Florida International University

Institutional Biosafety Committee

Standard Operating Procedures

I. Mission Statement

Florida International University (FIU) is committed to the safe and ethical use of recombinant DNA and synthetic nucleic acid.

Recombinant DNA is:

- DNA in which one or more segments or genes have been inserted, either naturally or by laboratory manipulation, from a different molecule or from another part of the same molecule, resulting in a new genetic combination.
- DNA molecules that are extracted from different sources and chemically joined; for example, DNA comprising an animal gene may be recombined with DNA from a bacterium.

Synthetic Nucleic Acid Molecules, or DNA or RNA derived from synthetic nucleic acid molecules that meet any one of the following criteria:

- Contain more than 100 nucleotides; or
- Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
- Have the potential to replicate in a cell; or
- Can be translated or transcribed.

The Institutional Biosafety Committee (IBC) shall:

A. Assure that activities involving recombinant DNA and biohazardous agents meet the ethical and legal requirements for the responsible use of these agents.
B. Establish policies and make recommendations to the University regarding such activities.
C. Maintain and promote an open and cooperative relationship with investigators and the FIU community.
D. Educate the FIU community concerning the regulatory requirements for the use of these agents.

II. IBC Charge

A. The Committee has the general charge of supporting a healthy and safe work environment and related ethical considerations as it relates to recombinant DNA.
B. The IBC is charged with reviewing activities involving recombinant DNA.
C. The Committee also has the charge of monitoring federal, state, and local regulations and assuring FIU's compliance with these regulations.

III. Responsibilities

FIU is responsible for supporting a safe working environment for all University activities and for compliance with all applicable federal, state, and local regulations concerning the use of recombinant DNA. Institutional responsibilities include the establishment and support of an IBC and Department of Environmental Health and Safety (EHS) and the appointment of an Institutional Official (IO) and Biosafety Officer (BSO). The IO responsible for biosafety-related matters is the Vice President for Research and Graduate Studies, hereafter referred to as IO.

A. Chairperson, Institutional Biosafety Committee
    1) Ensure that the IBC is properly constituted as described in Section IV of this document and fulfills its requirements under the appropriate regulations, rules, etc.
    2) Ensure that all members of the IBC are appropriately trained with regard to laboratory safety and implementation of the NIH Guidelines .
    3) Conduct meetings and serve as the signatory for correspondence generated by the IBC.

B. Institutional Biosafety Committee
    1) Review and approve containment levels for all research activities, or modifications of activities, conducted at or sponsored by the Institution involving recombinant DNA for compliance with the NIH Guidelines, BMBL and federal, state, and local regulations.
    2) Periodically review recombinant DNA research for approved protocols conducted at or sponsored by the Institution to ensure compliance with the NIH Guidelines, BMBL and federal, state, and local requirements.
    3) Ensure that all Principal Investigators (PIs) are appropriately trained for the proposed work and are aware of their responsibilities as PIs.
    4) Notify PIs of the results of IBC reviews and approvals.
    5) Report any significant problems, violations of the NIH Guidelines, research-related accidents, injuries, or illnesses of which the IBC becomes aware to the appropriate Institutional Official (IO) and together notify the National Institutes of Health/Office of Science Policy (NIH/OSP) within 30 days.
    6) Conduct investigations of serious violations or problems and to make recommendations to the IO for the resolution of continued noncompliance or serious infractions.
    7) Advise and provide technical expertise to FIU's Administration, BSO, and PIs on matters related to recombinant DNA within their respective areas of responsibility.
    8) Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.
    9) Review and recommend policies and procedures for biological risk assessment and biological risk reduction throughout the University.

C. Biological Safety Officer
    1) Conduct periodic inspections to ensure that laboratory biosafety standards are rigorously followed at Florida International University or affiliated institutions.
    2) Provide oversight and assurance that laboratory biosafety containment equipment is functioning properly, including assurance that field-testing and certification of biological safety cabinets is completed, when appropriate, at Florida International University or affiliated institutions.

3) Identify biological safety problems and immediately stop unsafe operations. Initiate, recommend, or provide corrective actions, verify the implementation of corrective actions, and notify the IBC.
4) Provide advice on laboratory security.
5) Provide technical advice to PIs and the IBC on research biosafety procedures.
6) Develop emergency plans for handling accidental spills and personnel contamination of recombinant DNA.
7) Investigate laboratory accidents involving recombinant DNA research and report to the IBC and the Institution any significant problems, violations of the NIH Guidelines, research-related accidents, injuries, or illnesses of which the BSO becomes aware.
8) Be knowledgeable about what recombinant DNA materials are at the Institution and where they are located.
9) Develop and provide biosafety training.
10) Serve as a member of the IBC.
11) Monitor federal, state, and local regulations and assure FIU's compliance with these regulations.

D. Environmental Health and Safety (EH&S)
1) Provide industrial hygiene and safety support for all laboratory operations.
2) Transport and dispose of all biohazardous wastes in compliance with all applicable federal, state, and local regulations.
3) Assist, as necessary, in the emergency response, cleanup, and decontamination of biological spills and accidents.
4) Administer the University Occupational Health Program.
5) Provide to laboratory personnel mandated training as required by the Department of Transportation/International Air Transport Association prior to the shipment of recombinant DNA (if applicable).
6) Conduct periodic inspections to ensure that laboratory biosafety standards are rigorously followed at Florida International University or affiliated institutions.

E. Office of Research Integrity (ORI)
1) Provide the necessary liaison among PIs, IBC, granting agencies, and regulatory agencies.
2) Serve as the Office of Record for documentation involving the IBC.
3) Provide all necessary documentation, forms, regulatory guidelines and regulations, etc., for PIs.

F. Laboratory Animal Resources (LAR)
1) Provide appropriate animal husbandry and care that meets or exceeds federal, state, and local requirements and specifications.
2) Ensure that animal housing systems are designed and utilized in a manner that will minimize the potential exposure of other animals or personnel to potentially biohazardous agents.

3) In cooperation with investigators, BSO, and IBC, develop and implement specific standard operating procedures, in adherence to the Animal Biological Safety Level (ABSL) classification of the agent being used, addressing animal care, research procedures, and procedures in case of accident or equipment failure.
4) Ensure that all animal care personnel are adequately trained and aware of the potential risks associated with each biohazardous agent.
5) Develop, in cooperation with the BSO, emergency plans for handling accidental spills, personnel exposures, unintentional animal exposure, equipment failure, etc.

G. Principal Investigator
1) On behalf of the Institution, the PI is responsible for full compliance with the NIH Guidelines in the conduct of research involving recombinant DNA and for fulfilling all conditions set forth in protocols approved by the IBC.
2) Submit protocol applications for all activities, or modifications of activities, involving recombinant DNA. Do not initiate or modify research prior to receiving such approval, and meeting all requirements of the NIH Guidelines, and other regulatory agencies as appropriate.
3) Report any significant problems, violations of the NIH Guidelines, research-related accidents, injuries, or illnesses of which the PI becomes aware to the BSO, ORI, LAR Director (if applicable), IBC, NIH/OSP, and other appropriate authorities (as applicable) within 30 days.
4) Report any new information bearing on the NIH Guidelines to the IBC and to NIH/OSP.
5) Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
6) Comply with NIH, federal, state, and local shipping requirements for recombinant DNA molecules and biohazardous agents and be aware that formal training and documentation may be required for certain shipments and that help is available from EHS as per Section III.D.5 of this document.
7) Ensure that all laboratory personnel are trained in the accepted procedures, including laboratory practices, containment methods, disinfection, waste disposal practices, personal protective equipment usage, and emergency plan implementation.
8) Ensure proper handling and disposal of all infectious wastes as outlined in the FIU Biomedical Waste Plan.
9) Maintain all biosafety equipment in appropriate operating condition and decontaminate laboratory equipment prior to maintenance or disposal. Biosafety cabinets will receive field certification by an accredited evaluator in accordance with National Sanitation Foundation/American National Standards Institute Standard 49.
10) Maintain records of recombinant DNA and biohazardous agents used in the laboratory and biological safety cabinets.

H. Laboratory Personnel
1) Do not conduct activities with rDNA until the protocol is approved by the IBC and all training is complete, as required.

2) Follow all established procedures, containment methods, and emergency plans for the activities conducted.
3) Properly utilize all personal protective equipment and containment devices.
4) Report all accidents and spills to the PI or PI designee as soon as possible.
5) Report unsafe conditions to the PI, BSO, or IBC.

IV. Committee Composition & Structure

A. The following guidelines will apply to the IBC composition and structure:
   1) The Chair is appointed by the IO. The IO may reappoint the Chair if there is no other qualified candidate agrees to serve.
   2) The IBC must be comprised of no fewer than five members selected to have the collective experience necessary to assess the safety of the proposed research.
   3) Committee members are appointed by the IO. Committee members may resign by notification to the Chair.
   4) At least two members shall not be affiliated with the institution, apart from their membership on the IBC.
   5) Any member with specialized skills related to biosafety may be asked to serve for additional terms in any capacity at the discretion of the IO, if agreeable. Such additional terms may be requested in the event there are too few people with specialized skills that are willing to serve.
   6) The IBC shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments involving recombinant DNA-containing plants, plant-associated biohazardous agents, and plant-associated small animals are being conducted.
   7) The IBC shall include at least one individual with expertise in animal containment principles when experiments involving recombinant DNA containing animals, or DNA derived therefrom, or animal-associated biohazardous agents are being conducted.
   8) Alternate members are designated to represent specific member types (e.g., scientist, non-scientist, nonaffiliated representative) when any member of that type is absent from a meeting. Alternates are encouraged to attend all meetings but may only count toward a quorum and vote in the absence of that type of member. Alternate members are appointed in the same manner as regular members.
   9) Non-voting members are designated to represent specific administrative units at FIU. Non-voting members are encouraged to attend all meetings, but they do not count towards a quorum. Non-voting members are appointed in the same manner as regular members.
   10) The IBC may use ad hoc consultants to ensure that the committee has adequate expertise and training.

V. Conducting Committee Business

A. A quorum consisting of a simple majority of the committee members is required to conduct business.
B. Meetings will be held monthly at a standing time and date. Additional meetings may be called as needed.

C. Any member of the Committee may call for a role call vote on any issue(s) being reviewed, discussed, or decided by the IBC.

D. Conflict of interest
   1) No member of the IBC may be involved (except to provide information requested by the IBC) 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.
   2) If for any reason an IBC member believes they have a conflict of interest in the review or approval of a project, they may recuse themselves at any time. The IBC member will not be required to give a reason for the recusal unless they so desire. Common examples of conflicts of interest include but are not limited to mentoring, supervisory, or recent collaborative relationships between the IBC member and the project investigators.

VI. General IBC Approval Procedures

A. Review Procedures Information:

1) Anyone intending to perform activities involving recombinant DNA must submit a protocol to the IBC for consideration, including those activities that are exempt from the NIH Guidelines.

2) All new protocols will be pre-reviewed by the Committee for 5 business days.

3) The Coordinator will summarize any comments if applicable and return to the PI who will then make any necessary changes to be reviewed at the next meeting.

4) For protocol applications reviewed by the IBC, the Chair will assign a primary reviewer for the application, who will present the application to the committee and provide comments on the protocol, including any concerns or questions that must be addressed.

5) Following review, one (1) of four (4) determinations will be made:

a. Approved - Protocol was approved without restrictions.

b. Approved pending modifications - Protocol was approved with some modifications required. The project shall not be initiated and the protocol will not receive final approval until the modifications have been addressed.

c. Disapproved - Protocol was disapproved. The reasons for disapproval are to be Summarized and provided to the PI.

d. Tabled - Pending receipt of additional information and/or clarifications. Any such tabled protocol shall be reconsidered at the next convened meeting after receipt of requested information.

6) PIs may be invited to present their protocols to the committee and to be available to answer committee questions. In such cases, the PI will be excused prior to discussion and voting.

7) Investigators may appeal usage decisions by petitioning the IBC. The IBC may call a special meeting to expedite the appeal process if necessary.

8) Clarifications involving minor changes may be approved by the IBC Chair via the electronic protocol system.

9) Clarifications involving major changes will be approved by the convened IBC. The IBC will determine whether the clarification is considered major at the time of the original review.

B. Approval Procedures for BSL-1

1) New protocol applications subject to Sections III-A through III-E of the NIH Guidelines must be reviewed by the convened IBC.

2) New protocol applications not subject to Sections III-A through III-E of the NIH Guidelines may be approved for exemption by the IBC Chair acting on behalf of the IBC. The IBC will require only outcome notification. Consultants may be called in as necessary.

C. Approval Procedures for BSL-2

1) All new protocol applications requiring containment conditions BSL-2 will be reviewed by the IBC.

D. Approval Procedures for BSL-3 or BSL-4

1) BSL-3 and 4 activities are not permitted.

E. Protocol changes (amendments)

1) All changes must be approved prior to implementing.

2) Changes include but are not limited to changes on biosafety level, procedures, host and source organisms and vectors. Substantial changes may require a new protocol.

2) The procedures for approving amendments with procedural changes are the same as those described above for new protocols, with the exception that minor changes may be administratively approved by both the IBC Chair acting on behalf of the IBC (i.e., personnel, project location, and addition of vectors unless it increases the biosafety level).

F. Protocol Lifespan

1) Each protocol shall remain active for a maximum period of three (3) years. At the end of this three-year period, it shall be automatically closed with an advanced notice to the PI. The PI will be required to submit a new application to the IBC to replace the expired protocol. IBC numbers shall be unique and not reused. Please note IBC exemptions will remain active for a maximum period of five (5) years.

VII. Continuing (Annual) Review of Protocols

A. Information for Continuing Review:

1) Two months before the yearly anniversary of a protocol, a courtesy reminder email will be sent to the PI informing them to submit a renewal application.

2) If a renewal application is not submitted, the protocol will be closed after a 30-day grace period.

3) Continuing review applications will be evaluated to ensure that the protocol is still active, that no major changes have been made to the protocol, that no accidents or injuries have occurred over the review period, that training and safety equipment are up to date, and that changes in regulations do not require modification of the protocol.