



POLICY ON INSTITUTIONAL DUAL USE RESEARCH OF CONCERN (DURC)

Date: *March 19, 2015*

Supersedes: None

I. PURPOSE

Life sciences research has innumerable benefits; however, certain types of research have the potential to generate information that could be used for harmful and/or illicit purposes. The United States Government (USG) Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) was developed to establish review procedures and oversight policies to evaluate research for possible risks, as well as benefits, and to engage the research community and funding agencies to emphasize the importance of upholding the integrity of science and prevent its misuse. New York Medical College (NYMC) has instituted this policy to establish procedures that will provide dual use awareness, identification of research that raises dual use concerns, a research review process and DURC determination, as well as risk mitigation development in compliance with the DURC regulations.

II. POLICY

All work with non-attenuated Listed Agents must be registered with NYMC's Institutional Biosafety Committee (IBC) and must be screened for the seven categories of experimental effects listed by the USG. Any work that is determined to fall into one or more of the seven categories or that meets the definition of DURC must be reviewed by the IBC (who also functions as NYMC's Institutional Review Entity (IRE)). The IRE will verify the initial assessment and make the final determination of the applicability of the DURC regulations to the project. Any failure to comply with this policy may result in disciplinary action, up to and including the immediate loss of approval to conduct research involving Listed Agents. Investigators and their staff who conduct research on any of the Listed Agents must be trained on DURC and on this policy.

III. SCOPE

This policy applies to all NYMC faculty, staff, students, volunteers, space licensees, and contractors, regardless of the source of funding.

IV. DEFINITIONS

Dual Use Research of Concern: 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, material, or national security.

Institutional Review Entity: An Institutional Committee that conducts reviews of research for dual use potential. It must be composed of at least 5 members, be empowered by the Institution to ensure it can execute requirements of the Dual Use regulations, have sufficient expertise to assess dual use potential, and include persons with knowledge of relevant US government policies and understanding of risk assessment and risk management, including biosafety and biosecurity.

Listed Agents: The fifteen agents and toxins listed in the *Policy for Oversight of Life Sciences Dual Use Research of Concern, March 2012*.

Risk Mitigation Plan: The process of tracking identified risks, identifying new risks, and developing actions to reduce threats.

Seven Categories of Experimental Effect: The seven categories of experiments that need to be reviewed for DURC in the *Policy for Oversight of Life Sciences Dual Use Research of Concern, March 2012*.

V. PROCEDURES

A. Identification and Initial Assessment.

The Principal Investigator (PI) must promptly register with the IBC and assess research that involves any of the Listed Agents, which include:

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (in any quantity)
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Reconstructed 1918 influenza
- Rinderpest virus
- Toxin-producing strains of *Clostridium botulinum*
- *Variola major* virus
- *Variola minor* virus
- *Yersinia pestis*

The initial assessment must determine whether the research will produce or can be reasonably anticipated to produce one or more of the seven categories of experimental effects listed below:

- 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; and
- Generates or reconstitutes an eradicated or extinct listed agent or toxin

The initial assessment must result in a conclusion of whether the research meets the definition of DURC.

B. Review

Upon receipt of a registration with a listed agent, the IBC will verify that work is with a non-attenuated form and will review the PI's initial assessment regarding whether the work produces or is reasonably anticipated to produce one or more of the listed categories of experimental effects. The IBC, functioning as the IRE, will conduct a risk assessment that includes the risks and benefits of the research. The IRE will make the final determination of whether the research meets the scope of this policy. Things that will be considered include (but are not limited to):

- The ways in which knowledge, technologies, or products could be misused;
- The ease that these items might be misused;
- The magnitude of the potential consequence of misuse

C. Risk Mitigation

For research determined to meet the scope of the DURC regulations, a draft risk mitigation plan will be developed by the IRE, in consultation with the Office of the General Counsel, Environmental Health & Safety and the Office of Research Administration, that will adequately manage identified risks. The risk mitigation plan will include but not be limited to:

- Biosafety and biosecurity measures;
- Available countermeasures (i.e. drugs, public health practices, etc.);

- Plans for responsibly communicating the research findings (e.g. assessing whether redaction is necessary, whether it should be serially published ;
- Education and training of staff regarding DURC concerns;
- Monitoring and re-review research projects (i.e., after certain experimental outcomes).

A copy of the draft risk mitigation plan will be submitted to the respective USG funding agency within 90 days of the IRE's determination that the research does comprise DURC for review and final approval.

VI. EFFECTIVE DATE

This policy is effective as of the date signed below.

VII. POLICY RESPONSIBILITIES

- A. New York Medical College faculty, contractors and/or volunteers.
1. Identify research with listed agents, and register the work with the IBC
 2. Assess projects with listed agents to determine if they fall into one or more of the listed 7 categories of experimental effects.
 3. Notify the IBC if changes to the research that could produce any of the listed seven categories of effects.
 4. Report any non-compliance issues to the IBC.
- B. Department of Environmental Health & Safety
1. Prepares and conducts training on Dual Use Research of Concern.
 2. Ensures that research with listed agents is registered with the IBC.
 3. Reports any non-compliance issues to the IBC.
 4. Acts as the Institutional point of contact for funding agencies regarding questions about DURC and implementation of the US DURC Policy.
 5. Reports research that meets the scope of the DURC regulations to the applicable funding agency and any changes in the research after approval within 30 days.
- C. Institutional Biosafety Committee
1. Functions as the Institutional Review Entity.
 2. Verifies work with non-attenuated agents and reviews initial DURC assessments.
 3. Performs risk assessments and makes the final determination of whether research falls under DURC requirements.
 3. Develops and revises DURC risk mitigation plans.
 4. Reviews active risk mitigation plans, at least annually.

VIII. POLICY MANAGEMENT

Responsible Executive: Vice President of Operations
Responsible Officer: Director, Environmental Health & Safety
Responsible Department: Environmental Health & Safety

APPROVED:

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Edward C. Halperin, M.D., M.A.
Chancellor for Health Affairs and
Chief Executive Officer

3/20/15

Date