FLORIDA ATLANTIC UNIVERSITY

Division of Research

SUBJECT:	Effective Date:	Policy Number:
Institutional Biosafety Committee: ***Biosafety Review Process***	September 5, 2023	10.12.03
	Supersedes:	**Page Of** 1 7
	Responsible Authorities: Vice President, Research	

I. Background

Federal guidelines mandate that any entity receiving federal funding and conducting research with recombinant/synthetic nucleic acid molecules must have an Institutional Biosafety Committee to review such activities. As a condition of this funding, all University activities involving recombinant/synthetic nucleic acid molecules must follow the National Institutes of Health (NIH) Guidelines. The Florida Atlantic University (FAU) Institutional Biosafety Committee (IBC) has been delegated the authority to set University policy with regard to research with recombinant/synthetic nucleic acid molecules, biological materials, and select agents and toxins. The FAU IBC functions include those designated for the IBC in the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

II. Purpose

The purpose of this document is to outline the process by which the IBC reviews projects submitted to it for compliance with Federal guidelines, university policy, and best practices for biosafety.

III. Policy

Project Review Process

1. The Institutional Biosafety Committee (IBC) shall be responsible for reviewing all research and teaching projects that deal with recombinant/synthetic nucleic acid

molecules, biological materials, select agents, and toxins at Florida Atlantic University (FAU). This review shall include (but not be restricted to): the applicant's experience, laboratory facilities, and compliance with applicable governmental regulations and FAU policies and procedures.

2. All grant proposals submitted through the Office of Sponsored Programs, regardless of the funding source, will be screened for the use of recombinant/synthetic nucleic acid molecules, biological materials, select agents, and toxins. Investigators submitting proposals will be asked to complete a checklist of questions outlining their use of these materials, and the Office of Sponsored Programs will contact Research Integrity and the Principal Investigator (PI) to confirm IBC compliance for all proposals that indicate their use.

3. The IBC Registration Application form will be filled out and sent to the IBC Coordinator. Those proposals involving use of recombinant/synthetic nucleic acid molecules, biological materials, select agents, and toxins that are exempt from the NIH Guidelines do not require full committee review by the IBC. The Biosafety Officer will determine if the Registration Application requires full IBC review.

4. Proposals that do not require full IBC review will be approved by the Biosafety Officer (BSO) and/or IBC Chair. The BSO is authorized to sign proposals that have been approved by the IBC.

5. Any grant funds being awarded will be placed on hold and no accounts will be set up until all necessary approvals have been obtained from the IBC, and other applicable committees. Application for registration with the IBC may be approved at any point before or during the funding process.

IV. Procedures

Procedures for Registration Submission

1. Investigators doing research utilizing recombinant/synthetic nucleic acid molecules, biological materials, select agents, and toxins, regardless of funding source, should submit an IBC Registration Application directly to the IBC Coordinator.

2. Once received by the IBC Coordinator, the application will be routed to the BSO for preliminary review. The BSO will make the determination if full IBC review is necessary. The BSO and IBC Coordinator will also review the application for content and communicate with the Principal Investigator and/or his/her representative about any items that may be missing or may require correction or additional information.

Registrations that typically require full committee review include: Projects falling into NIH Guidelines experiments in sections III-A, III-B, III-C, and III-D; Projects involving Risk Group 3 and above organisms; Projects involving the use of biological toxins or venoms; Projects that may be considered Dual Use Research of Concern; and Projects that are deemed to benefit from full committee review.

3. If an application does not require review by the full IBC, then the BSO and/or IBC Chair will approve the project once all the required documentation has been provided. Projects not requiring full review will be communicated to the IBC at the next scheduled meeting.

4. If an application requires full review, one or more IBC members will be selected to provide primary review and to present the application to the IBC at the next scheduled meeting. The IBC members may contact the PI to request additional information or clarification prior to the Committee meeting.

5. It is important that the PIs are timely in their responses to requests for additional information or clarification so that registrations can be approved at the meeting without further delay.

Meeting Process

1. **Requirements for Quorum**
   The conduct of official IBC business occurs at convened meetings that must include a quorum of members in order for the meeting to be held. The IBC defines a quorum as "more than half" the regular voting members. A registration is approved only if a quorum is present, and if more than 50% of the quorum votes in favor of registration approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

2. **Registration Review**
   Registrations not requiring full committee review will not be reviewed at an IBC meeting, however, the BSO or IBC Coordinator will inform the members of registrations that have been approved via expedited processing since the last IBC meeting. Registrations requiring review by the full IBC are assigned to designated reviewers who present the registration to the IBC.

3. **Procedures**
   IBC meetings are scheduled monthly. At the scheduled time and upon reaching quorum, the IBC Chair calls the meeting to order and follows a specific agenda prepared prior to the meeting. When reviewing registrations, there are several activities that

the IBC must carry out on behalf of the University:

- Conduct assessment of the containment levels required by the NIH Guidelines
- Assess the facilities, procedures, practices and training and expertise of personnel involved in research with recombinant/synthetic nucleic acid molecules and biological materials, agents and toxins
- Ensure compliance with the NIH Guidelines and the Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- Consider: Agent characteristics (i.e., pathogenicity, environmental stability); Types of manipulations planned; Source of nucleic acid molecules; Nature or function of the gene encoded by recombinant/synthetic nucleic acid molecules; Host(s) and vector(s) to be used; If a foreign gene will be expressed; and Biosafety risk for a chimeric organism

When a registration is presented for review the IBC member(s) assigned will present a brief description of the registration then discuss the completeness of the registration with respect to the considerations given above. Once presented, IBC members can discuss the registration. When discussion has ended, the IBC Chair will ask for a motion for outcome.

4. **Possible Review Outcomes**

All registrations that are required to go through full IBC review are presented and discussed individually and the IBC votes on the disposition of the registration. Possible outcomes include:

- **Approved:** When the IBC has determined that all review criteria, based on the IBC Policies and federal-mandated regulations have been adequately addressed by the PI, the IBC may approve the research, thus providing the PI permission to perform the research.
- **Approved with Modifications:** This status is used for registrations for which all required information has not been received, required training has not been completed and/or there are remaining issues or questions regarding the safety of the registration.
- **Tabled:** If the registration requires clarification in order for the IBC to make judgment, certain committee members with certain expertise are not present, the IBC wishes to seek external consultation, or a number of other reasons prevents

the IBC from conducting its review, then the IBC may wish to defer or table review.

- **Approval Withheld:** When the IBC determines that a registration has not adequately addressed all of the requirements of the IBC Policies and regulations as applicable, the IBC may withhold approval.

5. **Conflict of Interest**

The NIH Guidelines [Section IV-B-2-a-(4)] state that "No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest." A conflict of interest may also arise from a professional or personal relationship with the personnel of a project (e.g., a frequent collaborator, supervisor, supervisee, or spouse). All PIs and IBC members are required to disclose any potential conflicts of interest. Should an IBC member state a conflict of interest with a registration under review, then the membe, at the discretion of the committee:

- May be asked to provide information regarding the application as part of the normal review process

- Will be asked to leave the meeting room for discussion and voting

- Will not be counted towards quorum for any voting that takes place in their absence.

Any committee member may abstain from voting for any reason, even if the committee does not determine that a conflict of interest exists. Abstaining members are counted towards quorum.

6. **Minutes**

The NIH Guidelines require that the IBC minutes should offer 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 as described in section IV-B-2-b of NIH Guidelines. The minutes do not need to be transcripts or kept at a level of detail that attributes each remark to a specific individual.

Minutes of each IBC meeting are recorded in writing and contain:

- Date and place of meeting

- Individuals in attendance
- All major motions, major points of order, and whether motions were approved
- Registrations reviewed (identified by registration number and title)
- Consideration of points in Section 3 above
- Time of meeting adjournment

7. **Principal Investigator Notification**
Upon completion of the review process, the PI will receive written notification of the review decisions (approved/not approved) and whether any special conditions for approval of work is required. Included in the notification will be the IBC decision on biocontainment/biosafety level to be used for the proposed research, any special safety considerations, applicable sections of the NIH Guidelines, along with the approval period (begin/end dates).

8. **Reports to the Institutional Official**
Copies of minutes and reports of laboratory incidents, accidents, spills, potential or actual exposure to infectious or biohazardous materials, and incidents of noncompliance, suspension, or termination will be forwarded to the Institutional Official (IO). For many of the above, the IO, or their designee may be required to file a report with the NIH Office of Science Policy or other agencies.

9. **Meeting Frequency**
Convened meetings of the IBC are scheduled monthly unless cancelled by the IBC Chair. Meeting schedules are typically set six months in advance and posted on the IBC website. The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving recombinant/synthetic nucleic acid molecules and biological materials, agents and toxins.

10. **Relinquishing an IBC registration**
When PIs relinquish oversight of an IBC registration they must notify the IBC. Depending on the disposition of the potentially biohazardous materials outlined in the registration, the PI may need to take any of the following actions:

- If the materials no longer remain, or will be disposed of as outlined in the registration. The PI should notify the IBC so that the registration can be archived.

- If the materials will be transported to another location, the registration should be updated to include transportation and shipping procedures as needed.

- If a new PI will assume oversight for the registration, this PI should be added to the current registration. Once the existing PI has been removed from the registration, the new PI should review and modify the registration as needed, certify the changes, and submit the registration to the IBC for review. This submission will be reviewed by the full committee.

V. Policy Renewal Date

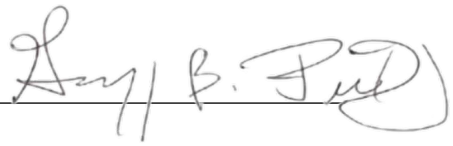
September 4, 2026

VI. References

NIH Guidelines - ops.od.nih.gov
BMBL - cdc.gov
Select Agents - selectagents.gov
DURC Policy - phe.gov

POLICY APPROVAL

Initiating Authority

Signature:  Date: 9/7/2023

Name: Gregg B. Fields, Ph.D, Interim Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)