IACUC POLICIES AND PROCEDURES

1. BACKGROUND AND ORGANIZATION
   A. INTRODUCTION & PURPOSE

   Florida Atlantic University is committed to the humane care and use of animals in activities related to research, testing and teaching. The University has adopted institution-wide principles regarding animal care as stated in the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals, and is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals in Testing, Research and Training. In order to accomplish the objectives inherent in these regulations and principles, there have been two separate organizational components designated to ensure their implementation in the overall animal care and use program.

   a) The Institutional Animal Care and Use Committee (IACUC) is the University’s central review body for matters relating to the care, use and treatment of animals in these areas.
   b) Office of Veterinary Services is responsible for oversight of all animal care and use and for ensuring compliance with federal, state and local regulations. The University Veterinarian (Attending Veterinarian) is the Director of this office.

   A. LINES OF AUTHORITY AND CHARGE

   a) The IACUC was established in accordance with the Animal Welfare Act and is under the authority of the Vice President for Research to ensure the humane care and use of animals for research and education at the University. The IACUC is facilitated by the Research Integrity unit within the Division of Research, under the authority of the Vice President for Research.
   b) The Office of Veterinary Services (VS) is administered by the University Veterinarian and is charged with the veterinary care and husbandry of the
c) The Vice President for Research serves as the Institutional Official.

Lines of Authority

University President

Vice President for Research (Institutional Official)

Attending Veterinarian

---

2. THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

A. Overview

a) The Florida Atlantic University process for reviewing all research, teaching and testing activities involving vertebrate animals is carried out by the Institutional Animal Care and Use Committee (IACUC). The IACUC is authorized to request modifications, approve, withhold approval, or suspend animal research and teaching projects.

b) 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, lab space and study areas at least once every six months. The IACUC also reviews and investigates legitimate concerns involving the care and use of animals at the institution and makes recommendations to the Institutional Official regarding any aspect of the animal program, facilities or personnel training.

c) All projects (with or without internal or external funding) which involve the use of vertebrate animals must undergo IACUC review and receive approval prior to initiation. Investigators are required to consult with the University Veterinarian about the project and submit a completed Animal Use Protocol Form (application) or Request for Exemption to the IACUC for review by the Committee.

d) The Committee is comprised of non-scientific/lay/non-affiliated members as well as scientific/affiliated members, to ensure a balance of professional
e) Meetings are routinely held on the last Friday of each month. The deadline for submission of materials for review is ten working days prior to the meeting. The decision as to the type of review a proposal receives (expedited or full committee) is based on the expected level of animal discomfort and types of procedures (University Veterinarian will suggest the appropriate category of review; any IACUC member can call for a full review at any time). The agenda, protocols, and other meeting materials are sent to members approximately one week prior to a meeting. Protocols are placed on the agenda as they come in. A quorum is considered to be one more than one half the total voting members. In addition to the Chair, at least one non-scientist and/or unaffiliated member must be present.

f) Once approved, each protocol is approved for three years. Projects involving USDA-covered animals are reviewed annually, or more frequently, if deemed appropriate or necessary by the IACUC. Renewal of ongoing projects is required every three years for both USDA-covered and non USDA-covered species.

g) A research project that is identical to an already approved project in regard to specific aims, hypothesis, and animal species and use, may be given executive review and approval by the Committee Chair. This approval is reported at a regularly scheduled meeting within 30 days of such an approval.

h) Protocols not requiring direct use of live animals (i.e., using animal material obtained from slaughterhouses or other specified sources) receive executive review and approval. An Animal Products Use Form must be completed and submitted to the IACUC.

B. Regulatory Aspects

a) Florida Atlantic University’s Institutional Animal Care and Use Committee (IACUC) has an Assurance on file with the Office for Laboratory Animal Welfare in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, for institutions that have research sponsored by the PHS.

b) The IACUC is also governed by the USDA Animal Welfare Act as documented in the Code of Federal Regulation Title 9, Subchapter A, Parts 1, 2 and 3.

c) The IACUC also applies the standards set forth in the Guide for the Care and Use of Laboratory Animals.
C. Membership
   a) Members shall be of varying professional and personal backgrounds and shall demonstrate a genuine interest in and commitment to the purpose of the Committee.
   b) Membership shall include one veterinarian who specializes in laboratory animals (attending veterinarian), one practicing scientist, one member whose primary concerns are in a nonscientific area and one individual who is not affiliated with the institution in any way other than as a member of the IACUC.
   c) A minimum of 5 members are required.

D. Contacting the IACUC

Research Integrity serves as the point of contact for information regarding the IACUC. All correspondence, including that directed to the Chair or other specific members of the Committee should be sent to the following address:

   Institutional Animal Care and Use Committee (IACUC)
   Division of Research/Research Integrity
   Administration Building, Suite 239
   Phone: 561-297-0777

3. Veterinary Services (VS)
   A. As stated above, the University Veterinarian is the Director of Veterinary Services (VS), which is charged with the veterinary care and husbandry of the animals, the occupational health and safety of personnel, and ensuring the appropriate training of personnel working with animals in accordance with all relevant regulations and guidelines governing the humane care and use of animal.
   B. Further information is available at http://www.fau.edu/research/rcs. Veterinary Services is located in Building 71, Room 324.

4. REGULATIONS, GUIDELINES AND POLICIES
   A. Regulations, guidelines and policies are available on the IACUC web site (http://www.fau.edu/research/rcs).
   B. Specific Veterinary Services’ Standard Operating Procedures (SOPs) are also available at http://www.fau.edu/research/ovs/administration/sop.php).

5. ANIMAL PROTOCOL SUBMISSION AND REVIEW
   A. SCOPE The Animal Use Protocol Form must be completed and approved for all work involving the use of live vertebrate animals at Florida Atlantic University regardless of the source of funding or the intended use (e.g., research, teaching or testing) of the animals.
   B. PROTOCOL SUBMISSION REQUIREMENTS - New protocol submissions, projects identical to previously reviewed and approved projects and those projects in which animal use is limited to animal products, breeding protocols, holding protocols, wildlife projects or exotic species must follow protocol submission requirements as specified in these policy and procedure guidelines.
C. PROTOCOL REVIEW PROCESS AND CRITERIA FOR REVIEW
   a) TYPES OF REVIEW/OVERVIEW OF THE APPLICATION PROCESS
      i. The process for reviewing and approving programs using animals begins with the completion of an Animal Use Protocol application. Information required for the Protocol is consistent with requirements detailed in the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the Animal Welfare Regulations. A consultation with the University Veterinarian is required for all proposals involving the use of animals prior to the protocol's submission and subsequent approval.
      ii. There are three types of Committee review: full, designated or executive. Determination of the type of review is usually based upon the expected level of animal pain or discomfort and types of procedures. All committee members receive a copy of all protocols. All actions on protocols are open for discussion and are voted on at a meeting with a quorum present. The following steps are involved in the review process:

   Step 1: Submission of the Protocol. Investigators submit one electronic copy and one original signed animal use protocol form (or fish use protocol form) to the IACUC Office. (If applying for a grant, one copy of the scientific portion of the grant application must be submitted with the protocol.)

   Step 2: Initial Review. Following the receipt of a Protocol, the type of review a proposal will receive will be verified (designated or full committee) based on the expected level of animal discomfort and types of procedures. The pain level is initially determined by the Veterinarian at the time the animal use protocol form is prepared and submitted for his/her review. This assessment is based on the USDA categories. Completeness of the protocol is also checked at this time.

   Step 3: Review (By Type) A copy of all the protocols up for review are sent to each member of the committee. At monthly meetings, the IACUC considers new protocols requiring full committee review and reviews the Reports of Designated Reviews and Reports of Executive Reviews. Possible outcomes of the Committee's review include unqualified approval, approval pending modification(s) and/or clarification(s), table (deferral), or disapproval. For approvals pending modifications or clarifications, the chair and/or a designated “expert” as requested by the committee will review the re-submitted information for completeness.

   b) FULL COMMITTEE REVIEWS - Protocols requiring full committee review (FCR) are forwarded to the entire IACUC one week prior to the meeting date. All committee members are required to review and discuss
i. **IACUC Actions Following Full Committee Review (in accordance with NOT-OD-09-035):** When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

1. If **all** members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review (DMR), or returned for FCR at a convened meeting.
2. If **all** members of the IACUC are not present at a meeting, the committee has the option to vote to return the protocol for FCR at a convened meeting or to employ DMR. If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so. (PHS Policy IV.C.2)
3. If the IACUC uses DMR subsequent to FCR, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date will be reported to OLAW as noncompliance with the PHS Policy. (PHS Policy IV.F.3)

   c) **DESIGNATED REVIEWS** - One designated reviewer is assigned. The protocol is forwarded to the designated as well as the IACUC committee members for review. The designated reviewer is given 7 days to complete the review and return to the IACUC office. The Committee is informed that they are to review the designated review for appropriateness of this type of review. Committee members are expected to respond within the 7 days if they want the application to be deferred to full committee review. If no comments are received from the members of the IACUC and there is no request for a full committee review, a letter requesting clarifications and/or modifications is sent to the investigator or if a recommendation to approve outright has been made, an approval letter is sent. Protocols that involve only momentary or slight pain or distress or are only breeding colonies or holding colonies fall into this category. A list of all Designated Reviews and their action are included in the agenda items of each meeting.

d) **EXECUTIVE REVIEW** - The Chair or their designee reviews and approves protocols falling in this category. This category includes the annual renewals of approved protocols, minor amendments, previously
i. **NOTE**: SCIENTIFIC REVIEW - The IACUC review focuses on the evaluation of pain and distress, appropriateness of animal numbers, the extent to which “the 3Rs” (replacement, reduction, refinement) have been addressed, procedures involving animals, and adequacy of investigator skills. Normally, scientific peer review is left to outside funding agencies. In lieu of outside review, the IACUC will conduct scientific review. If the IACUC lacks the expertise, it will request the department to provide a reviewer or will try to find a person with appropriate background to provide the review.

**Step 4: Investigator Notification.** If a protocol receives unqualified approval, the investigator is provided with a letter certifying the approval. In cases where the IACUC requires clarification(s) or modification(s), the investigator is notified by the IACUC Chair or staff in writing. In such cases, the approval is issued following receipt of an acceptable response from the investigator. In cases of a tabled or disapproved protocol, the investigator is notified by the Chair and advised as to available options.

e) **Criteria for Review**

i. All proposed activities are reviewed to ensure that the following federal requirements for granting IACUC approval are met:

1. **Activities** -- All activities involving animals must be in accord with USDA Regulations and/or PHS Policy, as applicable.

2. **Pain/Distress** -- Must avoid and/or minimize discomfort, distress and pain. If pain and/or distress are caused, appropriate sedation, analgesia or anesthesia will be used. The Attending Veterinarian must be involved in planning. Use of paralytics is prohibited without proper justification, proper training of personnel and equipment to properly monitor the animal. (Normally anesthesia is required but it requires special training to monitor the animal for proper levels of anesthesia.) Animals with chronic and/or severe pain that cannot be relieved will be euthanized according to proper procedures. If pain cannot be relieved, then it is designated as a Category E protocol, and requires a substantive justification for the unalleviated pain/distress.

3. **Alternatives** -- The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources (e.g., the
4. **Rationale and Methods** -- All proposals must include:
   A. Identification of the species and the approximate number of animals to be used;
   B. A 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.

5. **Duplication** -- Must provide assurance that activities do not unnecessarily duplicate previous efforts.

6. **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.

7. **Euthanasia**— The method of euthanasia must be consistent with AVMA Guidelines on Euthanasia (2007) or other appropriate and accepted methods (e.g., Guidelines for Euthanasia of Non Domestic Animals.)

8. **Housing and Health** -- Animal living conditions must be consistent with standards of housing, feeding and care directed by veterinarian or scientist with appropriate expertise. Medical care must be provided by a qualified veterinarian.

9. **Qualifications** --Personnel must be appropriately trained and qualified by the institution.

10. **Deviation from Requirements** --Must be justified and approved, in writing, by the IACUC.

11. The Committee’s review process always includes a check for compliance with all applicable IACUC and institutional policies and procedures.

**D. CONTINUING REVIEW, AMENDMENTS AND TERMINATION OF PROTOCOLS**

a) **Annual Review and Three-Year Renewal of Ongoing Projects**
   i. Animal research protocols are approved for a three-year term, unless they involve USDA covered animals.
   ii. Protocols involving USDA covered animals are subject to annual reviews in addition to a 3 year renewal.
b) **Annual Review Process:**
   i. A reminder is sent to the principal investigator two months prior to the anniversary date of the last review indicating that the USDA annual review is due.
   ii. The investigator must complete and return the *USDA Annual Review Form*, which is then reviewed by designated member review procedures or Full Committee.
   iii. Upon recommendation of the designated reviewer or Full Committee, the protocol is either approved outright for a period of time up to an additional year or a protocol modification is requested and the normal review process resumes.

c) **Three-Year Renewal:**
   i. At the end of the third year of a protocol approval period, the investigator must submit a new *Animal Use Protocol Form* to the IACUC in order to continue research activities. This form undergoes the same review process as any new protocol.
   ii. The renewal must include all previous modifications or amendments made to the protocol since its original approval.

d) **Modifications or Amendments to Approved Protocols**
   i. Modifications to approved protocols must be documented, reviewed, and approved appropriately. An amendment form is submitted to the IACUC describing the modification and including an explanation of the rationale for the change.
   ii. The Chair in consultation with the University Veterinarian will determine if the modification is “minor” or “significant.” Minor modifications may entail such things as small numbers of additional animal subjects, addition of new personnel, or perhaps changing the route of administration of drug. Minor modifications may be approved administratively by the IACUC Chair and the University Veterinarian without full committee review.
   iii. A significant modification may entail a large increase in numbers of animals being used or requested, an increase in invasiveness, a change in species, an increase in pain or discomfort, or a change in the method of euthanasia. Significant modifications require review by the full committee or by a designated member review, depending on the initial pain category of the protocol. The Veterinarian will notify the IACUC of any changes in choice of anesthetics or analgesics and any changes in their dosage.

e) **Termination of IACUC Protocols**
   i. It is the responsibility of the investigator to notify the IACUC when a project is completed. Projects that have been completed, withdrawn or terminated are closed immediately upon notification. The Office of Veterinary Service is notified by the IACUC Office of all closures. All animal use on a specified protocol is stopped. No further purchase of animals or experimental procedures can be made under the specified protocol number. All closed projects are archived for a 3-year period from date of closure.
6. OTHER IACUC STANDARD OPERATING PROCEDURES

A. Semiannual Review of Program and Facilities and Protocol Follow up
   a) Every six months, the IACUC is required to conduct a complete review of Florida Atlantic University’s Animal Care and Use Program and inspect facilities where animals are housed and/or used.
   b) The NIH Guide for the Care and Use of Laboratory Animals and Animal Welfare Regulations are the principal documents used by the IACUC in its evaluations.
   c) Researchers who house animals in their laboratories over 12 hours, or use animals in their laboratories should expect visits by the subcommittee of the IACUC at 6-month intervals.
   d) In addition to looking at the research facilities during the semiannual inspection IACUC members will conduct protocol follow-up. Members will discuss animal use procedures with the investigators and their staff as described in the applicable protocol(s), inspect drugs and materials intended for in vivo use, and inspect the research animal records.

B. Committee Training
   a) 4-STEP ORIENTATION PROGRAM.
      i. Each new member is "apprenticed" to a "veteran" committee member. The apprentice and veteran will be matched and will meet each other at the first IACUC meeting. The roles of apprentice and veteran are as follows:
         1. Apprentice's First Review
            A. Research protocols requiring full committee review are always assigned to the full committee for review. For the apprentice's first review, each veteran reviewer will be working together with an apprentice reviewer to help guide them through the process.
            B. The apprentices should read the protocol and the reviewer forms and then consult with their veteran. Ideally, the veteran will promptly review the protocol and send the apprentice a copy of the review. The apprentice will not be obliged to complete a formal review the first time. The chair will invite the apprentice to comment at the time the protocol is discussed. Therefore, the apprentice should attempt to develop a point of view about the work planned in the protocol.
         2. Apprentice's Second Review
            A. Again, the apprentice and veteran will share observations about a protocol. For the apprentice's second review, the apprentice will present the combined views of apprentice and veteran. The veteran is expected to help the apprentice prepare for this presentation and to take part in the discussion of the protocol at the meeting.
         3. Training Session
A. Staff will schedule a meeting of apprentices with staff, the University Veterinarian and the IACUC Chair. The purpose of this meeting is to discuss committee functions in light of the apprentice experience. Some aspects of the committee's history, the Animal Welfare Act and the Public Health Service Guidelines will be reviewed.

4. **Apprentice's Third Review**

   A. Depending on the number of protocols submitted, for the apprentice's third review, the apprentice will be expected to complete the review and fully participate at the meeting. A veteran will be expected to be available for consultation and advice.

   B. From that point on, the new member will assume full committee responsibilities. The IACUC staff, the Chair and the entire committee will function as a team to support every member.

5. **Orientation Materials**

   A. Basic introductory materials are provided to acquaint the new member with the Committee and its functions prior to the new member’s first meeting. Since all the regulatory information is available online the member will also be directed to the website at http://www.fau.edu/research/rcs to refer to all documentation.

   B. All members will be encouraged to attend a PRIM&R/ARENA meeting as soon as possible.