



POLICY ON THE USE OF RECOMBINANT AND SYNTHETIC NUCLEIC ACID MOLECULES AND BIOHAZARDOUS AGENTS

Date: October 2, 2015

Supersedes: *Policy on the Use of Recombinant and Synthetic Nucleic Acid Molecules and Biohazardous Agents dated June 2, 2014*

References: *Policy on Reporting Research-Related Incidents Involving Recombinant DNA and Biohazardous Materials, dated October 2, 2015*

I. PURPOSE

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

II. POLICY

The National Institutes of Health (NIH) has established strict guidelines that specify the practices and procedures required for the construction, containment, and handling of recombinant and synthetic nucleic acid molecules. All research involving recombinant or synthetic nucleic acid molecules and/or biohazardous agents must be registered with and approved by the Institutional Biosafety Committee (IBC) and all containment levels and work practices must comply with the *NIH Guidelines*, the Center for Disease's Control's (CDC) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), and all NYMC policies and procedures. Any failure to comply with this policy may result in disciplinary action, up to and including the immediate loss of approval to conduct research or teaching activities involving the use or generation of recombinant or synthetic nucleic acid molecules and/or biohazardous agents.

III. SCOPE

This policy applies to all faculty, staff, students, contractors, and volunteers that conduct research and experiments involving recombinant or synthetic nucleic acid molecules and/or biohazardous agents at NYMC (regardless of the funding source), as well as to research or teaching activities occurring at other locations when those projects involve NYMC funding or sponsorship.

IV. DEFINITIONS

Biohazardous Agents: Potentially infectious materials or recombinant agents that are classified amongst Risk Groups 2 or 3 as defined by the NIH Guidelines and the World Health Organization.

Biosafety Level (BSL): Levels of protection in ascending order (numerically designated from “1” to “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 pair with other naturally occurring nucleic acid molecules and cells, organisms and viruses containing such molecules.)

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

- Molecules that
 - are constructed by joining nucleic acid molecules, and
 - 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 still base pair with naturally occurring nucleic acid molecules;
- Molecules that result from the replication of those actions described above.

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. **Requirement for IBC Approval.** Before engaging in research, academic activity, and/or experiments involving biohazardous agents or recombinant or synthetic nucleic acid molecules, the work must be registered, reviewed by the BSO, and must be submitted for review and approval (when required) by the IBC. While all work with recombinant and or synthetic acid molecules must be registered (regardless of exemption status), work specifically defined by the NIH Guidelines as exempt may begin simultaneously with registration if the registration has received written initial approval by the Institutional Biosafety Officer (all non-exempt protocols must proceed to the IBC for review). For additional information on work that is exempt, refer to Section III-F of the NIH Guidelines. Work that is defined as “non-exempt” by the NIH Guidelines cannot begin until the IBC has granted the protocol full approval; any non-compliance with this constitutes a reportable incident under the NIH Guidelines and must be reported to the NIH Office of Biotechnology Activities (NIH OBA). (Note: work with RG1 agents as well as tissue culture work with human cell lines covered under 29 CFR 1910.1030 (OSHA’s “Bloodborne Pathogens” standard) does not require IBC registration and approval.
- B. **Protocol Review Requirements/Process.** To initiate the protocol review process, the Principal Investigator must electronically complete the appropriate registration form(s) and (Is attach all required supporting documentation. Incomplete submissions will not be reviewed by the IBC. All individuals that will be working on the project must be listed on the protocol, and they must demonstrate completion of all training requirements, including all basic annual and biosafety training (as required by EH&S), any hazard-specific training, and completion of NYMC’s training on the NIH Guidelines. The IBC may make changes to the requirements for the use of a recombinant or synthetic nucleic acid molecules and/or biohazardous agents at any time. Principal Investigators are required to update registration information whenever there are any changes in the protocol. The status of a registered project must be provided to EH&S every year of experimental duration via the appropriate annual renewal form. Protocols must be resubmitted for a full committee review every three years.
- C. **Commencement of Work Involving Recombinant or Synthetic Nucleic Acid Molecules or Biohazardous Agents.** Research defined as non-exempt by the NIH Guidelines cannot proceed until a full written approval is obtained from the IBC and/or Institutional Biosafety Officer. Any unapproved work with materials that are not specifically exempt from the NIH Guidelines (and/or work that has

not been specifically described within an approved and current protocol) is a violation of the NIH Guidelines and must be reported to the IBC and to the NIH OBA). All individuals working on the project must comply with all requirements of the approved IBC protocol; protocol compliance is periodically reviewed by EH&S during laboratory inspections, and compliance reports will be made to the Principal Investigator and the departmental chairperson. In instances of serious and/or repeated non-compliance, reports will also be made to the IBC and to the Office of the Dean.

- D. **Ordering Recombinant or Synthetic Nucleic Acid Molecules and Biohazardous Agents.** All requisitions for any recombinant and/or synthetic nucleic acid molecules that are defined as non-exempt by the NIH Guidelines and for all RG2 or RG3 agents must be approved by EH&S as a part of the purchasing approval sequence. In order for EH&S to approve a purchase, a valid IBC protocol number relating to the materials requested for purchase must be included with the requisition. If the materials relate to an approved protocol that has exceeded the three-year renewal date, the protocol must first be submitted for a renewal review and approved by the IBC before EH&S will approve the purchase(s).
- E. **Use of Risk Group 3 and/or Select Agents.** If a research protocol involves work with RG3 and/or select agents, and/or other regulated pathogenic organisms, additional review and approval is required by the IBC and EH&S. Additional approval by governmental agencies may be required, depending upon the agent involved. No RG3 agents may be transferred to NYMC without prior written approval from EH&S.
- F. **Disposal of Recombinant DNA Materials or Biohazardous Agents.** Recombinant or synthetic nucleic acid materials and/or biohazardous agents must be inactivated before disposal to prevent accidental release to the environment. Autoclave treatment or an approved method of chemical inactivation may be used; approved methods are material-dependent. Autoclaved materials cannot be disposed as normal solid waste and must be treated as regulated medical waste (RMW).
- G. **Transfer of Recombinant or Synthetic Nucleic Acid Molecules and Biohazardous Agents.** Intra-facility transfers of recombinant or synthetic nucleic acid molecules or biohazardous agents that require IBC approval must not be conducted without first notifying EH&S. Inter-facility transfers of recombinant and synthetic nucleic acid molecules and/or biohazardous agents must comply with all applicable national and international regulations (*i.e.* International Air Transportation Association (IATA) regulations).

- H. **Research-Related Incidents.** Both the NIH Guidelines and NYMC's "Policy on Reporting Research-Related Incidents Involving Recombinant DNA and Biohazardous Materials" require that specific research-related incidents be reported immediately to the Institutional Biosafety Officer, the IBC and, when necessary, the NIH's Office of Biotechnology Activities (OBA) and any other appropriate agencies (*i.e.*, CDC). Incidents that should be reported include research-related accidents resulting in overt exposures, illnesses, and the accidental release or improper disposal of recombinant or synthetic nucleic acid materials or biohazardous materials.

VI. EFFECTIVE DATE

This policy shall be effective as of the date signed.

VII. POLICY RESPONSIBILITIES

A. New York Medical College faculty, staff, students, contractors and/or volunteers

1. Register and get approval for research with biohazardous agents and recombinant or synthetic nucleic acid molecules by the IBC and/or the BSO;
2. Comply with this Policy and all guidelines published by the NIH, CDC, and NYMC;
3. Report incidents with recombinant or synthetic nucleic acid molecules or biohazardous agents to EHS.

B. Institutional Biosafety Committee

1. Review and approve research activities involving recombinant or synthetic nucleic acid molecules and biohazardous agents;
2. Review incidents/accidents with biohazardous agents and/or recombinant or synthetic nucleic acids and non-compliance with the *NIH Guidelines* and the most recent edition of the *CDC BMBL*;
3. Develop action plans for incidents and non-compliance which may include rescinding approvals for work with recombinant or synthetic nucleic acid molecules and/or biohazardous agents.

C. Environmental Health & Safety

1. Receive and pre-screen all IBC protocols before the protocols are presented to the committee;

2. Administratively approve amendments to IBC approved registrations that do not involve changes to work procedures, containment, or the recombinant or synthetic nucleic acid molecules or biohazardous agents utilized. Examples of changes that can be approved administratively include the specification of project funding, personnel changes, and project title changes;
3. Ensure that research involving recombinant, synthetic nucleic acid molecules, or biohazardous agents complies with all relevant regulations, policies and procedures;
4. Ensure that periodic inspections are conducted in laboratories where work with recombinant or synthetic nucleic acid molecules or biohazardous agents takes place; and,
5. Report incidents and items of non-compliance to the IBC and to the NIH OBA and/or other appropriate agencies when required;

VIII. POLICY MANAGEMENT

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

APPROVED:



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



Date