

Winthrop University
Institutional Biosafety Committee
Policy and Procedures

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.

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 projects 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 biohazardous 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/OSP if the project is NIH funded; and
 - i. Performing such other functions as may be delegated to the IBC.

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 Executive Director of Grants and Sponsored Research Development (GSRD) serves as an ex officio non-voting member, providing administrative assistance to the Chair.

The Executive Director of GSRD will serve as the University's IBC contact person with NIH/OSP.

In compliance with NIH Guidelines, Section IV-B-2-a-3, the Executive Director of the Grants and Sponsored Research Development (GSRD) Office shall annually file a report with the National Institutes of Health Office of Science Policy (NIH/OSP), 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 Executive Director of GSRD will maintain a record of all researchers having completed CITI Training and will send out renewal notices for refresher training within 60 days of expiration of the training certificate. CITI Training certificates will be valid for four years after the completion date of the training.

APPROVAL PROCESS

IBC procedures are federally mandated. Regardless of the source of supporting funding for the research, Principal Investigators (PI) must have IBC approval to use recombinant DNA or other biohazardous materials prior to the initiation of the research.

The principal investigator will be notified of the date, time, and location of the IBC meeting in which their protocol will be reviewed and will be invited to attend.

The use in research or classroom activities of the following types of materials must have IBC approval:

- Biohazardous materials
- Infectious agents
- Human blood/tissue
- Human cells and cell lines
- rDNA
- Select Agents (As defined by NIH)

To apply for IBC approval, the PI should obtain the Biohazardous Materials Declaration Form on-line at the IBC webpage. BSL1 and BSL2 Checklists must also be completed if biosafety Level 1 or Level 2 materials are being used in the project or classroom. The PI will complete the declaration form, sign, and obtain the signature of the Department Chair. An electronic copy of the signed declaration form and checklists will be submitted to the GSRD office. The signed paper copy will be maintained in the PI's project files and the electronic copy will be sent to the IBC Chair and committee for review and will be retained as the official record for the University.

The IBC review process will include the following:

- Are NIH guidelines being followed in the project?
- Do research designs contain reasonable safeguards necessary to protect research and classroom personnel, the public, and the environment?
- Are there provisions for review of activities to intervals appropriate to the risk, including conditions under which research should be continued or discontinued?
- Are all research and classroom participants adequately trained on the handling and use of the materials?
- Are emergency procedures documented and available to all participants and researchers?

The IBC will determine the biosafety levels of the materials covered in the Declaration. Only BSL-1 and BSL-2 materials may be used in research and classroom projects at Winthrop University.

Upon completion of the review, the IBC will do one of the following:

1. **APPROVED:** The IBC will issue a written approval of the project or classroom activity to the PI. Work may commence immediately upon receipt of the written approval. The approval letter will list the IBC control number, containment levels set by the IBC, project titles, and any additional requirements.

This approval is valid for a period of three years from the approval date. The PI must complete a renewal form annually after the first and second year after the initial year. At the conclusion of the third year, if the project is to continue, a new application must be submitted to the IBC.

2. **CONDITIONALLY APPROVED:** The IBC will issue a conditional approval in writing, citing minor changes or clarifications required to bring the protocol into compliance with Committee policies. The PI may begin the project upon receipt of the conditional approval, but must respond in writing to the IBC Chair within 30 days of the date of the conditional approval, addressing the minor changes or clarifications noted in the Conditional Approval. If the IBC Chair deems the PI has adequately addressed the IBC's concerns, then the project will be APPROVED and a new approval letter will be issued. If the response is not received within 30 days, or if the response does not adequately address the IBC's concerns, the project will be rejected and the PI will be

instructed to stop all activity related to the use of the biohazardous materials.

3. **TABLED:** The IBC votes to “table” a protocol when numerous and/or major changes or clarifications are required to bring the protocol into compliance with Committee policies. The IBC will issue a written statement to the PI of the deficiencies of the protocol. The PI must then revise the protocol to address the concerns of the IBC and submit the revised protocol to the IBC for consideration at the next regular committee meeting.
4. **REJECTED:** The IBC may vote to reject a protocol if it contains serious violations of committee policy and/or if repeated attempts to bring the protocol into compliance with committee policy have failed.

PUBLIC COMMENT ON IBC ACTIONS

In compliance with NIH/OSP Guidelines, Section IV-B-2-a-(7), any public comments on NIH supported research will be forwarded, along with the IBC’s response, to the Office of Science Policy, preferably by email to NIHGuidelines@od.nih.gov or to National Institute of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985.

The Executive Director, GSRD, will be responsible for filing this report with the NIH/OBA.

LABORATORY INSPECTIONS

Once a semester, the IBC will inspect at least one laboratory to ensure that laboratory standards are rigorously followed. The inspection team, comprised of at least 2 members of the IBC, will complete the Laboratory Inspection List, sign the form, and prepare a report to the researcher and department head of the results of their inspection.

The researcher will be given 30 days to correct minor deficiencies noted in the inspection. Significant deficiencies must be corrected before any research continues.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES:

The principal investigator is responsible for the safe conduct of research in the laboratory including the following:

1. Make an initial determination of the required levels of physical and biological containment;
2. Select appropriate microbiological practices and laboratory techniques to be used for research;
3. Submit the initial research protocol and any subsequent changes to the IBC for review and approval or disapproval;
4. Communicate with the IBC throughout the conduct of the project;
5. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
6. Instruct and train laboratory staff in (a) the practices and techniques required to ensure safety, and (b) the procedures for dealing with accidents. Maintain documentation to show that all laboratory staff and students have been trained on the handling and use of materials in the lab and on safety practices and techniques employed in lab operations, including the use of Protective Personal Equipment. This documentation will be kept in the PI’s laboratory.
7. Inform the laboratory staff of the reasons and provision for any precautionary medical practices advised or requested;
8. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed, including the use of Protective Personal Equipment;
9. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the IBC;

10. Correct work errors and conditions that may result in the release of biohazard materials;
11. Ensure the integrity of the physical containment and the biological containment; and
12. Comply with reporting requirements for human gene transfer experiments conducted in compliance with the NIH Guidelines.

REPORTING SIGNIFICANT INCIDENTS, VIOLATION, AND RESEARCH RELATED ACCIDENTS AND ILLNESSES ON NIH SUPPORTED RESEARCH INVOLVING RECOMBINANT DNA

The IBC Chair or GSRD Executive Director will notify the OSP of any significant incidents, violations, and research related accidents and illnesses on NIH supported research projects involving recombinant DNA. This notification will be submitted within thirty days of the event or illness.

This report will be made using the NIH provided report template and following the instructions provided by NIH provided at the following web page: <https://osp.od.nih.gov/biotechnology/faqs-on-incident-reporting/>

Reportable events are defined in the NIH OSP frequently asked questions found at: <https://osp.od.nih.gov/biotechnology/faqs-on-incident-reporting/>

MEETING MINUTES

The Executive Director of GSRD will be responsible for recording the minutes of all IBC Meetings, and will distribute the minutes to the committee members for correction, additions, and approval.

Meeting minutes will be made available to the public upon request. Before minutes are made available to the public, the IBC Chair will review the minutes and redact proprietary or private information judiciously and consistently for all requested documents. Some examples of information that may be redacted include:

- Trade secret information;
- Confidential commercial information;
- Home telephone numbers and home addresses of IBC Members; and
- Specific information whose disclosure would directly compromise institutional or national security.

At a minimum, the minutes will contain the following:

1. Date and place of the meeting
2. Statement of approval of prior meeting minutes
3. Individuals in attendance
4. Whether and why the meeting was open or closed
5. All major motions and points of order, and whether they were approved
6. Sufficient detail to serve as a record of major points of discussion and the committee's rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities
7. Minutes do not need to be transcripts or kept at a level of detail that attributes each remark to a specific individual
8. Time of meeting adjournment
9. A copy of each protocol reviewed at the meeting will be attached to the minutes to complete the record.

RENEWALS

The IBC will follow-up on all approved projects no less than annually and will send to the PI the Status of IBC Approved Projects to be completed and returned to the IBC within 30 days of receipt of the renewal request

The PI should identify on the status form any deviations from the approved project, changes in laboratory locations, changes in Laboratory Staff working on the project, and any project titles to be added. If there are significant deviations from the project, especially deviations that affect the containment level, the IBC may ask that the PI seek an additional approval to cover the additional experiments.

All new Laboratory Staff must have current certification of Biosafety Training through the CITI Training program.

MISCONDUCT OF RESEARCH: Failure to comply with the policies and procedures of the Winthrop University Biosafety Committee and with NIH regulations will be considered misconduct in research under the Winthrop University Misconduct in Research Policy. If an investigation determines that misconduct did occur, sanctions and disciplinary action called for by the Misconduct in Research Policy will apply.

UNIVERSITY ANNUAL REPORT

The IBC Chair will prepare an annual report for submission to the Provost due by September 1 for the committee work ending August 15 of the same year. The report will contain at a minimum:

1. Activities of the IBC during the academic year, including the number of times the committee met, the number of protocols acted upon, and the inspections, if applicable, that were conducted by the IBC.
2. Information concerning students involved in research reviewed by the IBC.
3. Assessments conducted by the IBC of compliance with Federal regulations and/or adequacy of the IBC's policies and procedures. Policy additions or modifications made as a result of this assessment.
4. Challenges faced by the IBC during the year, including community representation, new issues arising in protocol reviews, and the amount of time and/or resources required to conduct the committee business. Include any policy additions or modifications made as a result of addressing these challenges.
5. Presentations by the Chair or other IBC members concerning the mission and policies of the IBC.
6. Suggestions for consideration in future committee member selection and/or committee responsibilities.