

**Xavier University of Louisiana**

**Institutional Animal Care and Use Committee (IACUC)**

**Administrative Policies and Procedures**



## TABLE OF CONTENTS

	<u>Page</u>
Overview	2
Policy	3
Organization and Responsibility	3
A.    Administrative Organization for IACUC	3
B.    Committee Membership	3
C.    Responsibilities of the IACUC	4
D.    Meetings and Quorum	5
E.    Procedures Mandated by Federal Regulations	6
F.    Review Process for Research	6
G.    Expedited Review	8
H.    Appeal Process	8
I.    Post Approval Monitoring	9
J.    Forms	9
K.    Training	9
Administrative Responsibilities	
A.    Federal Reporting Requirements	10
B.    Minutes and Record Keeping	11
C.    Occupational Health and Safety	12
D.    Animal Care Facility	12

### Overview

Xavier University of Louisiana is guided by the ethical principles set forth in the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals with regard to the humane care and treatment of animals used in research. The Institutional

Animal Care and Use Committee (IACUC) ensure that the Xavier complies with Public Health Service (PHS) and U.S. Department of Agriculture regulations. The committee has the responsibility to maintain the highest quality of research and to provide for the humane care and treatment of animals used in research and training.

## **Policy**

The purpose of this policy is to establish clear lines of authority and responsibility between the Institutional Animal Care and Use Committee (IACUC) and the Institutional Official (IO) as mandated by the Animal Welfare Act, the Health Research Extension Act (HREA) of 1985, and as directed by the PHS Policy, the USDA and the National Research Council's Guide for the Care and Use of Laboratory Animals (The Guide).

### **I. ORGANIZATION AND RESPONSIBILITY**

#### **A. Administrative Organization of IACUC**

President of Xavier University

Institutional Official (IO)

Attending Veterinarian (AV)

IACUC

The President of Xavier University shall appoint the Institutional Official (IO) who bears ultimate responsibility for the program, although the overall program direction should be a shared responsibility among the IO, AV and IACUC. Program needs should be clearly and regularly communicated to the IO by the AV, the IACUC and others associated with the program (e.g., facilities management staff, occupational health and safety personnel, scientists). Any violations of ethical standards shall be brought directly to the IO.

As a representative of senior administration, the IO is responsible for resource planning and ensuring the alignment of program goals of quality animal care and use with the institution's mission.

#### **B Committee Membership**

The Chair and Committee Members will be appointed by the Senior Vice President for Academic Affairs and the Associate Vice President for Research and Sponsored Programs. Federal regulations require that the IACUC shall include at least:

- A Chair who has expertise in animal research;

- A Veterinarian either certified (e.g./by ACLAM, ECLAM, JCLAM, KCLAM) or with experience in laboratory animal science and medicine or in the use of the species at the institution;
- A public member who is not affiliated with the institution, who represent general community interest in the proper care and use of animals;
- A practicing scientist experienced in research involving animals; and
- A member from nonscientific background, drawn from inside or outside the institution

Except for the veterinarian and non-affiliate member, committee members typically will be Xavier faculty or staff members. The Director of the Animal Facility will be a voting member of the committee. Any members with a conflict of interest shall excuse themselves from committee deliberations related to the conflict. The Director of Environmental Health and Safety and the Compliance Officer are *ex officio* members of the IACUC. A list of the IACUC members is available in the Office of Research and Sponsored Programs.

Regular voting members will be appointed for five-year terms, renewable for one consecutive five-year period as long as the member continues to possess the required qualifications. If a regular member is chosen as the IACUC Chair, the duration of his/her membership will be extended automatically to allow completion of the term of appointment as Chair.

Regular voting members may resign their appointment after the completion of their first five-year term or anytime thereafter. In extenuating circumstances, the IACUC Chair and the IO may accept a resignation during the course of the first five-year term. An official letter of resignation should be submitted.

The Chair will be appointed to a five-term, renewable for two consecutive five-year terms and may resign his/her appointment after the completion of the first five-year term or anytime thereafter. In extenuating circumstances, the IO may accept a resignation during the course of the first five-year term. An official letter of resignation should be submitted.

Whenever the Chair is not available, the Chair shall designate a senior regular voting member of the IACUC to assume the Chair's responsibilities during the period of his/her absence.

Attendance at committee meeting is essential. More than one unexcused absence or three excused absences are grounds for removal. Members may also be removed for: breach of confidentiality, failure to protect animal rights, failure to comply with attendance requirements, and research fraud and abuse. Removal of a member shall be recommended by the Chair with approval from the IO.

### **C. Responsibilities of the IACUC**

The responsibility of the IACUC is to oversee and routinely evaluate the program. It is the institution's responsibility to provide suitable orientation, background materials, access to appropriate resources, and, if necessary, specific training to assist IACUC members in understanding their roles and responsibilities. In evaluating issues before the committee, the duties include the following:

- Review all research involving animal subjects and establishes policies and procedures regarding such research;
- Oversee and assess Xavier's animal care and use research programs;
- Assure the proper training of all investigators and staff;
- Ensure compliance with federal regulations, the committee inspects all animal care and use facilities at the institution;
- Ensure activities involving the use of laboratory animal care are in accordance with practices defined in The Guide For The Care and Use of Laboratory Animals;
- Investigate concerns raised by faculty and staff regarding the humane care and use of laboratory animals at the institution;
- Suspend any activity involving animals that violates the ethical standards outlined in The Guide; and
- Review annually all research projects. The Annual Review Form must be submitted by the principal investigators to the committee 45-60 days prior to the anniversary date.

#### **D. Committee Meetings and Quorum**

The committee shall meet regularly at least once a month or as necessary at the request of the Chair or any three members. A quorum consists of the Chair and two other committee members. Minutes of the proceedings shall be recorded and circulated by the Administrative Assistant to the membership, and shall include:

- Records of attendance, noting any members who leave the meeting early;
- Activities of the committee, including actions on prior minutes, presentation of program, policy, facility and compliance reports and decisions on policies, protocols and amendments;
- Deliberations relating to the IACUC decisions;
- Actions taken by the IACUC;
- Votes on IACUC actions, including the names and numbers of persons voting for, against or abstaining;
- The basis for causing modifications, withholding approval or deferring review; and
- The date of the next scheduled review of an approved project.

The minutes shall be retained for 3 years after completion of the research.

The meetings shall be conducted according to the principles of Robert's Rules of Order and the Chair shall use them as a guide at the request of any individual member. The order of business shall proceed as follows:

1. Review of minutes of the previous meeting
2. Old Business
3. New Business
4. Review of Applications for Research or Amendments to existing research.

For all matters considered by the committee, a simple majority vote of a quorum shall be required for approval.

#### **E. Procedures Mandated by Federal Regulations**

1. Review the institution's program at least once every six months for humane care and use of animals, using the Guide and OLAW checklists as a basis for evaluation;
2. Inspect all of the institution's animal facilities at least once every six months using the Guide as a basis for evaluation;
3. Prepare reports of the IACUC evaluations conducted as required and submit reports to the Institutional Official;
4. Review concerns involving the care and use of animals at the institution;
5. Make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training;
6. Review and approve, require modifications in (to secure approval) or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals;
7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and
8. Authorize the suspension of activity involving animals in accordance with the specifications set forth in the PHS Policy on Humane Care and Use of Laboratory Animals.

#### **F. Review Process for Research Protocols**

In accordance with the Public Health Services (PHS) Policy on Humane Care and Use of Laboratory Animals, review of PHS-conducted or supported research projects should be reviewed as follows:

1. In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with this Policy. In making this

determination, the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and that the research project is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the research project conforms with the institution's Assurance and meets the following requirements:

- (a) Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
  - (b) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
  - (c) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
  - (d) The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and nonmedical 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.
  - (e) Medical care for animals will be available and provided as necessary by a qualified veterinarian.
  - (f) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
  - (g) Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
2. Prior to review, each IACUC member shall be provided with a list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects. If full committee review is not requested, one member of the IACUC, designated by the chair and qualified to conduct the review, shall review those research projects. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum present. 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.

3. 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.
4. 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.
5. The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1-4 at least once every three years.
6. 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, the institution's Assurance, or IV.C.1.a.-g. of this Policy. 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 the majority of the quorum present.
7. If the IACUC suspends an activity involving animals, the Institutional Officer in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.
8. Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve any activity involving the care and use of animals if it not approved by the IACUC.

### **G. Expedited Review (DMR)**

For expedited review, all IACUC members will be provided with a copy of the application. Unless a member objects, the IACUC Chair or Veterinarian will review the application and give approval, require modification before approval, or ask that a decision be postponed until the full IACUC can be convened. This review is generally completed in about **two (2) weeks**. The results of the expedited review will be communicated to the investigator. All applications approved under Expedited Review will be reviewed by the full committee at the next IACUC meeting. The DMR should be approved by all members at the meeting at which the required modifications are developed or delineated and all IACUC members have agreed in advance in writing.

### **H. Appeal Process**

If the Committee does not approve a protocol, the investigator can make an appeal to challenge the decision within two weeks of notification by the IACUC Chair. The



appeal should be initiated by preparing a letter to the IACUC Chair addressing relevant issues. The IACUC Chair shall decide if the issues addressed in the appeal letter warrant inviting the Principal Investigator to the next regularly scheduled IACUC meeting to present his/her justifications. Any decision to reverse a disapproved study requires a vote of the IACUC, unless the study was disapproved on administrative grounds.

### **I. Post approval Monitoring**

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. Post approval monitoring (PAM) helps ensure the well-being of the animals and may also provide opportunities to refine research procedures. Both the Health Research Extension Act and the AWA requires the IACUC to inspect animal care and use facilities, including sites used for animal surgeries, every 6 months. Methods of (PAM) include the following:

- \* Continuing protocol review consists of annual review of protocols and a three-year review of protocols. The annual review requires the investigator to submit to any adverse or unanticipated events that occurred during the experiment or the investigator can submit any proposed amendments for future procedures. The 3yr review requires the investigator to submit a complete new protocol and a progress report on the use of animals during the previous 3 years;
- \* Laboratory inspections (conducted either during regular facilities inspections or separately every 6 months);
- \* Veterinary or IACUC observation of selected procedures;
- \* Observation of animals by animal care, veterinary and IACUC staff and members; and
- \* External regulatory inspections and assessments.

### **J. Forms**

The Application for Research Protocol Form in electronic form is available on the Xavier University of Louisiana's website. Forms can be downloaded from the website. The Animal Care Facility maintains forms for Animal Transfers in and out of the facility and the status of animals as they are used in the facility.

### **I. Training**

The IACUC Chair will conduct an orientation session with new committee members that addresses:

1. Goals and objectives of the committee
2. How meetings are conducted
3. How proposals and amendments are evaluated

In addition, all new members are required to take the online training offered by CITI on IACUC Chairs, Members and Coordinators - Basic Course.

Investigators and other individuals involved in animal care and use at Xavier will be required to become familiar with materials on CITI that are relevant and appropriate to their particular animal involvement. Investigators must be able to demonstrate that they have had the training and experience necessary to conduct humanely the proposed teaching or research activities. Those personnel designated by the PI as coming in contact with the animals should receive training from CITI on the species of animal covered on their research protocol. The primary investigator is responsible for the conduct of personnel and student researchers.

CITI online training is required before the PI and his/her research staff begins their animal research project. The CITI website contains information on different species and instruction on providing humane care to research animals. The Veterinarian will provide direct training on special techniques.

## **II. ADMINISTRATIVE RESPONSIBILITIES**

### **A. Federal Reporting Requirements**

#### **1. Annual Report to OLAW**

The IACUC, through the Institutional Official, shall report in writing to OLAW:

- a. any change in the institution's program or facilities which would place the institution in a different category than specified in its Assurance;
- b. any change in the description of the institution's program for animal care and use;
- c. any changes in the IACUC membership; and
- d. Notice of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities, and submitted the evaluations to the Institutional Official.

The annual report is due 30 days following the reporting period of January 1 through December 31 of each year.

#### **2 Annual Report to the USDA**

The IACUC, through the Institutional Official, shall report to the United States Food and Drug Administration, Animal and Plant Health Inspection Service. This report is due on December 1 of each year.

#### **3. Violations of the Guide**

The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- e. any serious or continuing noncompliance with this Policy;
- f. any serious deviation from the provisions of the Guide; or
- g. any suspension of an activity by the IACUC.

#### 4. The 4-year Assurance Application

The IACUC, through the Institutional Official, shall apply to OLAW every four years for the continuation of Xavier's Assurance. Xavier's assurance expires on August 31 of any given year; the application shall be submitted by the preceding April 30.

### **B. Minutes and Record Keeping**

The IACUC, through the IO, shall prepare and maintain adequate documentation of its activities and shall retain documents for a period of 3 years following the conclusion of a study. The records are confidential. The IACUC and the IO shall permit an authorized representative of the PHS, APHIS and funding agencies, at a reasonable time and with sufficient notice, to inspect and copy those records required to be maintained under Federal regulations.

As mandated by the PHS,

#### 1. The awardees institution shall maintain:

- a. a copy of the Assurance which has been approved by the PHS;
- b. minutes of IACUC meeting, including records of attendance, activities of the committee, and committee deliberations;
- c. records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
- d. records to semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official;
- e. records of accrediting body determinations;
- f. written policies and procedures for the IACUC;
- g. a list of current IACUC members; and
- h. copies of all correspondence between the IACUC and investigators.

#### 2. All records shall be maintained for at least three years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner. These records shall be kept in the Office of Research and Sponsored Programs.

### **C. Occupational Health and Safety Program (OHSP)**

The PHS Policy places the responsibility for ensuring a safe working environment for personnel involved in the animal care and use program with the institution.

At Xavier, the Director of Environmental Health and Safety provides access to the proper medical screening and attention. An effective OHSP requires input from health and safety specialists and should include the following elements:

- administrative procedures
- facility design and operation
- risk assessment
- exposure control
- education and training
- occupational health-care services
- personal protective equipment
- equipment performance
- information management
- emergency procedures
- program evaluation

A wide range of personnel (e.g., animal care staff, investigators, technical staff, students, volunteers, engineers, housekeepers, security officers, and maintenance personnel who care for or use animals, their tissues or fluids, or who may be exposed to them as a consequence of their job) should be provided the opportunity to participate in the OHSP. The principal investigators should outline the risks involved in his/her project to personnel.

The extent and level of participation of personnel in the OHSP should be based on risk assessment, including:

- hazards posed by the animals and materials used
- exposure intensity, duration, and frequency
- susceptibility of personnel
- history of occupational illness and injury in the workplace

### **D. Animal Care Facility**

The Director of the Animal Facility Care shall keep written records as to the number and breeds of animals, their arrival and transfer. Signs shall be maintained in the facility which display responsible management personnel who can be summoned for emergencies, especially and including holidays and weekends.

The Director of the Animal Facility Care shall report directly to the IACUC Committee and establish written policies for:

- provisions for weekend and holiday animal care
- provisions in the event of hurricane or other impending disaster or emergency
- euthanasia method
- Documentation indicating the number of animals received, present, transferred and euthanized.