VANDERBILT UNIVERSITY
MEDICAL CENTER

Policy: Dual Use Research of Concern (DURC)

Category	Research
Approval Date	January 2019
Effective Date	February 2019

I. Purpose:

To outline responsibilities for principal investigators (PIs), the institution, and the Institutional Review Entity (IRE) related to research that constitutes Dual Use Research of Concern (DURC), as established by the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

II. Guiding Statement:

Vanderbilt University Medical Center (VUMC) is committed to maintaining a research environment that fosters the creation and dissemination of new knowledge and enables open research that promotes academic freedom and the free exchange of ideas. Certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. The Federal Government defines this as "dual use research" and regulates such research accordingly. The VUMC IRE assesses proposed life sciences research that may fall under the definition of DURC.

III. Policy:

A. Each principal investigator (PI) is responsible to maintain awareness of and comply with federal and VUMC policies related to DURC and report potential DURC to the VUMC IRE in compliance with these policies.

B. The VUMC IRE assesses proposed life sciences research that may fall under the definition of DURC.

If a research project is determined to meet the definition of DURC, the IRE communicates the assessment to the appropriate funding agency and, working with the PI, submits a draft risk mitigation plan for approval by the funding agency. Once a risk mitigation plan is approved, the IRE will provide ongoing compliance oversight through the life of the project.

These requirements complement existing federal regulations and policies governing the possession and handling of pathogens and toxins, which include the Select Agent Regulations and U.S. Export Control Laws.

IV. Definitions:

A. Dual Use Research of Concern (DURC): 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.

B. Institutional Review Entity (IRE): The IRE is a committee established by the VUMC as described in and empowered to execute the requirements of the federal policy on DURC.

C. Institutional Contact for Dual Use Research (ICDUR): The ICDUR is an individual designated by VUMC to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC. The ICDUR is the liaison (as necessary) between the VUMC and the relevant federal funding agency.

V. Scope:

A. Agents and toxins:

1. Avian influenza virus (highly pathogenic)
2. Bacillus anthracis
3. Botulinum neurotoxin (any quantity, including Botox)
4. Burkholderia mallei
5. Burkholderia pseudomallei
6. Ebola virus
7. Foot-and-mouth disease virus
8. Francisella tularensis
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of Clostridium botulinum
13. Variola major virus
14. Variola minor virus
15. Yersinia pestis

B. Categories of experiments:

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

7. Generates or reconstitutes an eradicated or extinct agent or toxin listed in above (section IV.A)

VI. Requirements of the Institution

A. Designate an ICDUR to serve as an VUMC 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 6.2 of the 2014 United States Government Policy for Institutional Oversight of Life Sciences DURC and/or meets the definition of DURC, as found in either the 2014 policy or the complementary March 2012 DURC Policy. (Note: the 2014 and 2012 documents may be abbreviated throughout this document as "Federal Policy".)

When guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the VUMC and the relevant program officers at the federal funding agencies, or for non-United States Government (USG) funded research, between the VUMC and National Institute of Health (NIH), or the federal agency to which NIH refers the institution.

B. Establish an IRE to execute the requirements in Section 7.2.B.i-iii, v, and viii, of the 2014 Federal Policy.

1. Membership:

The IRE must be composed of at least five members and:

a. Be sufficiently empowered to execute the requirements in Section 7.2.B.i-iii, v, and viii, of the *2014 Federal Policy*;
b. Include persons with sufficient breadth of expertise to assess the dual-use potential of the range of relevant life sciences research conducted at VUMC;
c. Include persons with knowledge of relevant federal policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity;
d. May include, or have available as consultants, at least one person knowledgeable about VUMC's commitments, policies, and standard operating procedures;
e. On a case-by-case basis, recuse 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 IRE;
f. Engage in an ongoing dialogue with the PI of the research in question when conducting a risk assessment and developing a risk mitigation plan;

g. Review ongoing VUMC compliance efforts under the federal policy on DURC; and
h. Establish an internal mechanism for PIs to appeal decisions regarding research that is determined by the IRE to meet the definition of DURC.

1. Requirements:

The 2014 Federal Policy requires the IRE to undertake the following steps in its review of research:

a. Verify that the research identified by the PI directly utilizes non-attenuated forms of one or more of the listed agents.
b. 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 and the final determination of whether the research meets the scope of the 2014 Federal Policy.
c. For research that the IRE determines meets the scope of the 2014 Federal Policy, conduct a risk assessment and determine whether the research meets the definition of DURC. This assessment should involve the PI, as appropriate.
d. Assess the benefits of the DURC while also considering the risks identified in the previous step.
e. Develop a draft risk mitigation plan for the identified DURC. This plan should be based on the assessment of the risks and benefits performed in the previous step. More information on drafting risk mitigation plans can be found in Section D of the Institutional Policy Companion Guide.
f. Review, at least annually, all active risk mitigation plans at the institution. If the research in question still constitutes DURC, the IRE should modify the plan as needed. More information on the annual review of active risk mitigation plans can be found in Section E of the ***Companion Guide*.**

VII. Compliance

A. The Policy for Institutional Oversight of Life Sciences DURC applies to all institutions (and their investigators) that receive federal funding for life sciences research and that conduct research (funded by any source) involving any of 15 agents and toxins listed in the policy. The Policy for Institutional Oversight of Life Sciences DURC defines an institution as any government agency (federal, state, tribal, or local), academic institution, corporation, company, partnership, society, association, firm,

sole proprietorship, or other legal entity receiving funds for and/or conducting research.

B. If an institution (1) receives any federal funding for any life sciences research, and (2) is conducting work with one or more of the 15 agents and toxins listed in the policy, then any research at that institution with those 15 agents and toxins, regardless of the source of funding, must comply with the requirements articulated in the policy.

C. As defined in Section 6.3 of the 2014 Federal Policy, noncompliance with the policy may result in suspension, limitation, or termination of federal funding, or loss of future federal funding opportunities for the noncompliant USG-funded research project and of federal funds for other life sciences research at the institution, consistent with existing regulations and policies governing federal-funded research and may subject the institution to other potential penalties under applicable laws and regulations.

D. The 2014 Federal Policy further articulates the practices and procedures required to ensure that DURC is identified at the institutional level and risk mitigation measures are implemented as necessary.

VIII. Collaborative Research

The federal government recognizes that there will be situations where elements of a potential DURC project are being carried out at multiple institutions through a sub-award with a primary institution which directly receives the grant or contract from the federal funding agency.

In cases of such collaborations involving multiple institutions via a sub-award, the primary institution is responsible for the following:

A. Notifying the funding agency of research that falls within the scope of Section 6.2 and, if that research is determined to be DURC, providing copies of each institution's risk mitigation plan; and

B. Ensuring that DURC oversight is consistently applied by all entities participating in the collaboration.

IX. Lead Authors and Content Experts:

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Susan Meyn, Institutional Contact for Dual Use Research

X. Endorsement

John F. Manning, Jr. PhD, MBA — January 2019
Chief Operating Officer

Jennifer Pietenpol, PhD — December 2018
Executive Vice President for Research

Gordon Bernard, MD — January 2019
Executive Vice President for Clinical Research

XI. Approval:

Jeffrey R. Balser, MD, PhD — Date
President and CEO, Vanderbilt University Medical Center

XII. References:

VUMC Office of Research – Dual Use Research of Concern (DURC):
www.vumc.org/oor/dual-use-research-concern-durc

United States Government DURC homepage:
www.phe.gov/s3/dualuse/

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern:
www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx

Points to consider when using an IBC as an IRE:
www.phe.gov/s3/dualuse/Documents/durc-ptc.pdf

DURC Companion Guide:
www.phe.gov/s3/dualuse/Pages/companion-guide.aspx

Gain-of-Function Research
www.phe.gov/s3/dualuse/Pages/GainOfFunction.aspx

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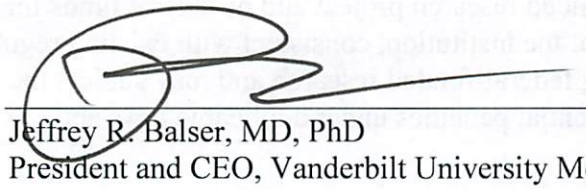

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Jeffrey R. Balser, MD, PhD — Date
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www.phe.gov/s3/dualuse/Documents/durc-ptc.pdf

DURC Companion Guide:
www.phe.gov/s3/dualuse/Pages/companion-guide.aspx

Gain-of-Function Research
www.phe.gov/s3/dualuse/Pages/GainOfFunction.aspx