensure compliance with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,* and with approved risk mitigation plans.

The IRE will report any occurrence of non-compliance with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, as well as mitigation measures undertaken by Virginia Tech to prevent recurrences of similar noncompliance, within 10 calendar days to the ICDUR.

As is required by the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* for the IRE, the Virginia Tech IBC is composed of a minimum of 5 members and

(i) Is sufficiently empowered by the institution to ensure it can execute the requirements of Section 7.2 of the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*.

(ii) Includes persons with sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility

(iii) On a case by case basis, recuses any member of an IRE who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity

(iv) Engages in an ongoing dialogue with the PI of the research in question when conducting a risk assessment and developing a risk mitigation plan.

2.2.4 Researchers and Personnel

Researchers and personnel at Virginia Tech who are participating in Life Sciences research will comply with the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*. Researchers and personnel have the following responsibilities concerning DURC:

(i) Notify the IRE as soon as: (i) The PI's research involves one or more of the agents/toxins listed in Section 2.1.1; (ii) The PI's research involves, or can be reasonably anticipated to include, one or more of the agents/toxins listed in Section 2.1.1 and one or more of the effects listed in Section 1.2.2; and/or (3) The PI's research falls within the scope of Section 6.2 of the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.*

(ii) Work with the IRE to assess the dual use risks and benefits of the DURC and to develop risk mitigation measures.

(iii) Conduct DURC in accordance with the provisions in the risk mitigation plan.

(iv) Be knowledgeable about and comply with all Virginia Tech and USG policies and requirements for oversight of DURC.

(v) Ensure that laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting life sciences research with one or more of the agents listed in Section 2.1.1 of this Policy have received education and training on DURC.

(vi) Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved risk mitigation plan.

3.0 Procedures

When research is identified by a PI (per Section 2.2.4(i)) or the IBC during protocol reviews as utilizing one of the agents or toxins listed in Section 2.1.1, an institutional review and oversight will be implemented by the IRE, ICDUR and the Virginia Tech Office of Export and Secure Research Compliance (OESRC), that as applicable will follow Section 7.2 of the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*.

4.0 Definitions

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern – The "*USG DURC Policy*" specifies the definition of DURC, and the responsibilities of Institutions, researchers and USG funding agencies involved in life sciences research.

"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, materiel, or national security.

Institutional Biosafety Committee (IBC) – The compliance oversight committee required by the *NIH Guidelines*. The expertise and membership of the IBC must be reflective of the research conducted at an institution, e.g., including plant or animal experts, a Biological Safety Officer (BSO), or other expertise as appropriate, and must also include at least two unaffiliated members who can represent the interests of the community surrounding the registered institution.

Institutional Review Entity (IRE) – A committee established by Virginia Tech and empowered to execute the requirements, as described in the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*. The IBC has been designated as the IRE for Virginia Tech.

Institutional Contact for Dual Use Research (ICDUR) – An individual designated by Virginia Tech 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 Virginia Tech and the relevant USG funding agency and/or NIH.

Principal Investigator (PI) – An individual(s) who has been designated by Virginia Tech to direct a project or program and who is responsible to the funding agency or Virginia Tech for the scientific and technical direction of that project or program.

Life Sciences – 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, 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.

5.0 References

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The policy can be downloaded from the NIH Office of Biotechnology Activities website. The Virginia Tech IBC office (ibc@vt.edu) also maintains a copy of the policy.

6.0 Appendix A

The below figure (Figure 1 *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*) is the overview of the process for the institutional review of life science research within the scope of the USG DURC policy.

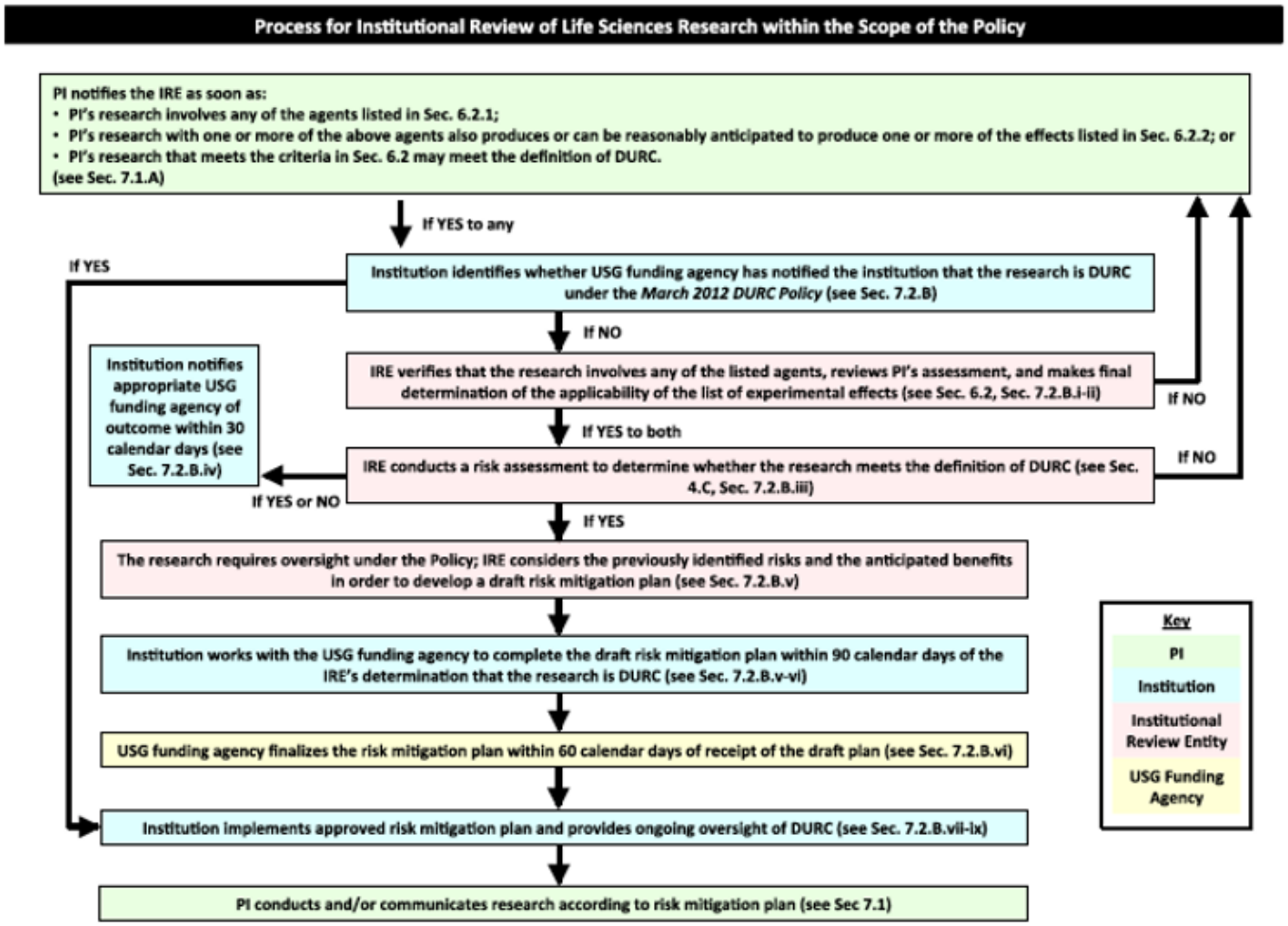
7.0 Approval and Revisions

Approved September 25, 2015 by Interim Vice President for Research, Dr. Dennis Dean.

- Revision 1
  - Technical updates for titles.
  - Section 2.2.3: Clarified IBC and IRE meetings are held independently.

  Recommended November 13, 2019 by Director, IBCP and IBC Administrator, Regina Allen. Approved November 22, 2019 by Vice President for Policy and Governance, Kim O'Rourke.

Appendix A


Process for Institutional Review of Life Sciences Research within the Scope of the Policy
PI notifies the IRE as soon as:
• PI's research involves any of the agents listed in Sec. 6.2.1;
• PI's research with one or more of the above agents also produces or can be reasonably anticipated to produce one or more of the effects listed in Sec. 6.2.2; or
• PI's research that meets the criteria in Sec. 6.2 may meet the definition of DURC.
(see Sec. 7.1.A)
If YES to any
If YES
Institution identifies whether USG funding agency has notified the institution that the research is DURC under the March 2012 DURC Policy (see Sec. 7.2.B)
If NO
Institution notifies appropriate USG funding agency of outcome within 30 calendar days (see Sec. 7.2.B.iv)
IRE verifies that the research involves any of the listed agents, reviews PI's assessment, and makes final determination of the applicability of the list of experimental effects (see Sec. 6.2, Sec. 7.2.B.i-ii)
If NO
If YES to both
IRE conducts a risk assessment to determine whether the research meets the definition of DURC (see Sec. 4.C, Sec. 7.2.B.iii)
If NO
If YES or NO
If YES
The research requires oversight under the Policy; IRE considers the previously identified risks and the anticipated benefits in order to develop a draft risk mitigation plan (see Sec. 7.2.B.v)
Institution works with the USG funding agency to complete the draft risk mitigation plan within 90 calendar days of the IRE's determination that the research is DURC (see Sec. 7.2.B.v-vi)
USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan (see Sec. 7.2.B.vi)
Institution implements approved risk mitigation plan and provides ongoing oversight of DURC (see Sec. 7.2.B.vii-ix)
PI conducts and/or communicates research according to risk mitigation plan (see Sec 7.1)
Key
PI
Institution
Institutional Review Entity
USG Funding Agency