



<b>SUBJECT:</b> The FAU Biosafety Program: <i>Organizational Structure</i>	<b>Effective Date:</b> June 19, 2020	<b>Policy Number:</b> 10.12.01
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	<b>Responsible Authorities:</b> 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/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 administrative structure of the FAU Biosafety Program and the duties and responsibilities of its components. These administrative offices and leaders interact with and provide resources to the many faculty, staff, and students who work with biological materials in their research, training, and exhibition activities. However, the program goes beyond administrative structures and procedures to comply with federal regulations. Research safety is a shared mission and every person at FAU including staff, faculty, and students, is expected to understand, implement, and maintain best

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practices for promoting and protecting the safety of people and animals while also protecting the environment.

### III. Policy

#### **Required components of the Institutional Biosafety Program:**

##### **1. The Institutional Official (IO)**

Federal regulations require that institutions appoint an IO who has ultimate authority and accountability for the IBC, including allocating fiscal and non-fiscal resources to the committee and ensuring compliance with the regulations. At FAU, the President has delegated that role to the Vice-President for Research. Although the overall direction of the IBC is a shared responsibility among the IO, Biosafety Officer (BSO), and IBC, the IO is the person who is ultimately held responsible by federal authorities. For that reason, the IO has the authority to withhold approval for any research activity, even if it has been approved by the IBC; however, the IO may not approve any activity where the IBC has withheld approval.

The responsibility for the IBC at FAU rests with the IO.

The IO:

- Appoints IBC members
- Oversees the IBC
- Evaluates allocation of resources to the IBC and adjusts as necessary

The IO has charged the IBC to review, approve and provide oversight and guidance to those research personnel who seek to use recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins in experiments or teaching. Any possession and/or use of recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins at the University must be conducted with appropriate safeguards and in accordance with University policies and federal guidelines and regulations.

##### **2. The Biosafety Officer (BSO)**

The BSO administers the Biosafety Program of FAU.

The BSO is responsible for:

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- Ensuring that biological research is conducted in a way that protects the health and well-being of all researchers at FAU
- Ensuring that University policies regarding the use of recombinant DNA, biological materials, select agents, and toxins prevent contamination of the environment
- Ensuring that researchers are following all applicable regulations and guidelines with regard to research with biological materials.

The BSO develops and participates in programs to promote safe biological practices, procedures, and proper use of containment equipment and facilities; stimulates responsible activities among workers; and provides advice on laboratory design. The BSO: performs periodic inspections to ensure that laboratory standards are rigorously followed; reports to the IBC and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses; develops emergency plans for handling accidental spills/personnel contamination and for investigating lab accidents involving biological materials and recombinant/synthetic nucleic acids; provides advice on laboratory security; and provides technical advice to PIs and the IBC on research safety procedures.

### 3. **The Institutional Biosafety Committee (IBC)**

The IBC is a faculty-led committee composed of scientists, non-scientists, the BSO, and members of the community (community members have no affiliation with FAU). The IBC is responsible for reviewing, approving, and monitoring all FAU research projects involving biological materials and recombinant/synthetic nucleic acids that may pose differing levels of safety, health, or environmental risk to plants, animals or humans.

Specific responsibilities include:

- Reviewing research involving use of biological materials or recombinant / synthetic nucleic acids
- Reviewing potential risk of research to the environment and public health
- Reviewing and investigating incidences of violations of guidelines or regulations
- Reporting to the IO regarding any aspect of research safety with biological

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materials.

The goal of the committee is to ensure work is conducted in a safe manner, and the researchers adhere to guidelines and regulations as stipulated in this document.

### **Additional Administrative Components of the FAU Biosafety Program**

The FAU institutional biosafety program includes responsibilities of oversight for all research activities involving recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins conducted by and at FAU. The extensive volume of paperwork and processes required by Federal regulations cannot be handled solely by the IO, BSO, and IBC. To administer a comprehensive Biosafety Program that spans four campuses, FAU relies on the support and collaboration of the following administrative units:

#### **4. Research Integrity (RI)**

RI, located in the Division of Research, is the primary administrative support office for all research compliance programs at FAU, including the IBC. RI supports the IO, IBC, BSO, faculty and students through a variety of functions including:

- Advising faculty and students on the protocol submission process
- Processing all biosafety protocols and related actions
- Coordinating and scheduling all IBC meetings
- Issuing all correspondence from the IBC and IO to faculty and students
- Interacting with federal agencies (e.g., NIH, CDC) to discuss and report any compliance issues
- Investigating non-compliance cases on behalf of the IBC
- Performing other related actions.

#### **5. Environmental Health and Safety (EH&S)**

EH&S is the primary contact at FAU for the Biosafety Program and for matters of health, safety and the environment. EH&S will support the FAU Biosafety Program by:

- Allocating fiscal and non-fiscal resources to the BSO

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- Creating University biosafety procedures and manuals
- Managing the occupational health and safety program known as the Medical Monitoring Program (MMP). Through the MMP, faculty and students working with biological materials will receive initial assessment and risk evaluation, referral to appropriate vaccinations and medical care, and ongoing monitoring of their health status.
- Managing efforts to minimize biological, chemical and radioactive hazards associated with research activities.

6. **Facilities Management.**

Facilities Management oversees services such as construction, building maintenance, and physical plant operations. Facilities Management coordinates with the IO, BSO, and IBC to ensure any facility and physical plant issues (utilities, construction, noise control, etc.) do not adversely affect the conduct of research at FAU. Both EH&S and Facilities Management report to FAU's Vice-President for Administrative Affairs.

Collectively, FAU's Institutional Official, Biosafety Officer, and IBC, in conjunction with the administrative offices noted above, work together to promote a safe research environment at FAU.

IV. Procedures

Specific procedures are outlined in policies or guidelines issued by the Vice-President for Research, Vice-President for Administration, IBC, EH&S, or other applicable units.

V. Policy Renewal Date

June 18, 2023

VI. References

[NIH Guidelines - ops.od.nih.gov](https://www.nih.gov/oc/ohrt/ohrt-guidelines)

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POLICY APPROVAL

*Initiating Authority*

Signature: \_\_\_\_\_

Date: 6/23/2020 \_\_\_\_\_

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

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