Barnard College
Policy for Institutional Oversight of Life Sciences
Dual Use Research of Concern (DURC)

Purpose of Policy

This policy ensures that Barnard College identifies Dual Use Research of Concern (DURC) and implements risk mitigation measures, as warranted. It applies to all research projects, regardless of the funding source, that involve one or more of 15 listed agents or seven categories of experiments listed below.

Policy Background

Barnard's policy was developed in response to the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, which requires institutional oversight of "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."

Additional guidelines developed by the U.S. Government that are relevant to DURC, including a companion guide with specific information for principal investigators (PIs), can be found here.

The following 15 agents and toxins, referred to in the 2014 U.S. Government policy, are considered to be DURC agents. Barnard College will evaluate research that involves any quantity of these for DURC potential:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin
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*

The 2014 U.S. Government policy also refers to seven categories of experiments of concern. Barnard will evaluate research that involves any of these:

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; or
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

Note that the following are *not* intended for review:

- 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).

Barnard Policy and Procedures

Barnard College has designated Angie Tse, Director of Laboratory Building Operations, as the Institutional Contact for DURC (Institutional Contact). She will respond to questions relating to compliance with this policy and serve as the liaison with the Columbia University Institutional Biosafety Committee. The Senior Director of Sponsored Research will work with the Institutional Contact to communicate with relevant funding agencies, as necessary, throughout the process described below.

Principal investigators are responsible for promptly alerting the Institutional Contact about research that meets the following criteria:

- Current or planned research directly involving one or more of the DURC Agents listed above; or
- Current or planned research with one of more of the DURC Agents that could be reasonably anticipated to involve one or more experimental effects of concern listed above; or
- The PI believes that his/her current or planned research might meet the definition of DURC.

PIs whose current or planned research meets any of the foregoing criteria should promptly notify the Institutional Contact, who will work with the PI to gather documentation to permit an initial review. This documentation might include the research proposal and reports as well as examples of similar research in the literature. If the Institutional Contact determines that the research may be subject to additional DURC oversight, she will work with the Columbia University Institutional Biosafety Committee to determine whether Barnard needs to conduct an institutional review. If an institutional review is warranted, the Institutional Contact will convene

an Ad Hoc Committee (the Committee) of appropriate College and external experts as well as representatives from Barnard's Offices of the Provost, Auxiliary Services, Facilities, Community Accountability, Response & Emergency Services (CARES), Sponsored Research, and the Office of General Counsel.

The Committee will use U.S. Government guidelines to assess the risks of dual use and determine whether the research is DURC. The Committee will notify the PI and any applicable funding agency of its determination. If the Committee concludes that the research does meet the definition of DURC, it will develop a draft risk mitigation plan, in consultation with the PI, within 30 calendar days and according to U.S. Government guidelines.

The mitigation plan will identify the DURC risks and specific mitigation measures to be employed, such as modifying the experimental design or methodology, educating and training research staff, and developing a detailed monitoring plan. The Committee will submit the draft plan to the Provost for review and approval.

The Senior Director of Sponsored Research will submit the plan for review to the applicable funding agency within its required timeframe and work with the Institutional Contact and PI to respond to any questions and to make necessary revisions.

The PI must conduct the research in accordance with the approved risk mitigation plan, notify the Provost of any substantive changes in the research, and ensure that all research personnel are fully trained on and conduct research within the parameters of the approved plan. The Committee will review the risk management plan, in consultation with the PI, at six-month intervals during the research project period and make recommendations and modifications, as necessary. All modifications will be approved by the Provost and communicated to applicable funding agencies.