THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Responsible University Officer
Director of Environment, Health and Safety

Responsible Office
Department of Environment Health and Safety

Dual Use Research of Concern Policy

I. Introduction and Purpose

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (hereinafter "Federal DURC Policy for Institutional Oversight for Institutional Oversight") was released on September 24, 2014 and takes effect on September 24, 2015. The Federal DURC Policy for Institutional Oversight covers certain types of research conducted for legitimate purposes which could be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research *of concern* (DURC) is a subset of dual use research defined in the Federal DURC Policy for Institutional Oversight 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, or national security. This Dual Use Research of Concern Policy ("Policy") is intended to ensure The University of North Carolina at Chapel Hill's (the "University's") compliance with the Federal DURC Policy for Institutional Oversight by outlining the roles and responsibilities of the University and its Principal Investigators when dealing with the high-consequence pathogens and toxins covered by the Federal DURC Policy for Institutional Oversight and provides a process for review of life sciences research, identification of potential DURC, and development and implementation of risk mitigation measures for DURC. This Policy seeks to preserve the benefits of life sciences DURC at the University while minimizing the risk that the knowledge, information, products, or technologies generated from such research could create the potential negative consequences identified in the Federal DURC Policy for Institutional Oversight.

II. Policy Statement

Life sciences research that meets the scope specified in Section 6.2 of the Federal DURC Policy for Institutional Oversight shall be subject to review by the University's Institutional Review Entity (IRE) in order to mitigate the risk that the knowledge, information, products, or technologies generated by DURC could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Such oversight includes the identification of life sciences research that raises dual use concern as well as the implementation of measures to mitigate the risk that DURC is used in a manner that results in harm. Measures that mitigate the risks of DURC should be applied in a manner that minimizes, to the extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.

III. Definitions

A. "Appropriate USG Agency" shall mean the department or agency of the United States Government (USG) that is providing funding for the life sciences research under University review. When a federal agency simply passes through funding from another federal agency to support research covered under this Policy, the agency originally providing the funding shall be considered the Appropriate USG Agency. For non-USG funded research, the National Institutes of Health (NIH) is the Appropriate USG Agency, and NIH will in turn refer the notification to another USG agency, based upon the nature of the research.

B. "To certify" is to attest to the USG that the University will comply with all aspects of the Federal DURC Policy for Institutional Oversight.

C. "Dual use research" is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.

D. "Dual use research of concern" (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.

E. "Institutional Contact for Dual Use Research" (ICDUR) is the individual designated by the University 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 University and the Appropriate USG Agency. At the University, the Biological Safety Officer functions as the ICDUR.

F. "Institutional Review Entity" (IRE) is a subcommittee of the University's Institutional Biosafety Committee (IBC) established by the University and empowered to verify if a project constitutes DURC, assess the risks associated with research proposals and reviews and approves the associated risk mitigation plans.

G. "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.

H. "Principal Investigator" (PI) is an individual who is designated by the University to direct a project or program and who is responsible to the Appropriate USG Agency or the University 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 institution(s).

IV. Audience

This Policy is applicable to all University personnel involved in the conduct or oversight of life sciences research.

V. Compliance

Non-compliance with the Federal DURC Policy for Institutional Oversight 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 University, consistent with existing regulations and policies governing USG funded research, and may subject the University to other potential penalties under applicable laws and regulations.

VI. Scope

The scope of the Federal DURC Policy for Institutional Oversight is limited to research that uses one or more of the agents or toxins listed in Section 6.2.1 of the Federal DURC Policy for Institutional Oversight, and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in Section 6.2.2. of the Federal DURC Policy for Institutional Oversight. These agents and effects are listed in Appendix A to this Policy, but are subject to change. Confirmation should be made against the Federal DURC Policy for Institutional Oversight.

VII. University Responsibilities

A. The University shall be responsible for implementation and periodic review of internal procedures and practices, detailed in this Policy, that provide for the identification and effective oversight of DURC.

B. The University shall establish an IRE that is composed of at least five members with sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at the University. IRE membership must include personnel with knowledge of relevant U.S. government policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity. The IRE may also include, or have available as consultants, at least one person knowledgeable in the University's commitments, policies, and standard operating procedures. The minimum membership of the University's IRE will be comprised of the Biological Safety Officer, the Responsible Official for Select Agents and Toxins, the Chair of the IBC, a Principal Investigator with expertise in microbiology and a community member. On a case by case

basis, any member of the IRE who is involved in the research project in question or has a direct financial interest in such research, shall be recused except to provide specific information requested by the IRE. A minimum quorum of three committee members in addition to the Biological Safety Officer and the Responsible Official for Select Agents must be present to convene a meeting of the IRE. Meeting minutes will be taken by the Biological Safety Officer or his/her designee to accurately reflect the topics of discussion. Meeting minutes will be reviewed, approved by the members, and maintained on file at the University's Department of Environment, Health and Safety (EHS). All meetings will be open to the public unless otherwise posted, and minutes will be provided to the public upon request.

C. When University research is identified by a PI, the Biological Safety Officer, the IBC or its High Containment Laboratory Subcommittee (HCLS) as meeting one of the characteristics listed in Section VIII. A. of this Policy, the University shall initiate a review and oversight process that includes the steps below, as applicable.

i. If the initial assessment that certain University research potentially falls within the scope of this Policy is made by the Biological Safety Officer, the IBC or the HCLS, the Biological Safety Officer will notify the PI of the impending IRE review of the research and the PI's obligations under Section VIII of this Policy.

ii. The IRE shall verify that the research identified by the PI utilizes one or more nonattenuated forms of the agents or toxins listed in Section 6.2.1 of the Federal DURC Policy for Institutional Oversight.

iii. The IRE shall review the PI's risk assessment of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2 of the Federal DURC Policy for Institutional Oversight and final determination of their applicability. If the IRE determines that the research in question does not involve one or more of the categories of experiments detailed in Section 6.2.2 of the Federal DURC Policy for Institutional Oversight, the research is not subject to additional review or oversight, but shall continue to be assessed by the PI. If there is a change in this research such that it can be reasonably anticipated to produce one or more of the seven listed experimental effect detailed in Section 6.2.2, the PI should notify the IRE and supply a revised assessment.

iv. If the research has been assessed to meet the scope of the Federal DURC Policy for Institutional Oversight, the IRE shall determine whether the research meets the DURC definition. If the IRE determines that the research in question does not meet the definition of DURC, the research is not subject to additional DURC oversight. The Biological Safety Officer, in the role of the ICDUR, shall notify the Appropriate USG Agency of the IRE findings. If the IRE determines that the research in question meets the definition of DURC, the IRE will inform the PI of its findings and provide the PI an opportunity to appeal the institutional decision. Research identified by the IRE as meeting the definition of DURC shall not commence until all the additional review and

oversight steps in the following subsections v-viii below have been accomplished.

v. Within 30 calendar days of the institutional review of the research for DURC potential, the Biological Safety Officer, in the role of the ICDUR, shall notify the Appropriate USG Agency of any research that involves one or more of the 15 listed agents and one or more of the seven listed experimental effects (Section 6.2 of the Federal DURC Policy for Institutional Oversight), including whether it meets or does not meet the definition of DURC. This initial notification should include: the grant or contract number related to the research (if the research is funded by the USG); the name(s) of PI(s); the name(s) of the agent(s) listed in Section 6.2.1 of the Federal DURC Policy for Institutional Oversight; and a description of why the research is deemed to produce one or more of the experimental effects listed in Section 6.2.2 of the Federal DURC Policy for Institutional Oversight. For research that is determined by the IRE to meet the definition of DURC, the notification should also include: the name of the investigator (if different from the PI) responsible for the performance of the DURC and a description of the IRE's basis for its determination.

vi. The IRE shall identify the anticipated benefits of the research identified as DURC. The anticipated benefits should be considered in conjunction with the previously identified risks in order to develop a draft risk mitigation plan to guide the conduct and communication of the DURC. A Template Risk Mitigation Plan is provided in Appendix B. The IRE should work with both the PI and Appropriate USG Agency to develop a risk mitigation plan.

vii. Within 90 calendar days of an IRE's determination that the research is DURC, the Biological Safety Officer, in the role of the ICDUR, shall provide a draft risk mitigation plan based on the thorough assessment of the risks and benefits of the research to the Appropriate USG Agency for final review and approval. USG agencies must provide an initial response within 30 calendar days and should finalize the plan within 60 calendar days of receipt of the draft plan.

viii. After a risk mitigation plan is developed and is approved by the Appropriate USG Agency, the Principal Investigator is responsible under Section VIII C. of this Policy to conduct the relevant DURC in accordance with that plan. The IRE shall review, at least annually, all active risk mitigation plans. If the research in question still constitutes DURC, the IRE should work with the PI to modify the plan as needed.

x. The IRE shall notify the Appropriate USG Agency, within 30 calendar days, of: 1) any change in the status of a DURC project at the University (including whether the research is determined by the IRE to no longer meet the definition of DURC), and 2) details of any changes to risk mitigation plans (as such changes are subject to approval by the funding agency).

xi. In cases of collaborations involving multiple institutions via a sub award, the primary institution on the award is responsible for the DURC oversight described in this Section B

including notifying the Appropriate USG 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 collaborating institution's risk mitigation plan. Furthermore, the primary institution shall ensure that DURC oversight is consistently applied by all entities participating in the collaboration.

D. The University's Biological Safety Officer will serve as the ICDUR, 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 6.2 and/or meets the definition of DURC. The ICDUR serves as the liaison between the University and the relevant program officers at the Appropriate USG Agency.

E. The IRE shall maintain records of its 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.

F. The University shall provide education and training on DURC for individuals conducting life sciences research with one or more of the agents listed in Section 6.2.1 of the Federal DURC Policy for Institutional Oversight, and maintain records of such education and training for the term of the research grant or contract plus three years after its completion.

G. The Biological Safety Officer, in the role of the ICDUR, will report instances of noncompliance with the Federal DURC Policy for Institutional Oversight, as well as mitigation measures undertaken by the University to prevent recurrences of similar noncompliance, within 30 calendar days to the Appropriate USG Agency.

H. As necessary, the IRE shall assist the PIs conducting life sciences research when questions arise about whether their research may require further review or oversight.

I. The University's Vice Chancellor for Research shall review any appeal by a PI of IRE decisions or any other University decision regarding research that is determined by the IRE to meet the definition of DURC. The Vice Chancellor for Research shall provide a final ruling on the appeal.

J. The IRE shall make information about the process for review of research subject to the Federal DURC Policy for Institutional Oversight available upon request, as consistent with applicable law.

K. When applying for or accepting USG funds for life sciences research, as applicable, the University shall certify that the University will be or is in compliance with all aspects of the Federal DURC Policy for Institutional Oversight.

VIII. Principal Investigator Responsibilities

A. Notify the IRE as soon as:

i. The PI's research involves nonattenuated forms of one or more of the agents or toxins listed in Section 6.2.1;

And

ii. The PI's research with nonattenuated forms of one or more of the agents or toxins listed in Section 6.2.1 also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven experimental effects listed in Section 6.2.2;

Or

iii. The PI's research that is within the scope of Section 6.2 may meet the definition of DURC.

The notification must include the PI's assessment of whether any research involving these agents or toxins produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2.

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

C. Conduct DURC in accordance with the provisions in the risk mitigation plan.

D. Be knowledgeable about and comply with all University and USG policies and requirements for oversight of DURC.

E. 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 6.2.1 of the Federal DURC Policy for Institutional Oversight have received and documented education and training on DURC.

F. Communicate about 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 about DURC should do so in compliance with the approved risk mitigation plan.

IX. Related Regulations, Statutes and Related Policies

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern was released on September 24, 2014 and takes effect on September 24, 2015.
United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern was released on March 29, 2012 and serves as a complement to the Federal DURC Policy for Institutional Oversight (2014)

X. Contacts

Subject	Contact	Telephone	Email
Dual Use Research of Concern	Garry Coulson, PhD Biological Safety Officer Institutional Contact for Dual Use Research	919-962-5722	garry.coulson@ehs.unc.edu
Dual Use Research of Concern	Mary Beth Koza Director, Environment, Health and Safety Responsible Official for Select Agents and Toxins	919-843-5913	MBKOZA@ehs.unc.edu

Document History

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Appendices

Appendix A: Select Agents and Toxins and Environmental Effects

Fifteen Select Agents and Toxins listed in Section 6.2.1

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

* The Federal DURC Policy for Institutional Oversight contains no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.

Seven experimental effects included in Section 6.2.2

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 and/or agricultural justification
3. 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
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 6.2.1.

Appendix B: Template Risk Mitigation Plan

1) Principal Investigator name and contact information:
2) Study Title:
3) Funding Agency:
4) Associated IBC / Schedule G # (if applicable):
5) Aim of Study:

6) Description of Experimental Design:

7) Characteristics of the agent that will be utilized prior to experimental modifications.

Organism:	Risk Group:
Host Range:	
Virulence:	
Mode of Transmission:	

8) Select the experimental effects that can be reasonably anticipated to occur as a consequence of the proposed experimental design.

	Experimental Effects
☐	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 that agent or toxin 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

9) Elaborate on how the experimental design could result in Dual Use Research of Concern. What are the anticipated consequences of the experiment?

10) What containment level will be utilized?

11) What monitoring will be in place to track the development of an experimental outcome that would constitute significant Dual Use Research of Concern? What actions will be taken if such an experimental effect is observed?

12) Will this study generate information that could be utilized for nefarious intent that would compromise public health, agriculture or the economy?

13) What are the potential benefits of the proposed research?

14) What would occur if there is a failure in containment leading to a laboratory-acquired infection or an environmental release? Consider the most likely consequences as well as reasonable worst case scenarios.

15) What security, containment and safety practices will be utilized to mitigate the risks associated with the proposed experimental design? List SOPs or other pertinent documentation as needed. Will there be any changes to previously approved SOPs?

16) Are there modifications to the experimental design, or alternative experimental designs, that might provide information similar to that being sought in the experiment, but that would entail less risk?

17) What plans have been made for communicating the rationale for, and the results of, the proposed experiments to either professional or lay audiences?