



SUBJECT: Institutional Animal Care and Use Committee: Role and Function	Effective Date: April 28, 2017	Policy Number: 10.4.1 (b)
	Supersedes: 10.4.1 FAU Policies and Procedures Manual	Page of 1 7
	Responsible Authorities: Vice President for Research	

I. Background

Florida Atlantic University (FAU) is committed to the humane care and use of animals in activities related to research, teaching and testing. The University has adopted institution-wide principles regarding animal care that are based on regulations set forth in the Public Health Service (PHS) policy on the Humane Care and Use of Animals and by the United States Department of Agriculture's (USDA) Animal Welfare Act.

To accomplish the objectives inherent in these regulations and principles, FAU's Institutional Animal Care and Use Committee (IACUC) was established in accordance with the Animal Welfare Act and PHS policy to ensure the humane care and use of animals for research and education at the University. The IACUC is responsible for oversight of the animal care and use program and its components. It is supported administratively by the Research Integrity unit within the Division of Research, under the authority of the Vice President for Research.

II. Purpose

The purpose of this policy is to delineate the functions, roles and responsibilities of the FAU IACUC membership.

III. General Statement

The Florida Atlantic University process for reviewing all research, teaching and testing activities involving vertebrate animals is carried out by the IACUC. The IACUC is appointed by the President of the University and the Vice President for Research (the Institutional Official (IO)) to implement federal, state and institutional policy. The IACUC is the institution's central oversight body for matters relating to the care, use and treatment of live vertebrate animals used for research, teaching and testing activities. The IACUC is authorized to approve, request modifications in order to secure approval, withhold approval, or suspend animal research and teaching projects.

The IACUC follows the principles of the “Three Rs” when considering the welfare of animals involved, Reduction, Refinement, and Replacement. **Reduction** refers to use of the minimum number of animals possible to achieve scientifically rigorous results; **Refinement** refers to modification of procedures to minimize pain and distress that may occur in research; and **Replacement** refers to consideration of other non-animal models whenever possible to achieve the same results.

In addition to reviewing specific research projects, the IACUC also carries out other federally mandated functions such as reviewing and reporting on the overall animal program as well as inspecting and evaluating all animal facilities, laboratory space, and study areas at least once every six months. It makes recommendations to the Institutional Official based on this review regarding any aspect of the animal program, facilities or personnel training.

IV. Policy

The IACUC is responsible for the review of all projects (regardless of whether the project is funded or not) that involve the use of vertebrate animals in research, teaching, and testing. All projects reviewed by the IACUC require approval by the IACUC prior to initiation.

V. Procedures

The IACUC is **not required to review the following projects** a) those involving only invertebrate animals; b) those involving field studies that meet the criteria for exemption; c) animals purchased with private funds, owned by FAU employees, and used in activities outside of FAU sponsorship (e.g., personal pets, unit mascots, service or therapy dogs, etc.); or d) animal tissues or materials obtained under certain specific circumstances.

The IACUC is responsible for the **oversight and review of all protocols** involving the use of vertebrate animals. IACUC members must formally review protocols and grant approval *prior* to any activities involving animals being initiated in accordance with the protocol review procedures outlined in institutional policy and following all applicable policies.

The IACUC will investigate and evaluate all **welfare concerns** raised by anyone regarding the care and use of animals at the institution.

The IACUC **will not conduct scientific merit review of protocols** involving the use of vertebrate animals; the IACUC is only responsible for confirmation that scientific merit review has been completed by an appropriate source and will request the PI have a scientific review completed of a project by an independent reviewer as applicable. The IACUC is responsible for assessing anything associated with and affecting the welfare of animals used. This includes, but is not limited to, the evaluation of pain and distress, appropriateness of animal numbers, the extent to which “the 3Rs” (replacement, reduction, refinement) have been addressed, all procedures involving animals, and assessing the adequacy of investigator skills.

Policy Number:	
10.4.1b	
Page	of
3	7

The IACUC will have standing **monthly meetings**, at a minimum. When necessary the IACUC will convene more often to address urgent issues. A quorum (defined as 1 more than one-half of voting members) of committee members must be present to conduct official business. Committee members may participate in meetings via teleconference and / or videoconference. IACUC members are responsible for reviewing meeting materials ahead of time and coming prepared to discuss and finalize protocols at regularly convened meetings. IACUC members are provided guidance to assist in standardizing their reviews of protocols. Meeting agendas are distributed approximately 5 working days prior to the scheduled meeting date. The IACUC will follow the agenda topics at each scheduled committee meeting. Each action will be following by a motion, a second, and a vote. A majority of the quorum present is required to pass a motion. All motions and subsequent votes will be recorded in the minutes. Specific protocol review procedures are referenced in institutional policy.

The IACUC will **review protocols** to ensure all proposals include the following in sufficient detail: a) Identification of the species and the approximate number of animals to be used; b) Rationale for the use animals as well as the appropriateness of the species and numbers of animals to be used; c) A complete description of the proposed use and procedures of the animals; d) A description of procedures designed to assure that discomfort and pain to animals will be limited to what is necessary for the conduct of scientifically valuable research; Provision for the use of analgesic, anesthetic, and tranquilizing drugs must be included where appropriate to minimize discomfort and pain to animals; and e) A description of any euthanasia method to be used. The IACUC will evaluate whether the following criteria have been adequately addressed in the protocol: a) Duplication (evidence that activities do not unnecessarily duplicate previous studies); b) Surgery (must meet requirements for aseptic surgery and pre and /or post-operative care. One animal cannot be used for more than one major operative procedure without meeting specified conditions including a substantive justification); c) Euthanasia (The method of euthanasia must be consistent with AVMA Guidelines on Euthanasia or otherwise providing strong scientific justification for alternative methods to be considered); d) Housing and Health (Animal living conditions must be consistent with standards of housing, feeding and care directed by a veterinarian or scientist with appropriate expertise; e) Qualifications (Personnel must be appropriately trained and qualified by the institution); f) Deviation from Requirements (any deviation from institutional or federal requirements must be justified and approved, in writing, by the IACUC.)

In accordance with *The Guide*, **IACUC Membership** includes, as a minimum, the following: a) a Doctor of Veterinary Medicine either certified for training and experience in laboratory animal science and medicine or in the use of the species at FAU; b) at least one practicing scientist experienced in research involving animals; c) at least one member from a nonscientific background drawn from inside or outside the institution; d) at least one public member to represent general community interests in the proper care and use of animals. Members shall be of varying professional and personal backgrounds and shall demonstrate a genuine interest in and commitment to the purpose of the Committee. A minimum of 5 members are required. An effort will be made to include membership that represents the diversity of research at FAU; hence a mix of wildlife and laboratory researchers will be sought. Tenured faculty members are

Policy Number:	
10.4.1b	
Page	of
4	7

encouraged to be on the IACUC. Members may be nominated by college deans, department chairs and colleagues among others. Those interested in serving on the committee may also volunteer to join the IACUC. Members are appointed to the IACUC by the IO for varying terms of between 1 to 3 years with the option to renew.

IACUC members will receive the following **training** documents and be required to complete the following activities: a) a copy of the latest Guide for the Care & Use of Laboratory Animals, the Arena/OLAW IACUC Guidebook, the USDA Animal Welfare Act and Animal Welfare Regulations, a copy of FAU's approved Animal Welfare Assurance, and an index of the IACUC's policies and procedures; b) completion of the "IACUC member" module through Collaborative Institutional Training Initiative (CITI); c) meet with the IACUC administrator for orientation and be provided an overview of the federal regulations and expectations of committee members; d) meet with the IACUC administrator for an overview of protocol review expectations; e) paired with veteran IACUC member to perform the initial protocol review activities.

Continuing education of IACUC members is provided in the form of attendance at conferences and webinars sponsored by Public Responsibility in Medicine and Research (PRIM&R), Office of Laboratory Animal Welfare (OLAW), the Scientists Center for Animal Welfare (SCAW), and the American Association for Laboratory Animal Science (AALAS) as well as discussion during monthly committee meetings through case studies presented by OLAW in Lab Animal Protocol Review Columns.

The Chair and Vice-Chair(s) of the IACUC must be animal researchers and have served for at least one year as an IACUC member. These positions are integral to the success of the animal care and use program and must actively participate in all aspects of this program. They will lead meetings, guide protocol discussion, attend national conferences for professional development related to animal care and use in research, head non-compliance investigations, communicate directly with researchers when necessary, participate in semi-annual inspections and program reviews, meet with the IO, deans and chairs and animal researchers when needed.

IACUC members conduct a **semiannual animal facility inspection and program review** every six months and report findings to the Vice President for Research, who serves as the Institutional Official of FAU. The standards of The Guide are used by the IACUC to conduct these reviews. All IACUC members are expected to participate in the conduct of these inspections and the program review. The IACUC administrator will coordinate the inspection teams and provide inspectors with checklists and information related to their responsibilities during inspection. IACUC members serving as inspectors must provide the IACUC administrator(s) with follow up requirements needed of the laboratories inspected including details for in the inspection report and deadline dates. This mandatory feedback must be provided by the inspectors within 48 hours after the inspection site has been conducted to be included. IACUC members are expected to participate in the animal care and use program review and identify areas in need of addressing or improvement. The members will communicate these areas to the IACUC administrator(s) to include in the final program report. The IACUC members will also be responsible for identifying facility or program areas that need to be reported to the Institutional Official as a result of the inspections and program review. This written

Policy Number:	
10.4.1b	
Page	of
5	7

report (including minority views) is compiled and provided to the IO about the status of the program including recommendations. The report will include a description of the nature and extent of the Institution's adherence to the Guide, and any departures from the Guide, identified specifically with reasons for each departure stated. The report will note any program or facility deficiencies, distinguish significant deficiencies from minor deficiencies, and include plans and schedules for correcting each deficiency. A significant deficiency is defined as one that is or may be a threat to animal health or safety.

The IACUC is responsible for the continuing oversight of animal activities through **post approval monitoring (PAM)** to ensure the well-being of all animals. The IACUC provides for PAM through continuing protocol reviews, semiannual lab inspections and program review, observation of protocol procedures when applicable, observation of animals by animal care, veterinary and IACUC staff and members, external regulatory inspections and assessments. The IACUC, veterinary, animal care and compliance staff may all conduct PAM, which also serves as an educational tool.

The IACUC has the authority to **suspend** any project involving the use of animals if it finds noncompliance with the PHS policy, Guide, Assurance, Institutional Policy or violations of the Animal Welfare Regulations. Instances of non-compliance must be appropriately investigated by the IACUC and all required reporting to federal oversight committees be satisfied. Suspension may occur 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. The IACUC must consult with the IO regarding the reasons for suspension. Appropriate corrective action must be taken by the IO including necessary reporting to OLAW.

The IACUC will exercise due diligence in avoiding **conflicts of interest (COI)** to assure the integrity of the institution's animal care and use program and, as such, will make known any potential or perceived COI concerning all business conducted by the IACUC. IACUC members in any of the following categories could have a COI for a specific protocol under review, or a COI for specific business issues under discussion: 1) Principal Investigator; 2) Co-Investigator, or Sponsor; 3) Investigator receiving funding from the study, as listed in the study budget; 4) In a supervisory role over the PI of the study; 5) Family member of PI; and/or 6) IACUC members listed on the accompanying grant proposal; and/or 7) A financial interest as defined by the DoR Financial Conflict of Interest Policy. Note: Peripheral knowledge or indirect involvement in certain activities may not rise to the level of a COI but might result in member abstention from a vote or discussion.

No IACUC member or IACUC administrator shall breach the **confidentiality** of the IACUC process by: a) disclosing confidential or proprietary information to any non IACUC member, and b) discussing, disclosing or communicating any details of IACUC business to any third parties without the consent of the IACUC Chair, Assistant Vice President of Research, or Institutional Official.

V. Definitions

AAALAC: American Association for the Accreditation of Laboratory Animal Care.

AWA: The Animal Welfare Act of 1966, the first federal law in the U.S. regulating animals in research. The AWA is administered by the United States Department of Agriculture.

Guide: Guide for the Care and Use of Laboratory Animals (8th Edition)

IACUC: Institutional Animal Care and Use Committee

IO: Institutional Official

OLAW: Office of Laboratory Animal Welfare

PAM: Post Approval Monitoring

PHS: Public Health Service

USDA: United States Department of Agriculture

VI. Accountability

The PI will be responsible for:

- Adhering to all policies and procedures of the animal care and use program when carrying out research, teaching or testing of vertebrate animals.

The IACUC will be responsible for:

- Carrying out the mission and functions of the FAU animal care and use program as outlined in this policy.

Comparative Medicine will be responsible for:

- Providing veterinary care and oversight of well-being of all vertebrate animals used at FAU
- Oversight of husbandry of animals housed within FAU facilities and appropriate maintenance of centrally managed animal housing facilities
- Coordinating training initiatives for faculty and students as outlined in institutional policy.
- Consulting with FAU faculty and students regarding study design and conduct prior to and throughout the lifecycle of an IACUC protocol.
- Supervising animal health surveillance, quarantine and pest control programs.
- Providing guidance to IACUC members with regard to veterinary and regulatory requirements, as well as input on logistical and environmental issues as part of IACUC protocol review.

The Research Integrity (RI) office will be responsible for:

- Coordinating the administrative aspects of the IACUC.
- Maintaining, updating and renewing all federal assurances (OLAW, USDA, etc.) within the appropriate timeframes, including annual reports to OLAW.
- Reporting, on behalf of the IACUC and the IO, non-compliance and other matters that affect the welfare of animals at FAU to appropriate federal oversight agencies.
- Investigating allegations or instances of non-compliance on behalf of the IACUC.
- Scheduling and coordinating, at least every six months, a comprehensive review of the program and animal facilities, and promptly reporting findings to the IO in writing and/or verbally if there are urgent findings.
- Maintaining records of assurances, meeting agendas and minutes, applications and protocols, forms, semi-annual inspection and program review reports, etc. within appropriate timeframes but at a minimum, for 3 years after completion of an animal protocol.
- Reporting any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked).

VII. Policy Renewal Date

April 28, 2020

VIII. References

U.S. Code, Title 7, Chapter 54.
 U.S. Code, Title 9, Subchapter A, Parts 1, 2, 3.
<https://grants.nih.gov/grants/olaw/tutorial/iacuc.htm>

POLICY APPROVAL

Initiating Authority

Signature: _____

Date: _____

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

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