

Florida Atlantic University
Institutional Biosafety Committee
Policy and Procedures

I. Introduction

The Institutional Biosafety Committee (IBC) has been delegated the authority to set University policy with regard to biological and recombinant DNA safety. The IBC must comply with the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules. The IBC is responsible for overseeing the use of all biological agents and recombinant DNA methods employed in research and teaching projects on Florida Atlantic University's campuses.

II. Composition of the Committee

The IBC consist of individuals knowledgeable in the safe use of biological materials and infectious agents. The IBC is required to have two members on the committee that represent the community. Furthermore, the IBC will enlist additional scientific experts if the project entails procedures and techniques beyond the scope of the committee. The chair of the IBC is elected by the IBC members. The current members are listed below.

David M. Binninger, Ph.D., Assoc. Professor and Assoc. Chair, Dept. of Biological Sciences

Dianne Patterson, SM(ASCP), CIC, Director of Infection Control, Boca Raton Community Hospital -
Community Member

Howard M. Prentice, Ph.D., Assoc. Professor, Dept. of Biomedical Science - Chairman

Mary Russell, Ed.D., MSN, Hospital Project Manager, Florida Department of Health - Community Member

Darlene Ward, Biosafety Officer, Environmental Health & Safety - IBC Coordinator

Jianning Wei, Ph.D., Asst. Professor, Dept. of Biomedical Science

Herbert Weissbach, Ph.D., Distinguished Professor and Director, Center for Molecular Biology and
Biotechnology

III. Project Review Process

The IBC shall be responsible for reviewing all research and teaching projects that deal with Biological and Recombinant DNA materials at FAU. This review will consist of scientific merit, applicant's experience, laboratory facility and compliance with applicable government regulations and FAU policy and procedures.

All grant proposals submitted through the Division of Sponsored Research will be screened for the use of Biological and Recombinant DNA materials. Investigators submitting proposals will be asked to complete a checklist of questions outlining their use of Biological and Recombinant DNA materials.

The Division of Sponsored Research will bring any proposals which suggest practices not already undertaken and approved for use at FAU to the attention of the Biosafety Officer (BSO). The appropriate registration application will be filled out and sent to the Coordinator of the IBC. Those proposals involving the use of

common microorganisms and recombinant DNA techniques that are exempt from NIH Guidelines do not require approval from the IBC but must be registered with the IBC. The Chair of IBC will determine if the proposal should be reviewed by the full IBC committee.

Proposals that do not require full committee review will be approved by the IBC Chair and/or BSO. The BSO is authorized to sign proposals that have been approved by the IBC. The Division of Sponsored Research will also alert the BSO of any investigator who is proposing the use of biological and/or recombinant DNA materials, but is not currently an approved user.

Any grant funds awarded will be placed on hold and no accounts will be set up until all necessary approvals have been obtained from the IBC, and/or other applicable committees.

IV. Meeting Requirements

The IBC will meet whenever necessary as requested by the Chair or any two IBC members. The IBC Coordinator will arrange the meetings at a time that facilitates maximum attendance. Four members of the IBC, including the Chair, shall constitute a quorum. The Chair shall have the option of approving projects that clearly represent "standard research protocols", without a vote of the IBC.

V. Committee Reporting

All recommendations, actions, and minutes of the IBC are maintained by the IBC Coordinator for license record-keeping compliance. Any recommendation, comments, or questions in the minutes pertaining to a specific research project or program are sent to the Principal Investigator in charge of that project. The IBC is also required to send an annual report to the NIH Office of Biotechnology.

VI. Project Approval

Project approvals that are authorized by the IBC shall be granted for a 3 year period. When the scope of the project or protocol changes substantially a new application must be resubmitted to the IBC. Additionally, the IBC must be notified if the project involves changes in the procedures, personnel and lab location by completing the Modification/Addendum form.

VII. Termination or Changes to Projects/Practices

The IBC shall have the authority and obligation to enforce changes in any project or practice to comply with regulations and to meet reasonable standards of safety and health. In the event that any project or practice presents imminent danger to the health or safety of any individual, or presents a threat to the safety of the environment or FAU property, the IBC shall have the authority to temporarily suspend the project or practice.

The IBC must immediately notify the Chair of the involved department, the Director of EH&S, the Director of the Division of Sponsored Research, and the Provost's office. The IBC will meet within the subsequent 72 hours and make a recommendation on how to address the situation before work will be allowed to resume.

In cases of non-compliance with the established safety rules, but where there is no imminent danger to individuals or property, the IBC will notify the user to correct the violation. In instances where the user refuses or neglects to rectify the violation, a three stage enforcement process will be followed:

Stage 1: The IBC will notify the faculty member in charge of the lab in writing describing the violation and personnel involved. A suggestion for how compliance with University procedures can be achieved will be

included and the faculty member will be asked to notify the IBC within 5 working days of the status of his efforts to make the correction. The laboratory will be scheduled for a follow-up inspection by the BSO.

Stage 2: If the IBC is not able to achieve compliance through efforts outlined in Stage 1, the status of the situation will be brought to the attention of the faculty member's department Chair. The department Chair will be asked to assist the IBC in making the corrections.

Stage 3: If for any reason the second stage action does not result in compliance, the University Safety Committee (USC) will take direct action. The USC will review the situation to determine the seriousness of the identified violation and the actions of the investigator. The investigator will be asked to meet directly with the USC to outline why he is unable to comply. The USC will take actions which it deems appropriate to meet compliance, which may include suspension of the investigator's approval to work with regulated materials on a temporary or permanent basis. Any actions taken by the USC will be reported to the investigator, department chair, college dean, director of EH&S, director of the Division of Sponsored Research, and the Provost's office.

VIII. Appeals

Any individual may appeal the actions of the IBC and/or USC through the chair of the USC and the Provost's office. Where specific rules, regulations, or licenses apply they will be used as guidance in making all final decisions. If there is no concurrence after the IBC, USC, and the Provost review, the case will be referred to the appropriate regulating agency for review.