

GUIDELINES[©]

for the

FGCU Institutional Animal Care and Use Committee (IACUC)

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Statement of Ethical Principles Guiding FGCU's Conduct of Animal Subject Use in Education or Research

Florida Gulf Coast University (FGCU) will adhere to the Laboratory Animal Welfare Act, [the PHS Policy on the Humane Care and Use of Laboratory Animals](#), the NIH [Guide for the Care and Use of Laboratory Animals](#) (hereinafter referred to as the NIH Guide) and the above cited laws and regulations in all research and teaching activities requiring animal experimentation. All FGCU classes using animal subjects for education or research will discuss regulatory and ethical responsibilities for safeguarding the welfare of animal subjects. This includes all projects, whether funded or not. In order to ensure the proper treatment of animals, the President appointed an Institutional Animal Care and Use Committee (IACUC).

All research and teaching projects that include the use of or possible impact on animals will be reviewed and monitored by the IACUC in accordance with the Laboratory Animal Welfare Act, the NIH Guide, the PHS Policy, and relevant state and federal regulations on native species. Purely observational field studies or studies involving invertebrates or dead vertebrates, except when permits are required to have possession of or parts of, are not reviewed by the committee.

Definitions

Animal: Any live vertebrate used or intended for use in research or education. The IACUC does not review research on invertebrates or dead vertebrates, except when permits are required to have possession of or parts of these organisms.

Animal Facility: Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

Bona Fide Scientific Research: Scientific research conducted by qualified personnel, the results of which would likely be accepted for publication in a refereed scientific journal or would likely contribute to the basic knowledge of biology or ecology.

Education: The use of animals in captivity or the capture of native species as part of a methods course.

Humane: The method of taking, importing, exporting, or other activity that minimizes pain and suffering to the animal involved.

Intrusive research: A procedure conducted for bona fide scientific research involving a break in or cutting of the skin or equivalent; insertion of an instrument or material into an orifice; introduction of a substance or object into the animal's immediate environment that is likely either to be ingested or to contact and directly affect animal tissues (i.e., chemical substances); or a stimulus directed at animals that may involve a risk to health or welfare or that may have an impact on normal function or behavior (i.e., audio broadcasts directed at animals that may affect behavior).

Marine mammal: Those mammals which are morphologically adapted to the marine environment, whether alive or dead, and any part thereof, including but not limited to, any raw, dressed or dyed fur or skin.

Principal Investigator (PI): The individual holding the primary responsibility or accountability for the research or educational activity.

Chapter 1: Research and Educational Activities with Animal Subjects

1.1. Introduction

Florida Gulf Coast University (FGCU) has the legal and ethical responsibility for safeguarding the welfare of animal subjects its students and faculty involve in research and education. FGCU expects all individuals working with animals to meet or exceed all applicable laws and regulations and, in addition, to act with the highest standards of care and consideration. The goal of FGCU is to meet educational and research outcomes and objectives while minimizing the impacts on the animals.

1.2. Authority

The [Federal Animal Welfare Act](#) (AWA) as amended (7 USC, 2131-2156) mandates minimal standards of laboratory animal care. These standards apply to nearly all academic and research institutions that use warm-blooded vertebrates in biomedical research, testing, and education programs. Institutions must register with the USDA. Registered institutions are subject to annual inspections and must have an Institutional Animal Care and Use Committee (IACUC).

The [Health Research Extension Act \(P.L.99-158\)](#) mandates that all institutions which receive Public Health Service (PHS) funds for “research, research training, and biological testing activities” involving the use of vertebrate animals, are required to adhere to the provisions of the [PHS Policy on the Humane Care and Use of Laboratory Animals](#) (hereinafter referred to as the *PHS Policy*) regardless of the species of vertebrate animal used.

The *PHS Policy* requires institutions to file an “Animal Welfare Assurance” with the Office for Protection from Research Risks (OPRR) and to have an IACUC. For a description of the Animal Welfare Assurance, refer to the *PHS Policy*, Section IV (A).

The [Endangered Species Act of 1973 \(16 U.S.C. 1531-1544, 87 Stat. 884\)](#) applies to specified species of animals which have been determined to be “endangered” or “threatened.” The provisions of the Act may apply to captive bred, as well as wild-caught, individuals of the listed species. Institutions using wild-caught or non-domestic vertebrates, including most species of nonhuman primates, should be familiar with the provisions of these Acts and the current version of the [Convention on International Trade in Endangered Species \(CITES, 27 U.S.T. 1087, TIAS 8249\)](#). Regulatory authority under the Endangered Species Act is vested in the secretary of the U.S. Department of the Interior (USDI) and implemented by USDI’s Fish and Wildlife Service. Implementing rules and regulations are published in the Code of Federal Regulations, [Title 50 \(Wildlife and Fisheries, Chapter 1 \(U.S. Fish and Wildlife Service, Department of the Interior\), Subchapter B, Part 17 \(Endangered and Threatened Wildlife and Plants\)](#).

The [Marine Mammal Protection Act of 1972](#), (16 U.S.C. 1361-1407, P.L. 92-522) applies to any program maintaining marine mammals in captivity or interacting with marine mammals in the wild. The act includes provisions for housing, handling and care, and restricts the taking, possession, transportation, selling, offering for sale, and importing of marine mammals.

In addition, various laws promulgated by the State of Florida Fish and Wildlife Conservation Commission and the Florida Department of Environmental Protection regulate the handling and possession of wild and native animals. In many cases, permits are required, as well as special permission for work on state and federal lands.

Chapter 2: Institutional Animal Care and Use Committee

FGCU's President shall appoint an IACUC, qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. Any individual planning to conduct research or teaching that uses or impacts animals must receive prior approval from the IACUC.

2.1. Members and Structure

Members are appointed on a staggered basis by the President for a minimum two-year term and may be reappointed at the discretion of the President of FGCU.

The IACUC shall consist of at least five members, and include at a minimum:

- One **Doctor of Veterinary Medicine**, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution;
- One **practicing scientist** experienced in research involving animals;
- One member whose primary concerns are in a **nonscientific** area ;
- One individual who is **not affiliated with the institution** in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.

Other committee members shall be faculty members involved in research. The Associate Vice President for Research or designee shall serve as an ex-officio member of the committee.

No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

2.2. IACUC Chair Responsibilities

The Chair is annually from and by the Committee membership at the last meeting of the academic year. Candidates for the position must have served at least one full academic year on the committee prior to serving as its Chair. The Chair:

- Presides at all meetings.
- Arranges for training of all IACUC members to ensure they are familiar with all governing laws, regulations, and relevant FGCU policies.
- Calls special meetings and appoint ad hoc subcommittees when necessary.
- Notifies PIs with ongoing projects of the deadline for the annual review, de novo review and may request the submission of an interim report.
- Assumes responsibility for the preparation of the annual report to the President or designee.
- Assumes responsibility of execution of Committee policies.

2.3. IACUC Responsibilities, Functions, and Authority

The IACUC reports through the Associate Vice President of Research to the President, who has responsibility of oversight and inquiry.

The IACUC insures that animals are used in education and research activities are handled and cared for in a responsible and ethical manner conforming to all laws and regulations. The IACUC may recommend policies and procedures to improve the FGCU animal research program. Additionally, the committee develops the decision-making structure and processes used in determining the degree of review, approval, and oversight required for vertebrates used in education and research activities.

The IACUC reviews and approves all activities involving animals; inspects animal housing areas and laboratories; ensures adequate veterinary care and oversight; keeps records to verify compliance with all regulations; and provides necessary training for faculty and students involved in research or education activates involving the use of vertebrates.

Specifically, the IACUC:

1. Reviews, at least once every six months, the FGCU's program for humane care and use of animals, using the *NIH Guide* and the *PHS Policy* as the bases for evaluation;
2. Inspects, at least once every six months, all of the institution's animal facilities (including satellite facilities) using the *NIH Guide* and the *PHS Policy* as the bases for evaluation;
3. Prepares reports of the IACUC evaluations conducted as required in the *PHS Policy*, and submit the reports to the President or the President's designee. The reports:
 - are submitted to the President or designee after the spring meeting each year;
 - are maintained by FGCU and made available to the Public Health Service Office upon request;
 - contain a description of the nature and extent of FGCU's adherence to the *NIH Guide* and the *PHS Policy* and identify any departures from the provisions of the *NIH Guide* and the *PHS Policy*, and state the reasons for each departure;
 - distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, consistent with the *PHS Policy*, and, in the judgment of the IACUC and the President or the President's designee, is or may be a threat to the health or safety of the animals.

If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.

4. Makes recommendations to the President or the President's designee regarding any aspect of the institution's animal program, facilities, or personnel training;
5. Reviews and approves, requires modifications in (to secure approval) or withholds approval of those components of protocols or activities related to the care and use of animals as specified in the *PHS Policy*;
6. Reviews and approves, require modifications in (to secure approval), or withholds approval of proposed significant changes regarding the use of animals in ongoing activities; and
7. Suspends an activity involving animals in accordance with the specifications set forth in the *PHS Policy*.

2.4. IACUC Meetings

The IACUC meets at least two times a year at scheduled and announced times. The chair may call additional meetings as deemed necessary.

Meetings are open to the public, in accordance with the Florida Sunshine Laws. Matters concerning personnel, security arrangements, conferences with an attorney, or issues required to be confidential by federal, state or local law may be held in executive session. Meetings will be convened and adjourned in public session.

A simple majority of the committee constitutes a quorum. One member of the quorum must be the veterinarian. The Committee functions from a majority rule. The committee shall actively work to reach consensus. To further evidence diversity of opinion, Minority Opinions will be included in the minutes of all meetings as well as the Semi-Annual Report.

2.5 Record Retention

The IACUC Chair is responsible for the preparation and maintenance of adequate documentation of IACUC activities, including the following. The committee's official records are held in ORSP.

- Copies of all research or educational projects submitted to the IACUC;
- Minutes of IACUC and actions taken by the IACUC;
- Evaluations of reviews and inspections;
- Copies of all correspondence between the IACUC and the Associate Vice President for Research or his/her designee;
- A list of IACUC members; and
- Written procedures for the IACUC in the same detail as described in this document.

The records required by this policy shall be retained for at least three (3) years after the expiration of the protocol and shall be kept in Research and Sponsored Programs.

Chapter 3: Review of Research and Educational Projects Using Animals

3.1. Guiding Principles

In order to approve proposed research or educational projects or proposed significant changes in ongoing research or educational projects, the IACUC conducts a review of those components related to the care and use of vertebrates and determines if the proposed research or educational activities are in accordance with the *PHS Policy*. In making this determination, the IACUC confirms (1) the project will be conducted in accordance with Federal regulations governing humane care and use of animals and (2) the project is consistent with the *Guide for the Care and Use of Laboratory Animals* published by the Institute of Laboratory Animal Resources, National Research Council. Further, the IACUC determines the project conforms with FGCU's Guidelines and, unless acceptable justification for a departure is presented, meets the following requirements:

1. Procedures with animals will, whenever possible, avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research or education design.
2. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia.
3. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure, or, if appropriate, during the procedure.
4. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
5. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
6. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
7. All permits required by federal, state, or regional regulations are current.
8. Methods of euthanasia will be consistent with the recommendations of the *American Veterinary Medical Association (AVMA) Panel on Euthanasia* or other guidelines as appropriate for specific species under consideration.

3.2. Review and Approval of Animal Use Activities

Faculty, staff and students using species as defined by this Policy in research or education, will submit an IACUC Application Form found on the [IRB webpage](#) to Research and Sponsored Programs. Research and Sponsored Programs will assign a protocol number to the submitted project, open a file, and make the original project submission the file copy.

a. Designated Member Review

Designated member reviews will be conducted on new applications, de novo reviews, and annual reviews and amendments to approved protocols, as appropriate. The IACUC Chair has the authority to approve minor amendments and conduct the annual reviews if no adverse

events or unanticipated problems were reported and there are no concerns with the protocol. Designated member reviews are conducted by a minimum of two IACUC members appointed by the IACUC Chair. Approval via a designated member review has equal validity to full committee review approval and does not require subsequent re-approval by a convened IACUC meeting.

Under a designated member review:

- Each IACUC member is provided with a copy of the proposed research protocol, de novo review or an annual review or amendment with significant changes as determined by the IACUC Chair.
- IACUC members have five business days to review the document and make their recommendation to the Chair re. the need for a full committee review.
 - An untimely or lack of response from a member implies agreement with the designated member review process.
 - If any member requests a full committee review, the designated member review is terminated and the protocol is sent for full committee review at a convened IACUC meeting.
- If a full committee review is not requested by an IACUC member, the IACUC Chair will assign a minimum of two IACUC members qualified to conduct the review.
- Designated reviewers have the authority to approve the protocol as written, request clarification, additional information or modifications from the PI before approval; or request a full committee review within 10 calendar days of their assignment. Designated reviewers cannot deny approval of an application. Only the full committee, in a convened meeting, has the authority to deny a proposal. Designated reviewers may not withhold approval of an application.
- The designated reviewers must be unanimous in any decision. If the designated reviewers cannot reach a unanimous decision, the protocol is sent for full committee review at a convened IACUC meeting.
- The date of action is the date the final designated reviewer approves the requested action on the protocol.

Protocols involving unalleviated pain or distress (Category E), major survival surgery, food or water restriction, the use of paralytics, or prolonged restraint are automatically reviewed and approved by the full committee.

The IACUC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

b. Protocol Approval Process

If the application is **approved**:

- The IACUC Chair will sign a notice of approval and forward it to the PI, his/her department chair and college dean indicating that the activity covered by the protocol may begin.

If the protocol is **approved pending clarification** or modification:

- A request for clarifications will be sent to the PI and he/she will be asked to respond by a prescribed time. A protocol will be considered withdrawn if a timely response is not received.
- Upon receipt of the clarifications, the designated reviewers or committee, whichever conducted the initial review, will review the response and approve the protocol or request additional clarifications. The PI has the option of requesting a meeting with the Board to address concerns with the study.

If the protocol is **disapproved**:

- The PI will be notified of the actions and reasons for the actions. The PI has the option of requesting a meeting with the Board to address concerns with the study.

Chapter 4: Monitoring Research and Educational Projects Using Animals

4.1. Annual Reviews

The IACUC Chair will conduct annual reviews for protocols with no adverse events, unanticipated problems or concerns with the protocol. The designated member review process will manage annual reviews with adverse events, unanticipated problems or protocol concerns. ORSP will send the annual review notice approximately 60 days prior to the due date.

4.2. De Novo Reviews

De Novo Reviews are conducted on protocols continuing beyond three years of its approval or last de novo review. The review requires the submission of an IACUC application. This review ensures the university's high standards of its vertebrate research and all animal use procedures, personnel, and training are updated and current. ORSP will send the de novo review notice approximately 90 days prior to the due date. The IACUC has the option of conducting a designated member review or conducting a full committee review of the de novo review.

4.3. Amendments to Approved/Pending IACUC Applications

PIs should use the amendment form, available on [IACUC webpage](#), to request a modification(s) to pending and existing protocols. All proposed modifications require review and **approval by IACUC prior** to implementation.

IACUC has developed two classifications of amendments - significant and minor - based upon the perception of risk. Proposed amendments classified as significant are reviewed and approved by the designated member review process or at a convened IACUC meeting. Proposed minor amendments are reviewed and approved by the IACUC Chair.

IACUC reserves the right to require a new application if the proposed modification(s) falls outside of the objectives, purpose, or aims stated in the original protocol. The IACUC Chair holds the final discretion on the classification of the amendment as significant or minor and whether the proposed modification requires a new application.

Examples of Significant Amendment to Protocol

Administrative

- Change in principal investigator
- Change in study objectives

Species

- $\geq 15\%$ increase in the original number of animal species
- Change in species (addition/deletion of)
- Increased proportion of expected animal deaths

Procedure

Examples of Minor Amendment to Protocol

Administrative

- Addition or deletion of personnel other than the PI
- Change in purpose or specific aim of study
- Change in protocol title

Species

- 11% -15%* increase in the original number of animal species ($\leq 10\%$ increase does not need to be reported to IACUC)
- Addition of another strain/stock of same species
- Decreased proportion of expected animal deaths

Procedure

Examples of Significant Amendment to Protocol

- Increased overall invasiveness of a procedure.
- Addition of or increase in a painful/distressful procedure
- Addition of major procedures requiring anesthesia with recovery, hazardous or infectious agents

Animal Maintenance

- Changes in animal care and monitoring practices
- Change in field site

Drugs

- Change of drug classification or regimen

Euthanasia/End Points

- Change in or addition of euthanasia procedures from an AVMA 'Acceptable Method' to an AVMA 'Conditional Method' (AVMA Guidelines)

Examples of Minor Amendment to Protocol

- Change in minor procedures
- Additional noninvasive specimens collected/analyzed
- Addition of surgery or procedure that is less invasive than already on the approved protocol
- Repetition of an already approved experiment

Animal Maintenance

- Change in animal care facility, housing unit or research facility

* IACUC Chair reserves the right to determine if the change is major or minor, based on species

4.4. Oversight

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the *Animal Welfare Act*, the *Guide*, or FGCU's guidelines. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

Mistreatment of animals is covered under FGCU's *Policy for Dealing with Allegations of Misconduct in Research or Scholarly Activities*. Any concerns about the welfare or treatment of animals at FGCU brought to the attention of the IACUC will be investigated to determine if activity should be suspended or if the concern falls under the *Policy for Dealing with Allegations of Misconduct in Research or Scholarly Activities*.