FLORIDA ATLANTIC UNIVERSITY

Division of Research

SUBJECT:	Effective Date:	Policy Number:
Institutional Biosafety Committee: ***Reporting Requirements***	July 22, 2021	10.12.06
	Supersedes:	**Page** 1 **Of** 4
	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 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 responsibilities of FAU faculty, students, and staff to report and address biosafety incidents.

III. Policy

It is a violation of University policy and of federal guidelines to conduct new or ongoing research without appropriate registration, review, approval, and oversight. Compliance with all FAU and NIH policies, including reporting procedures, is required for all activities at FAU regardless of whether those activities receive funding through the NIH.

Any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses must be reported to NIH within 30 days. Certain types of incidents must be reported on a more expedited basis: Spills or accidents occurring in Biosafety Level (BSL) 2 laboratories resulting in an overt exposure must be immediately reported to the NIH. In order to comply with these requirements, all significant incidents or exposures must be reported to the Biosafety Officer (BSO). The Principal Investigator (PI) takes responsibility for this reporting for all incidents related to the materials associated with their IBC registrations.

Exposures may be:

- Overt Exposures, where personnel are directly exposed to biological materials by injection, spill, splash, or aerosol inhalation

- Potential Exposures, where personnel have a high risk of exposure to biological materials as a result of containment or equipment failures

Failure by research personnel to follow federal and institutional regulations, guidelines, policies and procedures may also require reporting to the appropriate institutional, local, state and/or federal agencies.

IV. Procedures

1. **Principal Investigator Reporting**
   The Principal Investigator and their personnel must report any significant incident, violation of the NIH Guidelines, or any significant research-related accidents or illnesses to the Biosafety Officer within 24 hours.

   Reportable significant incidents include:

   - Any exposure (overt or potential) in a BSL-2 lab.

   - Overt exposure in a BSL-1 lab.

   - Any illness that may have been caused by the agents used in the laboratory

   - Any incident involving the improper disposal of recombinant or synthetic nucleic acid molecules or other biological waste.

2. **Biosafety Officer Reporting**
The Biosafety Officer is required, by the NIH Guidelines, to report to the IBC:

- All violations of the NIH Guidelines.
- All significant incidents
- Any significant research-related accidents or illnesses

3. **IBC and IO Reporting**
The IBC, through the Institutional Official (IO), will file an annual report with the National Institutes of Health Office of Science Policy (NIH/OSP) that includes a roster of all IBC members with biographical sketches and clear identification of the committee chair, contact person, BSO, plant expert, and animal expert. Expert committee members may serve ad hoc.

The IBC is required by the NIH Guidelines to report to the NIH/OSP within 30 days, any significant incidents, violations of the NIH Guidelines, or any significant research-related accidents and illnesses.

For each incident, the IBC will determine what actions, if any, are necessary to mitigate identified problems and their root causes and will complete the NIH Incident Reporting Template and submit it to the OSP as outlined in the NIH Guidelines.

Certain types of incidents must be reported to the NIH/OSP on an expedited basis. Spills or accidents in BSL-2 laboratories (involving recombinant/synthetic nucleic acid molecules) resulting in an overt exposure must be immediately reported to NIH/OSP. The IBC will report to the Institutional Official, who, in turn, will report to NIH/OSP, any of the above-described incidents.

As per Section IV-B-2-a-(7) of the NIH Guidelines, if public comments are made on IBC actions, the IBC, through the IO, will forward both the public comments and the IBC's response to the NIH/OSP.

The IO will notify the Centers for Disease Control and Prevention and U.S. Department of Agriculture of any incidents involving Select Agents and/or Select Toxins, and will notify any relevant state and local public health departments of any significant research-related illness or accident that may be hazardous to the public health

V. Policy Renewal Date

July 21, 2024

VI. References

NIH Guidelines - ops.od.nih.gov

POLICY APPROVAL

Initiating Authority

Daniel C. Flynn

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Date: 2021.08.02 12:09:40 -04'00'

Signature: _____ Date: _____

Name: Daniel C. Flynn, Ph.D, Vice President for Research

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