



## POLICY ON REPORTING RESEARCH-RELATED INCIDENTS INVOLVING RECOMBINANT DNA AND BIOHAZARDOUS MATERIALS

*Dated:* October 2, 2015

*Supersedes:* None

### I. PURPOSE

New York Medical College (NYMC) is fully committed to the health and safety of individuals who conduct research with recombinant DNA (rDNA) and biohazardous materials, as well as maintaining a research environment compliant with the National Institutes of Health's *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ("NIH Guidelines") and all other applicable federal, state and local regulations.

### II. POLICY

Reporting research-related incidents involving rDNA and/or biohazardous materials in a timely manner is a critical component of maintaining a safe research environment, and is required by both the National Institutes of Health (NIH) and NYMC policies. This policy requires the reporting of any incidents involving rDNA and/or biohazardous materials, and any violations of the NIH Guidelines or any significant research related accidents and illnesses to the Institutional Biosafety Officer, the IBC, and, when necessary, the NIH's Office of Biotechnology Activities (OBA), and any other appropriate authorities.

### III. SCOPE

This policy applies to all NYMC faculty, staff, students, volunteers, space licensees, and contractors utilizing recombinant DNA and/or biohazardous materials, regardless of the source of project funding.

### IV. DEFINITIONS

***Biohazardous Materials:*** Potentially infectious materials or recombinant agents that are classified amongst Risk Groups 2 or 3 as defined by the *NIH Guidelines*.

***Biosafety Level:*** Levels of protection in ascending order (numerically designated from 1-4) by the degree of protection provided to personnel, the environment, and the

community. Standard microbiological practices are common to all levels; specialized practices and means of physical containment enhance worker safety, environmental protection and address the risk of handling agents requiring increasing levels of containment.

**NIH Guidelines:** The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (“NIH Guidelines”) specify the practices required for constructing and the safe handling of recombinant nucleic acid molecules, synthetic nucleic acid molecules (including those that are chemically or otherwise modified but can base pair with other naturally occurring nucleic acid molecules, and cells, organisms and viruses containing such molecules).

**Potential Exposure:** Any irregular contact with a BSL-3 biological agent (recombinant or wild-type). According to the NIH rDNA guidelines, this contact would be reportable to NIH Office of Biotechnology Activities (NIH OBA). Examples of potential exposures to a BSL-3 agent are any accidents, spills outside of containment, equipment failure, or splash to intact skin.

**Overt Exposure:** Any contact between mucous membrane with a BSL-2 or BSL-3 organism and/or open skin, a skin puncture with a needle containing rDNA, and/or biohazardous material. According to the NIH rDNA guidelines, this contact would be reportable to NIH OBA. Examples of overt exposures are skin punctures with needles containing rDNA or splashes of rDNA agent affecting mucous membranes or non-intact skin.

**Recombinant/Synthetic Nucleic Acid Molecules:** In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:

- Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, *i.e.* recombinant nucleic acids;
- Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, *i.e.* synthetic nucleic acids, or;
- Molecules that result from the replication of those actions described above.

**Recombinant DNA Incident:** Section IV-B-2-b-(7) of the NIH Guidelines states that IBCs should report “any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses” to NIH OBA within 30 days. Appendix G of the NIH Guidelines specifies certain types of accidents that must be reported on a more expedited basis. According to Appendix G-II-B-2-k, spills or accidents in BSL-2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA (as well as to the Institutional Biosafety Officer). According to

Appendix G-II-C-2-q and Appendix G-II-D-2-k, spills or accidents occurring in high containment (BSL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA (as well as the IBC, and BSO).

**Risk Group (RG):** Risk Group Classification criteria as defined by the World Health Organization (WHO) and utilized by the CDC and NIH.

- **Risk Group 1 (RG1):** no or low individual and community risk. A microorganism that is unlikely to cause human disease or animal disease
- **Risk Group 2 (RG2):** Moderate individual risk, low community risk. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited.
- **Risk Group 3 (RG3):** High individual risk, low community risk. Effective treatment and preventive measures are available.
- **Risk Group 4 (RG4):** High individual and community risk. Effective treatment and preventive measures are not usually available.

## V. PROCEDURES

### A. Post-Incident Procedures

1. Exposed personnel must follow appropriate response plans for exposure prophylaxis that include seeking medical attention as necessary. Exposures, injuries and/or illness must be reported to Health Services. During non-business hours, incidents can be reported to the Infectious Diseases physician on-call.
2. Exposures, injuries (including animal bites by animals intentionally infected with RG2 agents) and/or occupational illnesses (both suspected and confirmed) must be reported to the Principal Investigator and/or lab Supervisor, the Institutional Biosafety Officer, and the Department of Health Services.
3. Spills involving rDNA and/or biohazardous materials outside of containment must be reported to EH&S, contained, and cleaned up appropriately.

### B. Reportable Incidents & Timelines

1. The following incidents should be reported immediately to the Institutional Biosafety Officer (and, for any incidents occurring at BSL-3, to the Responsible Official):

- a. Spills or accidents at BSL-2 resulting in an overt exposure, injury, and/or illness, or bites from/exposures to animals intentionally infected with RG2 agents;
- b. Spills or accidents at BSL-3 resulting in an overt or potential exposure, injury or illness;
- c. Release of a RG2 or RG3 agent or genetic material from a primary containment device (e.g. biosafety cabinet, centrifuge, primary container) into the laboratory;
- d. Spills or accidents that lead to personal injury and/or a breach of containment
- e. Failure to adhere to the containment and biosafety practices in the NIH Guidelines.

## 2. Prescribed Reporting Timelines

- a. Section IV-B-2-b-(7) of the NIH Guidelines states that "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" must be reported to the Office of Biotechnology Activities (OBA) within 30 days.
- b. Appendix G of the NIH Guidelines specifies that certain types of accidents/incidents (i.e. "1.a" and "1.b") must be reported immediately. A follow-up report will be submitted as needed.

## C. Incident Reporting Responsibilities

1. The Principal Investigator for the involved personnel is ultimately responsible for immediately reporting the incident to the Institutional Biosafety Officer. The Institutional Biosafety Officer will contact the Director of Environmental Health & Safety/Responsible Official, the IBC Chairperson, the Director of Comparative Medicine, and the Office of Research Administration on an as-needed basis.
2. The individual who experienced the incident is responsible for completing a Laboratory Exposure Incident Report Form (Appendix 1). The form must be completed in a timely manner (as determined by the nature of the incident and any applicable agency reporting timelines). The form will then be provided to the IBC for review.
3. The IBC will review the incident (including any supplemental information that is provided by the Institutional Biosafety Officer as a result of her/his investigation) and may make recommendations for

corrective actions in addition to those proposed by the Institutional Biosafety Officer.

4. The Institutional Biological Safety Officer will submit the final incident report to the appropriate federal agency on NYMC's behalf. The final incident report will be reviewed by the IBC, who will also review all prescribed corrective actions.
5. Copies of the incident report will be provided to the departmental Chair, the appropriate Dean, and the Office for Research Administration.

## **VI. EFFECTIVE DATE**

This policy is effective as of the date signed below.

## **VII. POLICY RESPONSIBILITIES**

### **A. Principal Investigators**

1. Ensure that all work with rDNA and/or biohazardous materials is appropriately registered with the IBC;
2. Ensure that he/she as well as all staff working on projects involving rDNA has completed NYMC's NIH Guidelines training;
3. Report all incidents with rDNA and/or biohazardous materials to the Institutional Biosafety Officer.

### **B. Department of Environmental Health & Safety**

1. Prepare and conducts training NIH Guidelines;
2. Ensure that research with rDNA and/or biohazardous materials is registered with the IBC;
3. Ensure that individuals working with rDNA have been appropriately trained.

- ### **C. Institutional Biosafety Committee - review all research incidents involving biohazardous materials and/or rDNA and makes recommendations for corrective actions.**

VIII. POLICY MANAGEMENT

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

APPROVED:

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

10/2/15  
Date