

Institutional Safety Committee

Guidelines



Office of Environmental Health & Safety

Florida Gulf Coast University
10501 FGCU Boulevard South
Fort Myers, Florida 33965

Introduction

The Institutional Safety Committee (ISC) at the Florida Gulf Coast University (FGCU) promotes and facilitates a safe campus environment by requiring all teaching or research activities meet Federal, state, local, and University safety policies and regulations. The “activities” may include, but are not limited to, class or laboratory projects/studies, self-initiated projects/studies, departmental research, FGCU internal awards, externally funded research grants and contracts, etc. To ensure compliance, ISC reviews, approves and monitors all applicable “activities.” ISC also serves as an advocate for students, faculty and staff in meeting the infrastructure, personnel training, and scientific materials handling guidelines.

Authority and Structure

The ISC was established for the purpose of reviewing, approving and monitoring all projects, studies, and activities involving the use of materials such as recombinant DNA, select agents, pathogens, controlled chemicals and radio-active material, processes that result in acutely hazardous waste, etc. Questions related to ISC meetings and/or applications to the ISC should be directed to the Office of Environmental Health & Safety (EH&S) at (239) 590-1037.

The ISC is composed of FGCU faculty and staff with experience and interest in safety and at least one community member. The Committee reports through EH&S to the Provost and President. The Director of EH&S and the Radiation Safety Officer serve as permanent ex-officio members of the ISC. All Committee members are appointed for a two-year term by the University President. If needed, members can serve unlimited consecutive terms. Nominations for ISC membership are made through the Director of EH&S. Specific individuals may be asked to serve in a consulting capacity to the ISC should specific expertise become necessary.

Each year in May, the Committee will elect a Chair-elect from among its members to serve a one-year term. The Committee Chair may be re-elected to serve consecutive terms. The Chair will call Committee meetings and direct the meeting agendas. In the absence of the Chair, the Chair-elect will run Committee meetings. In the absence of the Chair and Chair-elect, the Director of EH&S will run the meeting.

At the beginning of each academic year, the ISC will schedule a minimum of one meeting for the fall and spring semester. Advance notice of the meetings are posted on the EH&S website. Additional meetings may be scheduled to accommodate the need of the University community. To ensure full consideration, proposals should be received by EH&S at least two weeks in advance of a scheduled meeting. A quorum is required to conduct routine Committee business. A simple majority of the voting membership constitutes a quorum.

Committee Charges

The ISC is responsible for ensuring the University’s compliance with related legislation, regulations and policies established by Federal, state and local agencies, and the University. It achieves this through developing University policies, guidelines, and procedures related to the safe laboratory use of hazardous and toxic substances, reviewing the environmental impact of these substances in the laboratories and reviewing protocols involving the use of substances regulated by the following agencies:

Federal

- Chemical safety issues (Environmental Protection Agency, Food and Drug Administration, Department of Homeland Security)
- Radiation safety (Environmental Protection Agency, Department of Homeland Security, Department of Energy)
- Biological safety issues (Health and Human Services through the National Institutes of Health and the Centers for Disease Control and Prevention, US Department of Agriculture through the Animal and Plant Health Inspection Service)

State

- Chemical and radiation issues (Department of Environmental Protection)

Local

- Local issues and regulations will be handled by joint review by the Institutional Safety Committee and Environmental Health and Safety

University

- University policies, guidelines, and procedures related to the management of materials handled by joint review of the ISC and EH&S

As part of its charge, the ISC requires biosafety level two (BSL-2) biohazards or pathogens be registered at <http://itech.fgcu.edu/hazmat/biological.asp>. Links to relevant websites describing these regulations will be maintained by the EH&S on the [EH&S website](#). ISC application forms are also available on this page.

The ISC is also responsible for maintaining up-to-date information regarding these regulations and assisting students, faculty and staff in interpreting them for application to conduct “activities” at FGCU in order to meet compliance.

ISC Subcommittees

The ISC has two subcommittees, the Radiation Safety Committee and the Diving Control Board.

Radiation Safety Committee

The Radiation Safety Committee is responsible for establishing radiation protection standards. The [Radiation Safety Manual](#) for the University set forth in the Florida Control of Radiation Hazard Regulations, Chapter 64E-5 of Florida Administrative Code. The Radiation Safety Committee serves as a liaison between FGCU students, faculty and staff and the ISC.

The Radiation Safety Committee:

- Consists of at least three (3) members of which one is the Radiation Safety Officer. The other members are individuals knowledgeable in the safe use of radioactive materials.
- Meets at least twice during a calendar year or if requested by the Chair or any two (2) committee members

The ISC has final authority over all radiation safety operations at FGCU.

Diving Control Board

The Diving Control Board is responsible for establishing and reviewing scientific diving standards to assist students, faculty and staff in conducting scientific diving in a manner that will maximize the protection of divers from accidental injury, prepare divers to assist one another in the event of an injury and to establish standards that meet the conditions for the scientific diving exemption from the OSHA commercial diving regulations. SCUBA projects are approved and monitored by the Diving Control Board. The Diving Control Board:

- Consists of at least three (3) members of which one is the Diving Safety Officer. The other members are approved scientific divers with expertise in diving.
- The Diving Safety Officer is an ex-officio member of the ISC.

The Diving Control Board has final authority over all scientific diving safety operations at FGCU.

Committee Records

All applications and records pertaining to the ISC are maintained by EH&S. Approved Committee meeting minutes and approved/non-approved applications for ISC and its subcommittees are kept on file for a period of three years or as otherwise required by law or contractual obligation.

Guidelines, Laws and Regulations

The following guidelines may assist FGCU students, faculty and staff with the preparation of their reports.

Federal

- National Institutes of Health, [Guidelines for Research Involving rDNA Molecules](#)
- Centers for Disease Control, [Biosafety in Microbiological and Biomedical Laboratories, 5th Edition](#)
- 42 C.F.R. 73, [CDC Final Rule: Possession, Use, and Transfer of Select Agents](#)
- 9 C.F.R. 121, [USDA Animal and Plant Health Inspection Service \(APHIS\): Possession, Use, and Transfer of Biological Agents and Toxins \(livestock pathogens\)](#)
- 7 C.F.R. 331, [USDA-APHIS: Possession, Use, and Transfer of Biological Agents and Toxins \(plant pathogens\)](#)

State

- Chapter 64E-5 of Florida Administrative Code: [Radiation Safety](#)
- Chapter 64E-16, Florida Administrative Code: [Biomedical Waste](#)

University

- [FGCU Environmental Health & Safety web site](#)
- [FGCU Misconduct in Research](#)
- [FGCU Financial Conflict of Interest Policy](#)
- [FGCU Export Control Policy](#)

Submitting an Application to the ISC

The ISC reviews, approves, and monitors all projects, studies, and “activities” at FGCU involving specific devices, materials, and conditions below.

- Material or process resulting in an acutely hazardous waste
- Non-ionizing radiation generating device
- Work requiring use of BSL-3 facilities
- Recombinant DNA molecules
- Radioactive material
- Select agent or toxin as defined in 42 CFR part 73
- X-ray generating device
- “Activities” performed by minor(s) (e.g. science fair project) under the age of 18 unless the minor is a registered student or is participating in a supervised FGCU program

Applications for diving projects should be submitted to EH&S and Diving Control Board for review and approval.

The review process focuses on assisting FGCU students, faculty and staff in meeting the relevant legislation, regulations and University policies. The ISC may ask the applicant to provide more detailed information or may ask the applicant to alter the project methods in order to ensure compliance with regulations and policies.

Applicants will be notified of the meeting date at which their application will be considered and are encouraged to attend the review to answer questions from the ISC. Members of the ISC may not vote on applications that they have submitted for review or have an interest in.

ISC meetings are open and subject to public records requests. However, if an application includes confidential information or data, the ISC is protected from disclosing such information under FS (2). Applicants should indicate if the application includes confidential information that should not be disclosed or discussed in a public meeting on the application form. If an application does contain such information, the Chair of the ISC shall contact the applicant for further information.

The Application

An electronic version of the application is located on the [EH&S website](#). The applicant’s Department Chair and Dean must review and sign the application along with the applicant. Completed applications should be submitted to EH&S.

If the project was submitted to an external agency for funding, attach one copy of the external proposal to the application. If you intend to submit the project to an external agency for funding, forward a copy of the external support proposal to the Office of Research & Sponsored Programs as soon as feasible. It is important to remember that an applicant may **NOT** initiate any activities involving materials subject to the purview of the ISC until written approval of the protocol is received from the ISC.

Application Review and Approval Process

Receipt of Application

The EH&S Director or designee logs in all applications to the ISC and assigns each a unique identification number. The applicant will be notified in writing of the application's receipt and its identification number.

Review

The application will be forwarded to the ISC for review. The ISC will be convened to discuss and vote on the application. Applicants are invited to attend the meeting, but their attendance is not required. The EH&S Director or designee, at the direction of the ISC Chair, will notify the applicant of the results of the meeting.

Approval

ISC review and approval is protocol specific, not agent specific. Therefore, if an applicant is conducting two protocols with the same agent and that agent meets criteria for ISC review and approval, each protocol must be submitted to the ISC. Protocols are typically approved for one year following the date of approval.

Modifications to Approved Protocol

The ISC must approve any changes made to the originally approved protocol **prior** to the implementation of the changes. Modifications include protocol amendments, changes or additions of a procedure, consent form revision, staff change, request for recruitment, etc.

Annual Review

Approximately two months prior to the expiration of the approval, a short form, *Notification of Changes to an Approved Application*, will be sent on behalf of the ISC to the applicant. The completed form should be returned to the EH&S Director or designee within the specified timeframe, even if the protocol has been completed or is discontinued.