FLORIDA ATLANTIC UNIVERSITY

Division of Research

SUBJECT:	Effective Date:	Policy Number:
Institutional Biosafety Committee: ***Noncompliance Policy***	September 5, 2023	10.12.05
	Supersedes:	**Page Of** 1 7
	Responsible Authorities: Vice President, Research	

I. Background

Florida Atlantic University (FAU) is committed to maintaining the safety of employees, volunteers, students, the community, and the environment. Additionally, FAU is committed to compliance with Federal, State, and local guidelines and regulations as they apply to research. 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 NIH Guidelines. The FAU Institutional Biosafety Committee (IBC) has been delegated the authority to set University policy with regard to research with recombinant and 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, and the control of health hazards associated with the use of biological materials.

II. Purpose

This document outlines the policies and procedures for the investigation and amelioration, by the Institutional Biosafety Committee (IBC), of potential biosafety noncompliance issues associated with the faculty, students, staff, and resources of the University.

III. Role of the IBC

It is the responsibility of the Institutional Biosafety Committee (IBC) to address issues of noncompliance and potential noncompliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) as well as any applicable University policy, or federal, state, or local law, including The Federal Select Agent Program and The United States Government Policy for Oversight of Dual Use Research of Concern (DURC), or agreed upon best practices, including the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

The primary responsibility of the IBC in addressing these issues is to ensure the safety of FAU faculty, students, and staff, as well as the safety of the community and of the environment. Investigation of potential noncompliance will remain confidential to the extent possible.

Definitions

Noncompliance
Noncompliance is a failure, for any reason, to adhere to applicable regulations, policies, procedures, and laws, to methods and practices outlined in IBC registration documentation, to agreed upon best practices, or to decisions made by the IBC to ensure that adherence. Noncompliance can result from intentional or inadvertent action or inaction and can range from minor technical issues to serious threats to public safety. Noncompliance can include:

- Failure to register relevant activities with the IBC
- Deviating from procedures outlined in IBC registration documents
- Allowing an IBC registration to expire while continuing research activities
- Failure to ensure that all personnel have completed the appropriate training.
- Failure to properly report a biosafety incident
- Improper handling or disposal of biohazardous waste
- Handling recombinant or synthetic DNA in a manner outside the NIH Guidelines (regardless of funding source)
- Failure to adhere to compliance requirements of other funding sources
- Any other deviation from policies, procedures, regulations, or best practices.

Categories of Noncompliance:

1. Minor Noncompliance
   Noncompliance that does not pose a serious threat to the health or safety of University faculty, students, or staff, or to the safety of the community or the environment.

2. Serious Noncompliance
   Noncompliance that, in the judgement of the IBC, poses a potential increased risk to the safety or welfare of personnel, the public, or the environment.

3. Continuing Noncompliance
   A pattern of ongoing noncompliance of any kind that, in the judgment of the IBC, is likely to result in an increased risk to the safety or welfare of personnel, the public, or the environment, or indicates an inability or unwillingness to adhere to applicable regulations and policies.

Potential Noncompliance
Potential Noncompliance is any possible noncompliance that has come to the attention of the IBC, the Biosafety Officer (BSO), or Research Integrity. This may include an allegation of noncompliance by any person, a self-report of noncompliance by the Principal Investigator (PI), or an indication of noncompliance that arises in the course of normal oversight.

Corrective Action
Corrective Action is any steps taken to address noncompliance. Corrective action should include detailed plans or modifications to procedure that eliminate existing noncompliance, prevent future noncompliance, and deal with the root causes of noncompliance.

Emergency Deviation from Approved Procedures
In the event of an emergency, PIs should coordinate with the Biosafety Officer to safely transport and secure biological materials. This transportation and storage may deviate from the procedures described in the relevant IBC registration without constituting noncompliance. The PI should update the IBC registration within two weeks to reflect any changes made.

IV. Procedures

Process for the Evaluation of Potential Noncompliance

When a member of the IBC, the BSO, or Research Integrity staff become aware of any credible potential noncompliance, they will make the IBC Chairperson (or Vice-Chairperson),

and Biosafety Officer aware of that potential noncompliance as soon as possible. Once they have been made aware, the IBC Chairperson (or Vice-Chairperson) will oversee the IBC's response.

Initial Review:

1. The IBC Chairperson and Biosafety Officer will determine the immediacy of any potential biosafety concerns. The IBC Chairperson or BSO may, at any point in the evaluation process recommend to the Institutional Official (IO) immediate intervention for the safety of personnel, the public, or the environment.

2. Potential noncompliance that, as determined by the IBC Chairperson and BSO, is non-substantive, or does not have the potential to be serious or continuing noncompliance, can be immediately dealt with, either without corrective action, or with corrective action coordinated directly with the Principal Investigator (PI). The IBC may choose to make recommendations for the modification of procedure or IBC documentation, or for additional training to the PI. The full committee will be informed of noncompliance and any corrective actions at the next meeting of the IBC and the noncompliance will be documented in the meeting minutes.

3. Potential Noncompliance that is determined by the IBC Chairperson and BSO to be substantive will be evaluated by the IBC.

Evaluation:

1. If the IBC Chairperson and the BSO determine that the potential noncompliance may constitute serious noncompliance or continuing noncompliance, The IBC will take steps to further evaluate the potential noncompliance. These steps can include:

    - Forming a subcommittee to gather information and present it to the committee for deliberation
    - Calling a meeting of the committee to determine a course of action for evaluating the potential noncompliance
    - Collecting documentation relevant to the potential noncompliance
    - Requesting a report from the PI
    - Inspecting University facilities
    - Interviewing personnel

- Feedback from University legal and compliance offices.

2. The IBC, or a designated subcommittee, will take steps to gather any information necessary to determine whether noncompliance has taken place and will continue until the IBC has sufficient information to make a determination. The IBC may delegate any part of the information gathering process to individual committee members, EHS, Research Integrity, or any other appropriate designee.

3. The IBC Chairperson, the BSO, and the full committee may be briefed and consulted at any time during the information gathering process.

4. Once the IBC, or subcommittee, has sufficient information to make a determination regarding the potential noncompliance, they will present a report to the full committee for review. This report will include all relevant facts, recommendations to the IBC regarding the determination of noncompliance and, if applicable, an outline of potential corrective action.

Deliberation:

1. At a convened meeting of the committee, the IBC will consider all of the available information and make a determination as to whether noncompliance has occurred and the relative seriousness of any noncompliance. In determining the level of seriousness, the committee will consider:

    - The relative level of potential risk to personnel, the public, or the environment caused by the noncompliance

    - The frequency and duration of the noncompliance

    - The extent to which the noncompliance deviated from documented procedure, policy, or regulation

    - The intent of anyone involved in the noncompliance

2. The IBC, or its designee, will create a report of any findings of noncompliance and their severity. This report will be sent to the PI and to any other applicable persons or organizations depending on the nature of the noncompliance. Depending on the circumstances reporting may be necessary to:

    - The Institutional Official

- The PI's Department Chair
- The NIH
- Any other relevant oversight body or funding agency

Correctice Action:

1. The IBC may decide to present a corrective action plan to a PI, or to request a corrective action plan from a PI. Any proposed corrective action plan should directly address the finding of noncompliance, take steps to prevent similar noncompliance in the future, and address the root causes of the noncompliance.

2. The IBC will review any proposed corrective action plan to ensure that it effectively addresses the finding of noncompliance and communicate with the PI to ensure that an effective corrective action plan is implemented. Corrective actions may include:

    - Modification of existing procedures
    - Addition of new procedures
    - Additional training
    - Additional record keeping
    - Additional IBC oversight
    - Collaboration with other faculty

Additional Actions:

The IBC may also take steps to ensure compliance and the safety of FAU faculty, students, and staff, as well as the community and the environment. These steps may include:

- Suspension of a PI's approval for use of recombinant and synthetic nucleic acid molecules and/or biological materials, select agents or toxins.
- Termination of a PI's approval for use of recombinant and synthetic nucleic acid molecules and/or biological materials, select agents or toxins.

In cases where the IBC determines that there is an immediate and serious threat to the safety of FAU faculty, students, staff, the community or the environment, they may make

a recommendation to EHS, and any relevant administrators to take immediate action to ensure the safe handling of biological materials, up to and including:

- Restriction of access to a laboratory in order to ensure suspension of research activities.
- Confiscation of a PI's recombinant and synthetic nucleic acid molecules and/or biological materials, select agents or toxins.
- Destruction of a PI's recombinant and synthetic nucleic acid molecules and/or biological materials, select agents or toxins.
- Any other action necessary to protect the public and/or University

V. Policy Renewal Date

September 4, 2026

VI. References

NIH Guidelines - ops.od.nih.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)