Research and Teaching Activities Involving Biohazardous Agents and Requiring Institutional Biosafety Committee (IBC) Review

Category: Academic Affairs - Operational
Responsible Department: Office of Research Services
Responsible Officer: Director of Research Compliance
Effective Date: 1/11/2017

Policy Summary
This policy provides general information about DePaul's program for ensuring the safe acquisition, use, and disposal of all biohazardous agents used in research and teaching at DePaul, in compliance with the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), the Biosafety in Microbiological and Biomedical Laboratories (BMBL), Center for Disease Control (CDC) /HHS/USDA-APHIS guidance for select agents or toxins, and Occupational Safety and Health Administration (OSHA) regulations and laws. Detailed information about the policies of the Institutional Biosafety Committee can be found in the DePaul University Institution Biosafety Committee (IBC) Policy and Procedure Manual posted on the IBC section of the Office of Research Services website.

This policy and the DePaul University Institution Biosafety Committee (IBC) Policy and Procedure Manual arise from the university's obligation to comply with federal regulations, guidelines, and laws governing the use of biohazardous agents, and, accordingly, the authority to establish and revise this policy lies with the Institutional Biosafety Committee (IBC), administered through the Office of Research Services under the Direction of the Associate Provost (AP) for Research.

Scope
This policy affects the following groups of the University:

- Full-Time Staff
- Part-Time Staff
- Full-Time Faculty
- Part-Time Faculty
• Students

This policy affects:

• Faculty, staff, and students working with biohazardous agents, such as recombinant or synthetic nucleic acid molecules, infectious materials, biological toxins, or select agents or toxins
• Members of the Institutional Biosafety Committee
• Office of Research Services staff supporting the IBC

Policy

A. Purpose of the IBC:
It is the responsibility of the DePaul University Institutional Biosafety Committee (IBC) to review, approve, and oversee the use of recombinant or synthetic nucleic acid molecules, biohazardous agents (as defined by IBC policy), and select agents or toxins in all research or teaching activities conducted by DePaul University faculty, staff, and students at DePaul University or at DePaul owned facilities.

B. Mission of the Institutional Biosafety Committee (IBC):
The IBC is a university-wide committee granted the authority by DePaul's President to ensure the safe acquisition, storage, use, and disposal of all biohazardous agents at DePaul University. The DePaul IBC safeguards human health and the environment by maintaining adherence to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), the Biosafety in Microbiological and Biomedical Laboratories (BMBL), the Occupational Health and Safety Administration (OSHA) Blood borne Pathogen regulations and Occupational Safety and Health Standards, Hazard Communication regulations, and the CDC/HHS/USDA-APHIS Select Agents and Toxins regulations.

Through outreach and support for research and teaching personnel at DePaul, the IBC has the responsibility for and will:

• Assure that research and teaching activities that involve recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins meet the ethical and legal requirements for the responsible use of these agents by evaluating the activities for biological safety considerations.
• Establish appropriate health and safety policies and procedures in accordance with federal regulations, guidelines, and laws that cover biological safety and make recommendations, when necessary to ensure compliance with policy. and
• Minimize risks to DePaul faculty, staff, and students, the community, and the environment by educating the DePaul community regarding the regulatory requirements for activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins.

C. Scope of the IBC Authority:
The IBC policies apply to all DePaul faculty, staff, or students engaged in research teaching activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents or toxins under their role or duties as a DePaul employee or student at DePaul
(i.e., teaching or research), including listing their affiliation with DePaul in any resulting publications, presentations, or other method of disseminating research results when the projects meet one or more criteria:

- They are Federally funded, funded by other external sources, are sponsored (funded) by DePaul University, or unfunded (no funds of any kind will be utilized to conduct the activity),
- They are conducted using DePaul owned property and facilities or under the direction of DePaul personnel off DePaul's campus or in non-DePaul facilities when these activities are not covered under the policy of another institution's IBC or the site is otherwise not regulated.
- They involve receiving, storing, using, transferring, or disposing of these materials at DePaul owned facilities or on DePaul property,
- They involve research at other institutions conducted on behalf of DePaul, such as when grant work is sub-contracted and DePaul is the lead site.

D. Charge and Authority

The IBC is charged with the review, approval, and oversight of research and teaching activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins. The responsibilities of the IBC include assessment of facilities, procedures, and practices, and the training of personnel to assure compliance with the NIH Guidelines and other pertinent guidelines and regulations. In order to successfully carry out these responsibilities, the appointed IBC members must have knowledge and expertise in biomedical research and biosafety concerns and procedures. IBC members are appointed by the DePaul University President in consultation with the Office of Research Services and the current IBC Chair.

The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend, or terminate research or teaching activities, as needed, and to investigate potential violations or non-compliance related to this policy in order to assure adherence to the appropriate regulations and guidelines. The IBC has been charged with these duties as part of the planning and implementation of the DePaul University Biosafety Program which has the overall purpose and goal of ensuring the health and safety of all persons working with recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents and toxins. Activities that have been approved by the IBC may be subject to further review and disapproval by institutional officials (e.g., President, Provost, AP for Research, Deans of the Colleges). However, those officials do not have the authority to approve of activities for the IBC or instead of the IBC or to approve of activities specifically disapproved by the IBC. The IBC is responsible for establishing and implementing policies that provide for the safe conduct of activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins to ensure adherence to the NIH Guidelines, the BMBL, OSHA blood borne pathogen regulations, OSHA Occupational Safety and Health Standards, Hazard Communication, and CDC/USDA/APHIS regulations. The IBC reviews individual proposals using these materials in compliance with the established policies and procedures. The IBC has the authority to require progress reports from investigators and oversee the conduct of any activity, as well as to approve or disapprove of amendments or changes to activities.
The IBC’s regulatory responsibilities in regards to recombinant or synthetic nucleic acid molecules activities are outlined in the *NIH Guidelines*. The IBC is given the authority to oversee all research and teaching activities involving other biohazardous agents, select agents or toxins by the DePaul's President. The IBC has the authority to suspend or terminate any activity that is not in compliance with IBC policies.

**Procedures**

None.

**Divisional Collaborations**

Environmental Health and Safety

**Contact Information**

Institutional Biosafety Committee Website
http://offices.depaul.edu/ors/research-protections/ibc/Pages/default.aspx

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**Appendices**

DePaul University Institutional Biosafety Committee (IBC) Policy and Procedure Manual (on Office of Research Services- IBC website)

**History/Revisions**

Origination Date: 09/06/2006
Last Amended Date: 8/13/2019
Next Review Date: N/A