Final – February 10, 2015

COLUMBIA UNIVERSITY POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN

Update as of May 13, 2025. *On January 10, 2025, NIH issued NOT-OD-25-061 to provide guidance implementing the U.S. Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) that was announced in May 2024 (May 2024 Policy). The NIH guidance was to take effect on May 6, 2025. However, on May 7, 2025, NIH rescinded that guidance via NOT-OD-25-112, in light of the May 5, 2025 Executive Order on Improving the Safety and Security of Biological Research. Section 7 of the Executive Order states that, within 120 days, the Director of the Office of Science and Technology Policy will revise or replace the May 2024 Policy. Accordingly, Columbia's pre-existing policy – set forth below – will remain in effect until new federal guidance is issued. In the meantime, recipients of federal funding should ensure that their work complies with the terms and conditions of their specific awards. Columbia's Office of the Executive Vice President for Research will continue to monitor federal developments and provide additional guidance as appropriate. Please contact biosafety@columbia.edu with any questions.*

I. BACKGROUND

Despite its value and benefits, certain types of research conducted for legitimate purposes can 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 and is defined 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."

On March 29, 2012, the U. S. Government ("USG") released the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern [http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf] to establish the requirements for the oversight of DURC by the USG. On September 24, 2014, the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (the "2014 Policy") [http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf] was released to establish the requirements for institutional (i.e., non-USG) oversight of DURC. The USG considers these two Policies to be complementary.

The following additional USG documents that have been issued in connection with the 2014 Policy and provide guidance in understanding the regulations:

- Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern (the "Companion Guide") http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf.
- Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies http://www.phe.gov/s3/dualuse/Documents/12-case-studies-durc.pdf.
- Training on the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern http://www.phe.gov/s3/dualuse/Documents/durc-us-policy-trng.pdf.

See also the National Institutes of Health ("NIH") Notice NOT-CD-15-017: NIH Implementation of the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern issued on November 21, 2014.

II. PURPOSE

The purpose of this Policy is to strengthen the institutional review and oversight by Columbia University ("Columbia" or the "University") of certain research to identify potential DURC and to develop and implement risk mitigation where appropriate. In so doing, this Policy seeks to preserve the benefits of life sciences DURC research while minimizing the risk that the output of such research would be used for harmful purposes.

This Policy sets forth explicit instructions for individuals and committees at Columbia who are responsible for the implementation of the University's requirements with respect to DURC.

All research conducted at the University involving DURC Agents (as defined in Section III below) is subject to this Policy, regardless of the source of funding.

III. DEFINITIONS

For purposes of this Policy, certain terms are defined as follows:

Dual Use Research: as defined in Section I.

DURC: as defined in Section I.

DURC Agents: the following 15 agents and toxins referred to in the 2014 Policy:

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

Experimental Effects of Concern: the following 7 categories of experiments referred to in the 2014 Policy:

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or 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 the definition of DURC Agents above.

IBC: the Columbia University Institutional Biosafety Committee

ICDUR: Institutional Contact for Dual Use Research, who is 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 University has designated the Associate Vice President for Environmental Health and Safety as the ICDUR.

IRE: Institutional Review Entity.

US Funding Agency: the USG agency that is funding the subject research or, if the research is not USG-funded, the USG agency designated by the NIH, based on the nature of the research. If a federal department or agency simply passes through funding from another federal department or agency to support life sciences research involving one or more of the DURC Agents, the agency originally providing the funding shall be considered the US Funding Agency.

IV. POLICY REQUIREMENTS FOR PRINCIPAL INVESTIGATORS

A Principal Investigator ("PI") must submit for institutional review any of his/her research that meets any of the following criteria:

- The research directly involves nonattenuated forms of one or more of the DURC Agents;
- The research with nonattenuated forms of one of more of the DURC Agents that also produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern; or
- The PI concludes that his/her research may meet the definition of DURC.

If a PI's research meets (or future research during the grant writing phase) any of the foregoing criteria, he/she will also assess whether the research produces, aims to produce or is reasonably anticipated to produce one of more of the Experimental Effects of Concern. Upon completion of such assessment, he/she will promptly notify the IBC by contacting Environmental Health and Safety ("EH&S") and provide the IBC with documentation indicating the reasons for his/her conclusion that his/her research involves potential DURC and sufficient data to permit the IBC to complete the review required by Section V below.

The PI's self-screening will be assisted by

- Sponsored Projects Administration (SPA), which will include a question in the Rascal proposal tracking module as to whether the proposed research involves a DURC Agent.
- Columbia Technology Ventures (CTV), which will ask the same question as part of its review of Material Transfer Agreements.
- Procurement, which processes Select Agent purchases.

If a DURC Agent is identified by any of the foregoing methods, it should be reported to EH&S. EH&S will also conduct periodic reviews of the information collected by SPA, CTV or Procurement.

V. POLICY REQUIREMENTS FOR INSTITUTIONAL REVIEW

The 2014 Policy requires an institution to designate an IRE to execute the institutional review of potential DURC Research. At Columbia, the IRE is made up of two committee components: (1) the IBC and (2) an *ad hoc* committee (an "Ad Hoc Committee") established by the Executive Vice President for Research ("EVPR"). The roles of the IBC and the Ad Hoc Committee are delineated below.

A. Review by the IBC

The first step of the IBC review process is to verify that the subject research directly involves nonattenuated forms of one or more of the DURC Agents based on the materials provided by the PI and any other relevant materials. The USG also deems any of the following not intended for review under the 2014 Policy:

- The use of any of the DURC Agents in attenuated forms (unless the experiment will reconstitute a virulent agent);

- The use of the genes from any of the DURC Agents;
- *In silico* experiments (e.g., modeling experiments, bioinformatics approaches) involving the biology of the DURC Agents); or
- Research relating to the public, animal and agricultural health impact of any of the DURC Agents (e.g., modeling the effects of a toxin, developing new methods to deliver a vaccine, developing surveillance mechanisms for a DURC Agent).

Questions regarding the determination as to whether any research constitutes DURC may be addressed to the program officer at the applicable US Funding Agency.

Based on the foregoing, if the IBC concludes that the research is not subject to additional DURC oversight, it will so notify the PI in writing.

If the IBC concludes that the research does involve one or more DURC Agents, it will assess whether the research produces, aims to produce or is reasonably anticipated to produce one of more of the Experimental Effects of Concern based on the materials provided by the PI and any other relevant materials.

Based on the foregoing, if the IBC concludes that the research is not subject to additional DURC oversight, it will so notify the PI in writing.

If the IBC concludes that the research does involve one or more DURC Agents and Experimental Effects of Concern, the IBC will refer the review to the EVPR (and notify the PI that it has done so).

B. Review by the Ad Hoc Committee and the EVPR

Promptly after notification from the IBC, the EVPR will convene an Ad Hoc Committee, whose members will include appropriate internal and/or external experts, the Vice President for Research Operations, the IBC Chair and representatives of EH&S and the Offices of the General Counsel, Research Compliance and Training and Public Safety. The choice of members will be made by the EVPR in consultation with the PI and EH&S.

The first step of the Ad Hoc Committee review process is to assess the risks of dual use and determine whether the research is DURC. In so doing, it should examine descriptions of the research, the PI's assessments and other relevant information such as the project proposal, any project reports, any previous outcomes of Dual Use reviews and examples of similar research in the literature. When considering whether the research in question meets the definition of DURC, the Ad Hoc Committee will first identify the risks associated with the potential misuse of the knowledge, information, technologies or products (collectively, the "Research Output") that may be generated and will assess the following:

- The *ways* in which the Research Output could be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel or national security;
- The *ease with which* the Research Output might be misused and the feasibility of such misuse; and
- The *magnitude, nature and scope* of the potential consequences of misuse.

Guidance on points to consider while making this assessment can be found in Section C.3.2 of the Companion Guide. The applicable US Funding Agency may be consulted for advice.

If the Ad Hoc Committee determines that the subject research does not meet the definition of DURC, it is not subject to additional institutional oversight and the Chair of the Ad Hoc Committee will promptly so notify the PI and, within 30 days, the applicable US Funding Agency. The Chair of the Ad Hoc Committee and/or the ICDUR may consult with the USG Funding Agency with respect to the Committee's determination.

If the Ad Hoc Committee concludes that the subject research does meet the definition of DURC, it will promptly so notify the PI and within 30 calendar days, the applicable US Funding Agency, and shall proceed to develop a risk mitigation plan.

In order to determine the acceptable level of risk associated with the DURC and the best mitigation strategies, the Ad Hoc Committee should assess the potential benefits of the Research and then weigh the risks and benefits. Guidance on points to consider in making this assessment can be found in Section C.3.2 of the Companion Guide.

The next step for the Ad Hoc Committee is to develop a draft risk mitigation plan (the "Risk Mitigation Plan") in consultation with the PI. The Plan should indicate the DURC-associated risks, the specific risk mitigation measure to be employed and how these measure address the identified risks. Strategies for mitigating risks include:

- Applying additional biosafety or biosecurity measures
- Modifying the experimental design or methodology
- Planning for medical countermeasures
- Determining a plan for responsibly communicating the research findings
- Educating and training research staff
- Developing a specific monitoring plan
- Not conducting certain aspects of the research.

Guidance on points to consider in drafting a Risk Mitigation Plan and in creating a responsible communication plan can be found in Sections D and F of the Companion Guide. The applicable US Funding Agency may also be consulted for advice.

At the conclusion of its review, the Ad Hoc Committee will submit its findings and its recommendations as to the elements of the draft Risk Mitigation Plan to the EVPR. The EVPR will decide whether or not to act on the recommendations of the Ad Hoc

Committee as to whether the research constitutes DURC and the adequacy of the Committee's draft Risk Mitigation Plan and may require revisions to the draft Plan.

The EVPR's decision and any other institutional decision regarding DURC may be appealed by the affected PI to the Provost. The Provost will have the final word as to all institutional decisions regarding DURC that have been appealed.

C. Notification to the USG Funding Agency

Within 90 calendar days following the final institutional approval of the draft Risk Mitigation Plan by the EVPR (or the Provost), the ICDUR shall submit such draft Plan to the applicable USG Funding Agency for final review and approval. The USG Funding Agency must provide an initial response within 30 calendar days following receipt of the draft Plan. The ICDUR and the PI will work with the USG Funding Agency to respond to any questions or concerns it may have regarding the draft Risk Mitigation Plan. The USG Funding Agency must finalize the Plan within 60 days following receipt of the draft Plan. The EVPR must also approve the final Risk Mitigation Plan.

D. Subawards

If elements of a potential DURC Research project are being carried out at multiple institutions through a subaward with a primary institution that directly receives the grant or contract from the US Funding Agency (the "Prime Institution"), the Prime Institution will be responsible for notifying the applicable US Funding Agency of research that may constitute DURC and if such research is determined to be DURC, providing copies of each institution's Risk Mitigation Plan. The Prime Institution should also ensure that DURC oversight is consistently applied by all entities participating in the collaboration. If the Prime Institution's procedures or standards are less rigorous than Columbia's, the more rigorous standard will be applied.

VI. ONGOING INSTITUTIONAL RESPONSIBILITIES

1. Responsibilities of the PI

The PI will:

- Conduct DURC Research in accordance with the final Risk Mitigation Plan;
- Notify the ICDUR of the addition of any DURC Agents or Experimental Effects of Concern, or any other substantive change in the conduct of the DURC Research;
- Notify the IBC if for whatever reason (e.g., changes in the research, new discoveries), he/she feels that the research should be reconsidered by the IBC because it might constitute DURC, or is no longer DURC; and
- 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 research with one of more of DURC Agents have received education and training on DURC.

2. Responsibilities of the ICDUR

The ICDUR shall:

- Ensure that the IBC reviews each DURC Research Risk Mitigation Plan annually;
- Provide education and training on DURC for individuals conducting research with one or more of the DURC Agents and maintain records of such education and training for the term of the research grant or contract plus three years after its completion;
- Maintain records of institutional DURC reviews and completed Risk Mitigation Plans for no less than eight years, unless a shorter period is required by law or regulation;
- Notify the applicable US Funding Agency within 30 calendar days of any change in the status of any DURC, including whether such Research has been determined by the IBC to no longer meet the definition of DURC. The notification should include details of any changes to an approved Risk Mitigation Plan, which must be approved by the US Funding Agency; and
- Report within 30 calendar days to the applicable US Funding Agency instances of noncompliance with this Policy, as well as mitigation measures undertaken by the University to prevent recurrences of similar noncompliance.

3. Responsibilities of the IBC

The IBC shall review, at least annually, all active Risk Mitigation Plans at the University. In reviewing such Plans, the IBC will follow the same procedures as are described in Section II(A) of this Policy. If the research in question still constitutes DURC, the IBC, working with the PI, should modify the applicable Risk Mitigation Plan as needed to ensure that the Plan still adequately mitigates the risks associated with the DURC.