New York University
Policy on Identification and Oversight of Dual Use Research of Concern (DURC)

Effective Date: October 5, 2016

I. Policy Summary & Purpose

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 misused to pose a significant threat with broad consequences to public health and safety, agricultural crops and other plants, animals, the environment, or national security. The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (the "USG Policy") describes the policies, practices, and procedures required to ensure DURC is identified and risk mitigation measures are implemented.

Pursuant to its obligations under the USG Policy, New York University and its School of Medicine and College of Dentistry (collectively, "NYU") must identify and evaluate research that involves one or more of the agents or toxins listed in Group 1 below and produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Group 2 below. For the purposes of the USG Policy and this Policy, there are no exempt quantities.

Group 1: Agents and toxins subject to DURC policy

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (any quantity)
4. *Burkholderia pseudomallei*
5. *Burkholderia mallei*
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*

Group 2: Categories of experimental effects

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 susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above

Research that involves one or more of the agents or toxins listed in Group 1 above must be evaluated for DURC potential and may only be conducted at NYU in accordance with the terms of this Policy. For any research subject to this Policy, NYU's Institutional Review Entity (IRE) will determine whether the research is DURC and will perform the additional review and DURC oversight steps required by this Policy, including implementing an appropriate risk mitigation plan, where appropriate. The Institutional Contacts for Dual Use Research (ICDUR) shall serve as the institutional points of contact for questions regarding compliance with and implementation of the requirements for oversight of NYU research subject to this Policy.

In addition, NYU recognizes that research that does not involve the agents or toxins listed in Group 1 and that does not risk producing the effects listed in Group 2 may still be DURC. The Principal Investigator is responsible for identifying and disclosing to the applicable ICDUR any research that may be DURC. The applicable ICDUR, in consultation with the IRE (if necessary), will determine whether this Policy applies to such research.

All NYU faculty engaging in research subject to this Policy will comply with the requirements of this Policy and any risk mitigation plans implemented hereunder.

II. Policy Scope and Applicability

This Policy covers all research conducted at or under the auspices of NYU that (i) involves one or more of the agents or toxins listed in Group 1 above or (ii) otherwise is determined to be DURC research. This Policy applies to all such research conducted at or under the auspices of NYU Langone ("NYU Langone Research") as well as all such research conducted by other units of New York University, including but not limited to non-NYU Langone Research conducted on the NYU Washington Square campus.

III. Policy

A. **General Policy**. The Principal Investigator of a proposed research project at or under the auspices of NYU has primary responsibility for knowing whether this Policy applies to the research and for not engaging in an activity that requires prior reviews or approvals under this Policy without first seeking and obtaining that review or approval as outlined in this Policy. When the Principal Investigator proposes research that involves one or more of the agents or toxins listed in Group 1 in Section I above, the Principal Investigator must submit a completed registration to the IRE. The IRE is responsible for reviewing and evaluating potential DURC research and for performing the additional review and DURC oversight steps required below, including implementing an appropriate risk mitigation plan, where appropriate. Where the IRE determines that the risks of DURC research outweigh the anticipated benefits and such risks cannot be appropriately mitigated, such research will not be conducted at or under the auspices of NYU.

B. **Institutional Review Entity**. NYU has established an Institutional Review Entity (IRE) and has charged it with executing the requirements in Sections 7.2.B.i-iii, v. and viii and 7.E. of the USG Policy and conducting the reviews contemplated by Section 7.2.B.i-vi of the USG Policy (See Appendix 1: Process for Institutional Review of Life Sciences Research within the Scope of the Policy). Certain responsibilities of the IRE are listed in Section IV below.

C. **IRE Charter**.

i. *Membership*. The IRE is an independent committee comprised of at least five (5) members of the New York University Institutional Biosafety Committee ("IBC") (excluding non-affiliate members) and such other members as may be designated by NYU Langone's Senior Vice President and Vice Dean for Science with input from NYU's Senior Vice Provost for Research

(or his or her designee). All members of the IRE will meet the requirements for IRE membership set forth in Section 7.2.E. of the USG Policy.

ii. *Chair*. NYU's Chair of the IBC will be the Chair of the IRE.

iii. *Quorum*. A majority of members of the IRE is required to be present to conduct official business at a convened meeting.

iv. *Scheduling*. The IRE will meet immediately after regularly scheduled IBC meetings as required.

v. *Records*. Records of institutional DURC reviews and risk mitigation plans will be maintained for the term of the research plus three years after its completion, but not less than eight years, unless a shorter period is required by law or regulation.

vi. *Recusal*. Members of the IRE will be recused from consideration of any research when the member is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the IRE.

vii. *Appeals*. If the IRE determines that the research meets the definition of DURC, the Principal Investigator may appeal the decision to the IRE in writing within five (5) working days of the IRE's notification. Appeals on matters related to NYU Langone Research will be considered by the IRE in good faith, with input from NYU's Senior Vice President and Vice Dean for Science (or his or her designee) and senior leadership in the offices of Research Integrity and Compliance, and Environmental Health & Safety. Appeals on matters related to other NYU Research will be considered by the IRE in good faith, with input from NYU's Senior Vice Provost for Research or his or her designee) and Environmental Health & Safety.

D. **ICDUR.** An Institutional Contact for Dual Use Research (ICDUR) serves as an institutional point of contact for questions regarding compliance with and implementation of the requirements for oversight of NYU research subject to this Policy. At NYU, there are two ICDUR's: one is responsible for NYU Langone Research; the other, for other NYU research. The ICDUR for NYU Langone Research will be NYU Langone's Director of the office of IACUC and IBC or such other individual as NYU Langone's Senior Vice President and Vice Dean for Science (or his or her designee) shall appoint from time to time. The ICDUR for other NYU research will be NYU's Senior Environmental Biosafety Specialist or such other individual as NYU's Senior Vice Provost for Research or his or her designee) shall appoint from time to time.

E. **Training**. Education and training on DURC for individuals conducting life sciences research with one or more of the agents listed in Group 1 of Section I above will be conducted by NYU Langone's Environmental Health & Safety for individuals involved in NYU Langone Research and NYU's Environmental Health & Safety for individuals involved in NYU Research. Training must be completed before any investigator may participate in any research subject to this Policy. Records of such education and training will be maintained by Environmental Health & Safety for the term of the research plus three years after completion.

F. **Non-Compliance.** Non-compliance with the USG Policy and this Policy may result in suspension of the research, suspension, limitation, or termination of USG or other funding, or loss of future funding opportunities for the non-compliant USG-funded research project and the loss of USG funds for other research at NYU. It may also subject the institution to other potential penalties under applicable laws and regulations.

Instances of noncompliance with the USG Policy, as well as mitigation measures undertaken by NYU to prevent recurrences of similar noncompliance, must be reported within thirty (30) calendar days to the applicable sponsoring agency of the U.S. Government. In the case of non-USG funded research, reports of non-compliance will be made to the USG agency designated by the NIH.

Reports of non-compliance related to NYU Langone Research to applicable sponsoring agencies will involve senior leadership in the Office of Science and Research, Research Integrity and Compliance, the Chair of the IRE, the applicable ICDUR, and Environmental Health & Safety, as applicable.

Reports of non-compliance related to other NYU research to applicable sponsoring agencies will involve senior leadership designated by the Senior Vice Provost for Research, the Chair of the IRE, the applicable ICDUR, and Environmental Health & Safety, as applicable.

IV. Responsibilities

A. **NYU Langone's Office of Science & Research**. NYU Langone's Vice Dean for Science, with the support of the applicable ICDUR, is responsible for informing the appropriate Department Chairs at NYU Langone Medical Center of their responsibilities under this Policy, and for all institutional reporting and notifications required by the USG Policy.

B. **NYU's Senior Vice Provost for Research**. NYU's Senior Vice Provost for Research, with the support of the applicable ICDUR, is responsible for informing the appropriate NYU School Deans of their responsibilities under this Policy, and for all institutional reporting and notifications required by the USG Policy.

C. **Responsibilities of NYU Langone Department Chairs/ NYU School Deans**. NYU Langone Department Chairs for NYU Langone Research and NYU's School Deans for other NYU research are responsible for:

1. Informing all faculty of the existence of this Policy and its requirements regarding potential DURC research, and the existence of the IRE, and ensuring that the appropriate faculty receive all pertinent information (e.g., copies of the IRE policies, guidelines and procedures). Should a Department Chair or School Dean not have this information, it may be obtained from the applicable ICDUR or Environmental Health & Safety.

2. Directing researchers to complete pertinent training and to register with the IRE as specified in this Policy.

3. Reporting in a timely manner to the IRE or the applicable ICDUR any instances of non-compliance with this Policy or with IRE-approved DURC risk mitigation plans to which the Department Chair or School Dean becomes aware, or any other occurrence(s) or development of the research that could raise DURC concerns.

4. For NYU Langone Research, addressing issues of non-compliance in consultation with the Office of Science and Research, Research Integrity and Compliance, the Chair of the IRE, the applicable ICDUR, and Environmental Health & Safety, as applicable.

5. For other NYU Research, addressing issues of non-compliance in consultation with senior leadership designated by the Senior Vice Provost for Research, the Chair of the IRE, the applicable ICDUR, and Environmental Health & Safety, as applicable.

D. **Responsibilities of Principal Investigator**. Principal Investigators are responsible for:

1. Registering proposed research involving one or more of the agents or toxins in Group 1 in Section I above to the IRE for review, before initiation of the research.

2. Identifying and disclosing to the applicable ICDUR any other research that may be DURC and subject to the requirements of this Policy.

3. Conducting an initial assessment of proposed research with Group 1 agents or toxins for DURC potential (i.e., assessing whether the proposed research aims to produce or is reasonably anticipated to produce one or more of the effects listed in Group 2 above) and providing a description of the assessment and determination as part of the IRE registration and before initiation of research.

4. Conducting on-going assessments for DURC potential regardless of the initial IRE determination. If, at any time, a Principal Investigator determines that his or her research with one or more of the Group 1 agents or toxins produces or could reasonably be anticipated to produce one or more of the Group 2 effects, the Principal Investigator shall be responsible for immediately notifying the ICDUR, providing an updated IRE registration form, and suspending potential DURC research until a determination has been made.

5. Implementing and complying with all requirements of IRE-approved DURC risk mitigation plans.

6. Immediately reporting to the IRE or the ICDUR any instances of non-compliance with IRE-approved DURC risk mitigation plans to which the Principal Investigator becomes aware, or any other occurrence(s) or development of the research that could raise DURC concerns.

7. Notifying in a timely manner the IRE or the applicable ICDUR of any change in the status of DURC research at NYU.

It is the PI's responsibility to be the expert on agents used in his or her laboratory or under his or her supervision. If there are any concerns regarding DURC potential of <u>any</u> agent proposed to be used under the supervision of the Principal Investigator, including but not limited to, elements of a potential DURC project that are carried out at other institutions through a subaward in which NYU is the primary institution (i.e., where NYU or NYU School of Medicine directly receives the grant or contract from the applicable sponsoring agency of the U.S. Government or another sponsor), the Principal Investigator should contact the IRE or the applicable ICDUR promptly, but in any event within 30 calendar days.

E. **Responsibilities of the IRE**. Among other things required by the USG Policy, the IRE is responsible for:

1. Verifying whether research submitted to it involves any of the listed agents in Group 1 of Section I above.

2. Reviewing submitted research and Principal Investigator's initial and on-going assessments for DURC potential.

3. Making a final determination of the applicability of the list of experimental effects listed in Group 2 of Section I above.

4. Conducting a risk assessment to determine whether submitted research meets the definition of DURC.

5. Identifying the anticipated benefits of submitted research identified as DURC research and assessing whether such benefit outweigh the risks of performing the research.

6. Developing a risk mitigation plan, with the support of the applicable ICDUR and the office of Environmental Health & Safety, to guide the conduct and communication of the DURC and submitting the same to the applicable sponsoring agency for final review and approved, where required.

7. Reviewing at least annually, all active DURC risk mitigation plans.

V. Violations

Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with NYU, in accordance with the applicable NYU disciplinary policies and procedures.

VI. Relationship to Other Policies

This Policy replaces NYU Langone Medical Center's *Policy on Identification and Oversight of Dual Use Research of Concern* dated September 24, 2015.

Resources

- FAQs on the U.S. Government Policy for Institutional Oversight of Life Sciences DURC
- U.S. Government Policy for Institutional Oversight of Life Sciences DURC
- A Companion Guide to the U.S. Government Policies for Oversight of Life Sciences DURC
- Federal Register: Notice Response to Comments and Notice of Final Action Regarding the United States Government Policy for Institutional Oversight of Life Sciences DURC
- Case Studies on the Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC
- National Institutes of Health (NIH) Office of Science Policy: DURC
- NIH: National Science Advisory Board for Biosecurity (NSABB)
- U.S. Department of Health and Human Services

APPENDIX I

Process for Institutional Review of Life Sciences Research within the Scope of the Policy