

Policy Number/Title: 1.2.1.12 Institutional BioSafety Committee
Effective Since: 10/01/2011
Last Revision Approved: 10/01/2011
Responsible Office: Institutional BioSafety Committee; Academic Affairs

1. Scope:

This section was intentionally left blank.

2. Definitions:

This section was intentionally left blank.

3. Policy:

Mission Statement

The Institutional Biosafety Committee (IBC) oversees the safety of research and classroom projects involving recombinant DNA or other biohazardous materials. The IBC sets containment levels in accordance with National Institutes of Health (NIH) Guidelines and the Center for Disease Control and Prevention (CDC). It also periodically reviews previously approved research projects for changes which would necessitate increasing or decreasing the containment levels.

Recombinant DNA consists of molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA Molecules that can replicate in a living cell, or molecules that result from their replication.

Biohazardous materials are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals or the environment. The risk can be direct through infection or indirect through damage to the environment. Biohazardous materials include certain types of recombinant DNA; organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia); and biologically active agents (i.e. toxins, allergens, venoms) that may cause disease in other living organisms or cause significant impact to the environment or community.



IBC Membership

The IBC membership is comprised of three faculty members, two community representatives not affiliated with Winthrop University and the Winthrop University Environmental Health and Safety Manager. Faculty members and Community Representatives are appointed by the Provost. The faculty members will serve three year terms, with one faculty member rotating off the IBC each year. The Director of Sponsored Programs and Research (SPAR) serves as an ex officio non-voting member, providing administrative assistance to the Chair. The Director of SPAR will serve as the University's IBC contact person with NIH/OBA.

In compliance with NIH Guidelines, Section IV-B02-a-3, the Director of the Sponsored Programs and Research (SPAR) Office shall annually file a report with the National Institutes of Health Office of Biotechnology Activities (NIH/OBA), providing the following information:

A roster of all Institutional Biosafety Committee members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or ad hoc consultant (if applicable); and

Biographical sketches of all Institutional Biosafety Committee members (including community members).

IBC Member Conflict of Interest

No member of the IBC may be involved (except to provide information to the IBC) in the review or approval of a project in which he/ she, his/her spouse or child, has been or expects to be engaged or has a direct financial interest.

BioSafety Training

Members of the IBC must complete Biosafety Training, provided by the Collaborative Institutional Training Institute (CITI) program sponsored by the University of Miami. This training is available on-line and certification of completion of the training is required prior to service on the IBC.

All Principal Investigators (PI), Instructors and Laboratory Staff using recombinant DNA or biohazardous materials in their research or classroom instruction, must complete biosafety training, provided by the CITI program. Each PI and Instructor will be responsible for ensuring that students working in the lab with the PI or Instructor have been adequately trained. Documentation of such training will be maintained in the laboratory of the PI or Instructor.



The Director of SPAR will maintain a record of all researchers having completed CITI Training and will send out renewal notices for refresher training within 90 days of expiration of the training certificate. CITI Training certificates will be valid for three years after the completion date of the training.

Revised 10-11--11 IBC Membership: The IBC membership is comprised of three faculty members, two community representatives not affiliated with Winthrop University and the Winthrop University Environmental Health and Safety Manager. Faculty members and Community Representatives are appointed by the President. The faculty members will serve three year terms, with one faculty member rotating off the IBC each year. The Director of Sponsored Programs and Research (SPAR) serves as an ex officio non-voting member, providing administrative assistance to the Chair. The Director of SPAR will serve as the University's IBC contact person with NIH/OBA.

In compliance with NIH Guidelines, Section IV-B02-a-3, the Director of the Sponsored Programs and Research (SPAR) Office shall annually file a report with the National Institutes of Health Office of Biotechnology Activities (NIH/OBA), providing the following information:

- A roster of all Institutional Biosafety Committee members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or ad hoc consultant (if applicable); and

- Biographical sketches of all Institutional Biosafety Committee members (including community members).

IBC Member Conflict of Interest

No member of the IBC may be involved (except to provide information to the IBC) in the review or approval of a project in which he/ she, his/her spouse or child, has been or expects to be engaged or has a direct financial interest.

Biosafety Training

Members of the IBC must complete Biosafety Training, provided by the Collaborative Institutional Training Institute (CITI) program sponsored by the University of Miami. This training is available on-line and certification of completion of the training is required prior to service on the IBC.

4. Procedures:



Specifically, the responsibilities of the IBC are:

1. Reviewing recombinant DNA and biohazardous materials research and classroom activity conducted at or sponsored by the University for compliance with standards set forth in NIH Guidelines and approving those projects that are found to conform with NIH Guidelines, including
 - a. An independent assessment and establishment of containment levels,
 - b. Assessment of the facilities, procedures, practices and training and expertise of personnel involved in the project
 - c. Ensuring compliance with all surveillance, data reporting and adverse event reporting requirements
 - d. Notifying the Principal Investigator of the results of the IBC's review and approval/disapproval
 - e. Periodic review of on-going project to ensure compliance with the approved protocol and procedures
 - f. Periodic laboratory inspections to ensure that laboratory standards are rigorously followed
 - g. Reviewing and adopting emergency plans covering accidental spills and personal contamination resulting from recombinant DNA or other biohazard materials research or classroom activity
 - h. Reporting, any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate University official and NIH/OBA if the project is NIH funded.
 - i. Performing such other functions as may be delegated to the IBC.

5. Resources:

This section was intentionally left blank.

6. History of Revisions:



10/01/2011 Policy first established

7. Approvals:

Responsible Officer Signature/Date:

Vice President/Senior Administrator Signature/Date:

President Signature/Date: