FLORIDA ATLANTIC UNIVERSITY

Division of Research

SUBJECT:	Effective Date:	Policy Number:
Institutional Biosafety Committee: ***Functions***	June 19, 2020	10.12.02
	Supersedes:	**Page** 1 **Of** 8
	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 delineate the functions of the FAU IBC.

III. Policy

1. **Purpose of the IBC**
   It is the responsibility of Florida Atlantic University's Institutional Biosafety Committee to review, approve, and manage the use of recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins in all teaching, research, or testing activities conducted using University facilities or by research personnel. Laboratory work can involve exposure, not only to recombinant/synthetic nucleic

acid molecules, biological materials, select agents and toxins, but also to chemical and radiological hazards. Therefore, IBC policies should be considered independently, and not as a replacement or supplement to any other pertinent University policies and procedures.

2. **Charge and Authority of the IBC**

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 program 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 IBC has been charged with the planning and implementation of the campus Biosafety Program with the purpose of ensuring the health and safety of all personnel working with recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins. The IBC:

- Makes certain that research conducted at the University is compliant with the National Institutes of Health (NIH) Guidelines, Biosafety in Microbiological and Biomedical Laboratories (BMBL), the Health and Human Services (HHS) and United States Department of Agriculture (USDA) regulations, and the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)

- Drafts campus policies and procedures that guide the use and monitoring of recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins

- Reviews individual research proposals using recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins.

The University receives NIH funding for research involving recombinant/synthetic nucleic acid molecules, and, as a condition of this funding, all University activities involving recombinant/synthetic nucleic acid molecules must follow the NIH Guidelines. Failure to adhere to the guidelines can result in action by the NIH, including: suspension or termination of NIH funding, or a requirement for prior approval by the NIH of any or all recombinant/synthetic nucleic acid molecule projects at the insti-

tution. The IBC is therefore responsible for establishing and implementing policies that provide for the safe conduct of research involving recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins to ensure adherence with NIH Guidelines. IBC responsibilities with regard to activities involving recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins are specified in the NIH Guidelines. Also, as delineated in the IO's charge to the IBC, the committee is given authority to oversee all research involving recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins including suspension or termination of research that does not comply with IBC policies.

3. **Scope**

The IBC policies apply to all research personnel engaged in activities and/or research involving recombinant/synthetic nucleic acid molecules, biological materials, select agents and toxins that are:

- Sponsored by the University
- Conducted by University research personnel
- Conducted using University property and facilities
- Received, stored, used, transferred or disposed of at any University facilities
- Research at other institutions conducted on behalf of the University

4. **Federal Registrations**

The FAU IBC is registered with NIH Office of Science Policy (OSP). The purpose of registration and annual membership updates are:

- Provide assurance of local review of biosafety risks to the NIH/OSP
- Indicate University point of contact
- Provide a census of the field

The IBC is registered with NIH/OSP for purposes of recombinant/synthetic nucleic acid molecules research. An annual report is filed with NIH/OSP, which includes an updated list of IBC members indicating the role of each member and biosketches for each member. The NIH/OSP is notified of any changes in IBC membership when they occur. Such notice shall include a revised list of members, contact information and a biosketch for each new member. The FAU Office of Research Integrity (within the Division of Research) notifies NIH/OSP of changes in IBC membership and submits an annual report on behalf of the University.

Should a Principal Investigator request use, possession or transfer of a biological material listed as a Select Agent and/or Select Toxin, and not listed as an exempt strain or quantity, the University will initiate a Laboratory Registration for Select Agents and Toxins with the National Select Agent Registry.

5. **Regulations and Guidelines**
The IBC Policies are based upon the following regulations and guidelines:

- **NIH Guidelines** This document specifies practices and provides guidelines for constructing and handling recombinant/synthetic nucleic acid molecules and organisms containing recombinant/synthetic nucleic molecules. Institutions conducting or sponsoring recombinant/synthetic nucleic acid molecules research covered by NIH Guidelines are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the NIH Guidelines and are available online: NIH Guidelines.
- **BMBL** Biosafety in Microbiological and Biomedical Laboratories is published by the Centers for Disease Control and Prevention (CDC) and the NIH. This document contains guidelines for microbiological practices, safety equipment and facilities that constitute the four established Biosafety Levels. The BMBL is considered the standard for biosafety. It is available online: BMBL.
- **Select Agents and Toxins** The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) regulations, 42 CFR Part 73, and the United States Department of Agriculture (USDA) regulations, 9 CFR Part 121, establish requirements regarding the possession, use, receipt and transfer of listed select agents and select agent toxins. The regulations set forth the requirements for registration of listed select agents and toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections and notifications. For more information, visit: selectagents.gov.
- **United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (IODURC)** IODURC is a US Government (USG) policy established with the purpose of instituting regular review of USG-funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to: a) mitigate risks where appropriate; and b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. IODURC addresses the institutional oversight of DURC, which includes policies, practices and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. For more information, visit: The Federal Select Agents Program and DURC Policy.

IV. Procedures

1. **Membership and Organization of the Committee**

- The IBC shall have no less than five (5) members. Each member shall be appointed by the Vice-President for Research or his/her designee. Membership shall include: the BSO; at least two community members unaffiliated with FAU; at least one animal expert; at least one plant expert (if plant research is being done at FAU); at least one expert in recombinant/synthetic nucleic acids; and at least one expert in human gene transfer (if human gene transfer research is being conducted at FAU). The Vice-President for Research or his/her designee may appoint additional members at his/her discretion and the Committee shall meet the membership requirements of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. In addition, the IBC may appoint ad hoc consultants to the IBC to provide expertise as needed.

- The Vice-President for Research or his/her designee also may appoint additional persons from any component or discipline in the University to serve as full voting committee members in an ex-officio capacity.

- The Chairperson of the Committee will be appointed by the Vice-President for Research or his/her designee from among the Committee membership. A Vice-Chairperson may be appointed by the Vice-President for Research or his/her designee. The Chairperson and Vice-Chairperson will each serve staggered terms of up to three years, with the potential for renewal. The Chairperson, Vice-Chairperson and committee members may be reappointed for additional terms at the discretion of the Vice-President for Research.

2. **Duties of the Committee**

- Recommends policies regarding biological safety matters to the Vice-President for Research for approval prior to implementation by appropriate organizational components.

- Provides advice and assistance to the Division of Research on matters relating to safety polices involving research with recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins.

- Identifies substantive research and operational areas where biological health hazards may exist involving research with recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins.

- Recommends procedures for approving activities involving recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins that require special containment facilities or practices, which, in the judgment of the Committee, may constitute a hazard to faculty, staff, students or the environment.

- Reviews all research involving the use of recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins.

- Reviews reports of accidents or other incidents resulting in the exposure of faculty, staff, students or the environment to recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins, as well as reports of noncompliance with established University policies or regulatory requirements regarding the safe conduct of research or use of these materials.

- Performs functions of an IBC as specified in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

- Establishes working groups and appoints ad hoc members or consultants to the Committee as deemed necessary to effectively carry out the duties of the Committee.

- Advises the Division of Research on State and Federal regulatory requirements as they relate to the purchase, use, storage and disposal of biomedical materials.

- Reviews all research associated with Dual Use Research of Concern (DURC)

- Reports issues and findings to the IBC as appropriate.

3. **Duties of the IBC Chair**

- Serves as one of three contacts for all regulatory agencies (in addition to the BSO and the IO, who may delegate this function).

- Acts as liaison between the research personnel and IBC.

- Assigns subcommittees as needed to review an issue prior to official committee decisions made at the convened meeting.

- Approves the agenda for the convened meeting of the IBC.

- Calls the meeting and directs the meeting deliberations, requests motions and seconds, and closes the meeting once it has concluded business.

4. **Duties of the BSO**
The BSO shall be a voting member of the IBC. The BSO's responsibilities include:

- Performing periodic inspections of laboratories conducting research using recombinant/synthetic nucleic acid molecules and biological materials, select agents and toxins to ensure that laboratory standards are rigorously followed.

- Performing primary reviews of submitted IBC projects to determine if full committee review is required.

- Performing review and approval (along with IBC Chair, if necessary) of IBC projects not requiring full committee review.

- Performing and reviewing the required risk assessment to determine appropriate Biosafety Level for handling of an organism.

- Working with the IBC to develop a risk mitigation plan for those proposals determined to be DURC.

- Providing technical advice to research personnel and the IBC on research safety and security procedures.

- Providing advice on laboratory construction with regard to safety and containment.

5. **Duties of Research Integrity**
Research Integrity (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 maintain necessary registrations and to discuss and report any compliance issues
- Maintaining all documentation and reporting required of IBC activities on behalf of FAU
- Organizing and facilitating the assessment, inquiry, and investigation by the IBC into any allegations of non-compliance.
- Performing other related actions.
- Ensuring and overseeing appropriate biosafety training for committee members and for faculty, staff, and students involved in the use of recombinant/synthetic nucleic acid molecules, biological materials, or select agents and toxins.

V. Policy Renewal Date

June 18, 2023

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: 6/23/2020

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

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