New York University Institutional Biosafety Policy
Updated 08/03/2015

New York University and its School of Medicine and College of Dentistry are committed to ensuring that the performance of basic and clinical research involving biological materials is accomplished as safely as feasible and in accordance with existing laws, regulations, nationally recognized standards, and standards of best practice. To assist in the accomplishment of safe biological research, the University has established an Institutional Biosafety Committee (IBC) and has charged it with providing necessary leadership, direction and institutional policy(s). In addition, the IBC is charged with the authority to take all necessary and appropriate actions when learning about breaches in regulations, policy and best practice standards.

Disputes regarding interpretation of this policy or decisions made by the IBC are referred for adjudication to the Vice Dean for Administration of the School of Medicine (for the Medical Center Campus) or the Senior Vice Provost for Research (for all other NYU entities)

I. Introduction

The Institutional Biosafety Committee (IBC) at New York University (NYU) oversees all research involving biohazards (as defined in Section II, below) conducted at or sponsored by NYU and its approved divisions and affiliates at the Washington Square, Dental Center and Medical Center campuses, including NYU Hospitals Center (all of which are hereinafter referred to as NYU). The extent of this oversight is defined in Section III. All research involving biohazards, irrespective of the source of funding, must be carried out in accordance with this policy and with applicable federal, state, and local regulations and guidelines. Major regulations and guidelines are shown in the following table. Additional regulations and guidelines are listed in Section II.

<table>
<thead>
<tr>
<th>Research Involving</th>
<th>Responsible Federal Agency</th>
<th>Major Regulation/Guidelines</th>
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</thead>
<tbody>
<tr>
<td>Human organs, tissue, cells, blood, and body fluids</td>
<td>Occupational Safety and Health Administration (OSHA)</td>
<td>Bloodborne Pathogens Standard 29 Code of Federal Regulations, Part 1910.1030</td>
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The IBC oversees compliance with federal, state, and local guidelines and regulations. Furthermore, the IBC has the responsibility to recommend additional safeguards as deemed necessary.

II. Definitions

Applicable regulations and guidelines include:

  http://www.selectagents.gov/Regulations.html
  http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61

**Biohazard** – recombinant DNA; select agents; human pathogens; oncogenic biological material; and primate cells, tissues, organs, blood, and body fluids.

**CDC Guidelines** – *Biosafety in Microbiological and Biomedical Laboratories,* current edition.

**Human Gene Transfer (gene therapy)** – the process of transferring genetic material (DNA or RNA) into a person. This type of experimentation is sometimes called “gene therapy” research.

**Human Pathogen** – a biological agent that can cause disease in human beings.

**IACUC** – Institutional Animal Care and Use Committee

**IBC** – Institutional Biosafety Committee

**IRB** – Institutional Review Board

**NIH Guidelines** – *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*

**Oncogenic biological material** – a material that can induce malignant tumors. An example is an oncogenic virus.
Recombinant DNA - Referral to rDNA throughout will apply to (i) molecules that a) are constructed by joining nucleic acid molecules, and b) can replicate in a living cell (i.e. recombinant nucleic acids); (ii) 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 (iii) molecules that result from the replication of those described in (i) or (ii) above.

Registration – completing the appropriate institutional Registration Form and submitting it to the IBC coordinator.

Select Agents - microorganism (viruses, bacteria, fungi, prions) or toxins that have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. They are regulated by the CDC and USDA and are described at http://www.aphis.usda.gov/wps/wcm/connect/APHIS_Content_Library/SA_Our_Focus/SA_Animal_Health/SA_Import_into_US/SA_Ag_Select_Agent. More information on Select Agents can be found on the Biosafety section of the EH&S website.

III. Committee Responsibilities

The IBC shall:

1) Establish institutional policies governing all research activities conducted by NYU personnel or at NYU facilities that involve the use of biohazards, in accordance with the applicable regulations and guidelines.

2) Advise NYU’s Senior Vice Provost for Research and the Vice Dean for Administration of the School of Medicine on actions necessary to maintain and/or improve biosafety in facilities owned or operated by NYU.

3) Provide personnel who work with biohazards with opportunities for training.

4) Identify based on risk the types of materials used in research and instructional activities that require registration with the IBC.

Research involving the following materials shall not require routine registration with or review by the IBC but shall be conducted in accordance with applicable regulations and guidelines.

- Human and other primate pathogens assigned to biosafety levels 1 or 2
- Human organs, tissue, cells, blood, and body fluids
All Research involving the following materials shall require registration with the IBC.

- All recombinant DNA (including research that is exempt from the *NIH Guidelines*)
- Select agents and toxins*
- Human and other primate pathogens assigned to biosafety level 3 or 4
- Oncogenic biological material

*Final approval remains, under federal law, the purview of the Responsible Official or Alternate Responsible Official.

5) Review and approve for biosafety research and instructional activities that have been registered with the IBC.

6) Ratify the Biosafety Level and Exempt/Non-exempt status for all research involving recombinant DNA. Some research projects involving recombinant DNA require only that the IBC be notified simultaneously with the initiation of the research (Section III-E of the *NIH Guidelines*). However, the investigator must register all recombinant DNA research, including the necessary Biosafety Level information, even if the experiments are exempt from the *NIH Guidelines*, for ratification by the IBC.

7) Request that Environmental Health and Safety (EH&S) inspect laboratory facilities in which research that involves biohazards is conducted, to ensure that appropriate facilities, equipment and safety work practices are in use. Inspections are based on criteria for biosafety levels established in the applicable regulations and guidelines. The *CDC Guidelines* and the *NIH Guidelines* will be used as a primary source of information. Unannounced inspections can be made.

8) Notify the Institutional Animal Care and Use Committee (IACUC) of the biosafety level required for protocols involving the use of biohazards, including rDNA, in animals and require appropriate animal containment facilities. The inspection of the animal care facilities for biosafety practices falls under the jurisdiction of the IACUC.

9) Recommend disciplinary action when a facility or individual is found to be in noncompliance with the applicable regulations and guidelines. Such actions may include, but are not limited to, the following:

- Informing the Principal Investigator and the Department Chair of the noncompliance;
- Requiring re-inspection by (EH&S) to substantiate that the facility is subsequently in compliance;
- Referring issues of noncompliance to the SOM Dean and/or the Senior Vice Provost for Research for further action; and
• Contacting the appropriate oversight agency, if significant noncompliance continues.

10) Provide scientific support to EH&S and resolve differences of interpretation of applicable regulations and guidelines and/or best practice between faculty and administrative oversight staff.

IV. IBC Membership

The IBC is comprised of at least five members with collective experience and expertise in rDNA technology and biohazards and the capability to assess the safety of such research and identify any potential risk to public health or the environment. The Vice President of Science Operations for the SOM appoints Committee members for NYU School of Medicine; the NYU Senior Vice Provost for Research appoints members from the Washington Square campus of New York University. Members serve a renewable three-year term. The members are so selected that the IBC is composed of:

1. At least two members who are not affiliated with NYU (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment, such as officials of state or local public health or environmental protection agencies, members of other local government bodies, or persons active in medical, occupational health, or environmental policy and practice in the community;
2. At least one member representing the laboratory technical staff;
3. At least one member with expertise in rDNA technology, biological safety, and physical containment;
4. The Biological Safety Officer;
5. At least one individual with expertise in containment principles of plants, plant pathogen, or plant pests when experiments involve plants and require IBC approval (See NIH Guidelines, Appendix P);
   • At least one scientist with expertise in animal containment principles when experiments involve animals and require IBC approval (See NIH Guidelines, Appendix Q)
   • At least one member who has expertise in and is familiar with clinical practices related to infection control in the hospital and clinical laboratories.

The IBC should have available, as consultants, persons knowledgeable in NYU commitments and policies, applicable law, standards of professional conduct and practice, community attitudes and the environment. IBC meetings are held at least once a month. A quorum of five members is required to conduct official IBC business.

NYU will file an annual report with the National Institutes of Health/Office of Biotechnology Activities (NIH/OBA), which includes:
1. A roster of all IBC members; and
2. Biographical sketches of all IBC members, including community members.

No member of the IBC will be involved, except to provide information requested by the IBC, in the review or approval of a project in which he/she has been or expects to be engaged or has a financial interest (See Investigator Financial Disclosure and Conflict of Interest Policy).

V. Responsibilities

The Vice President for Science Operations in the Office of Science and Research of the School of Medicine and the Senior Vice Provost for Research are responsible for informing the appropriate Deans and Department Chairs of their respective organizations of their responsibilities under this policy.

The Institutional Biosafety Committee (IBC) reports to the Vice Dean for Administration.

**Biological Safety Officer**

The institution shall appoint a Biological Safety Officer

The Biological Safety Officer is appointed by the Dean of the School of Medicine and approved by the NIH.

The Biological Safety Officer shall be a member of the IBC.

The duties of the Biological Safety Officer include, but are not be limited to:

- Providing training on applicable regulations and guidelines and laboratory safety to NYU personnel who work with biohazards.
- Conducting periodic inspections to ensure that laboratory standards are rigorously followed.
- Reporting to the IBC and the institution any significant problems, violations of applicable regulations and guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator;
- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research;
- Providing advice on laboratory security; and
- Providing technical advice to Principal Investigators and IBC on research safety procedures.
Responsibilities of Department Chair

Department Chairs shall inform all faculty of the existence of the IBC and ensure that the appropriate faculty receives all pertinent information (e.g., copies of the IBC policies, guidelines and procedures). Should a Department Chair not have this information, it may be obtained from the EH&S. Additionally, the Department Chair shall direct researchers to complete pertinent training and register with the IBC as specified in the next section.

The Department Chair is also responsible for addressing and resolving issues of noncompliance.

Responsibilities of Principal Investigator

Principal Investigators are responsible for:

1) Complying with the IBC guidelines and procedures, and applicable regulations and guidelines, and all conditions approved by the IBC.

2) Registering protocols for activities or modifications of activities involving biohazards with the IBC as required. Obtaining approval of the IBC before initiation of the activities or modifications, when required.

The investigator must register all recombinant DNA research, including the necessary Biosafety Level information, even if the experiments are exempt from the NIH Guidelines, for ratification by the IBC.

Submitting human gene transfer research protocols, as required by the NIH Guidelines, to the NIH Office of Biotechnology Activities (OBA) and obtaining approval by the NIH Recombinant DNA Advisory Committee (RAC) before obtaining approval by the NYU IBC. No research participant may be enrolled in a clinical study until the RAC review process is completed and IBC and IRB approvals and applicable regulatory authorizations have been obtained.

Ongoing human gene transfer projects must be reviewed at least annually by the IBC, and the IBC has the right to require more frequent monitoring, if necessary. Other recombinant DNA projects must be reviewed annually by the IBC and re-registered every 3 years. However, at any time, if there is a significant change in the experiment, e.g., in the containment level, a new and complete Registration Form must be submitted; the IBC Chair may approve minor changes, subject to review by the full IBC at the next meeting. Note: Research involving Select Agents requires approval of the NYU Responsible Official or Alternate Responsible Official, submission of an application to the CDC or the USDA, and a
background check by the Federal Bureau of Investigation (FBI) before any research can be initiated.

3) Ensuring that all laboratory personnel listed on the rDNA registration complete the online course EH&S – Recombinant DNA: Use and Safe Handling every 3 years.

4) Ensuring that all laboratory personnel, including students and volunteers, complete the training course entitled Introduction to Biosafety. Personnel who work with human cells, tissues or fluids must complete annual training entitled Bloodborne Pathogens and personnel who ship or receive biological materials must complete training entitled Shipping and Receiving Biological Materials. All trainings are available on iDevelop.

5) Ensuring that all laboratory personnel, including students and volunteers, receive any additional training needed to work safely with biohazards and to respond to incidents.

6) Incorporating biosafety procedures into standard operating procedures or into a biosafety manual adopted or prepared specifically for the laboratory by the principal investigator.