

FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE BYLAWS

I Mission

Guided by the Catholic ethical principal of beneficence and the Franciscan core value of respect for all life, the Franciscan Missionaries of Our Lady University (FranU) IACUC ensures the humane care and ethical use of animals for research within the institution.

II. Purpose

The Institutional Animal Care and Use Committee (IACUC) FranU is responsible for overseeing the use of animals and animal facilities, and for the review of basic science and biomedical research and teaching activities involving animals conducted at, or in association with, FranU. The IACUC ensures that animal care and use follow all federal, state, and local regulations. The basis of compliance is determined by the Federal Animal Welfare Act and Animal Welfare Regulations (AWAR), the Institute for Laboratory Animal Research (ILAR) Guide for the Care and Use of Laboratory Animals, the Guide for the Care and Use of Agricultural Animals in Research and Teaching, the Public Health Service (PHS) Policy on the Care and Use of Laboratory Animals, the Food and Drug Administration (FDA) Good Laboratory Practices, and other applicable regulations. The IACUC is the principal advisory source on humane care and use of animals within the University and, as such, the appropriate body for reviewing and investigating concerns or complaints involving the appropriate care and use of animals. The Committee has the authority to negotiate modifications, suspend or terminate animal use that is not in compliance with these regulations.

The Committee shall review the University animal program, inspect all University animal facilities, and review and approve the care and use of all animals as described in animal use protocols as needed, at least once per fall and spring semester. The Committee shall recommend to the designated Institutional Official changes or improvements to the University animal program or facilities necessary to maintain a high-quality animal use program that follows all appropriate regulations.

As stated in the PHS Assurance Document, the IACUC shall:

- Review the institution's program for humane care and use of animals at least once every six (6) months.
- Inspect all the institution's animal facilities, including satellite facilities, at least once every six (6) months.
- Review concerns involving the care and use of animals at the institution.
- Make written recommendations to the appropriate Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training in their respective areas.
- Review and approve, require modifications, or withhold approval of protocols for the use of animals.
- Review and approve, require modifications, or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.
- Notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of protocols related to the care and use of animals or of modifications required to secure IACUC approval.

- Be authorized to suspend the use of animals.

III. Membership

A. Composition

The IACUC must be qualified through the experience, expertise, and diversity of its members to maintain oversight of the use of animals, animal facilities, and to provide review of basic science and biomedical research and teaching animal use conducted within the University.

All members shall be appointed by the University President or his/her designated representative. The Committee will be composed of a Chair and at least one individual from the following: a Doctor of Veterinary Medicine, a faculty member actively involved in animal research, one individual whose primary vocation is nonscientific in nature, and one public member nonaffiliated with the University who represents the general community. An individual who meets the requirements of more than one of the categories may fulfill more than one requirement. Excluding the laboratory animal veterinarian(s), no more than three members shall be from the same department.

As deemed necessary, the Committee may also call on consultants, with a special expertise in areas of interest to the Committee.

B. Officers and Responsibilities

- The Chair of the Committee is appointed by the President or his/her designated representative. The Chair must be an individual with previous research involving animals. The Chair shall preside over IACUC meetings, create or delegate the creation of meeting minutes, store minutes, and upon agreement with the IACUC Committee members, approve animal research protocols. The Chair shall send approval letters to those who submit protocol applications.
- An attending veterinarian shall serve as a voting member of the IACUC for an indefinite term. It is the responsibility of the veterinarian to provide veterinary review of protocols and to oversee the adequacy of all aspects of animal care and use for all animals.
- Various University officials and specialists and non-University consultants may be asked to serve as nonvoting ex-officio members of the IACUC.

C. Terms and Appointment

All voting members of the Committee (all members of the Committee are voting members except for the Ex-Officio who is the Institutional Official) as well as the Committee Chair are appointed for an indefinite period. If a Committee member wishes to leave the Committee temporarily or permanently, a new member will be appointed by the President or Authorized Official.

D. Responsibilities of Members

The IACUC recognizes that University research scientists must conduct their research in a timely and responsible fashion. Therefore, to facilitate research while assuring animal welfare, the Committee must conduct its business as efficiently as possible. This can only be accomplished when all Committee members participate fully in Committee activities.

Committee members should make every effort to attend and actively participate in all regularly scheduled meetings, promptly conduct complete reviews of assigned protocols, and participate in facility and program

reviews. Committee members must also recognize the sensitive nature of Committee activities and maintain confidentiality.

All IACUC members are expected to:

- Complete the online Collaborative Institutional Training Initiative (CITI) modules on research involving animals. Required modules include:
 - IACUC Community Member: Member not otherwise affiliated with the University
 - IACUC Chair: Chairperson
 - Essentials for IACUC Members: All members
 - Post-Approval Monitoring: All members
 - I Work with Fish, Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress, etc.: As needed basis
- Maintain currency with required CITI modules. Members who are not current may not conduct reviews or vote. If not renewed by the end of the academic year, the member will be removed from the IACUC.
- Evidence of completion of training from another accredited source, such as American Association for Laboratory Animal Science (AALAS), may be accepted on a case-by-case basis
- Attend regularly scheduled meetings of the IACUC. Three or more consecutive absences from scheduled meetings per year (except under documented extenuating circumstances) are unsatisfactory. The Chair will communicate this to the committee member in writing and determine whether membership in the IACUC continues.
- Review protocols and all other documents included in the meeting packet prior to the monthly scheduled Committee meeting.
- If a Designated Member Review (DMR) will be conducted, the Committee member assigned as the Presenter will review assigned protocols completely, including contacting the PI when necessary, regarding incomplete or ambiguous responses and other concerns prior to the committee meeting.
- Members may elect to participate in program review and animal facility inspections or may be assigned. Program review and facility inspections will occur semiannually.
- Maintain confidentiality about Committee activities.

The efficient operation of the IACUC depends on the full participation of its members. The name of any member who exhibits repeated unsatisfactory performance shall be submitted to the IACUC Chair. The Chair shall provide necessary documentation to the University President, or his/her designated representative, who shall make the final decision regarding dismissal from the Committee.

IV. Meetings

All meetings shall be governed by The Modern Edition of Robert's Rules of Order, except as otherwise indicated in this document.

A. Regularly Scheduled Meetings

The IACUC shall schedule at least one meeting per fall and spring semester. The meeting may be cancelled if the IACUC has no current business and may be rescheduled in extenuating circumstances. Emergency meetings may be called by the Chair if required. It is the University's policy that at least one non-scientific committee member be present in order to conduct business.

B. Voting

A motion may only be passed at a convened meeting of a quorum of the IACUC if it receives the affirmative vote of the majority of the quorum present. A tally of the numbers of members who vote for, against, or abstain from voting shall be recorded in the minutes. Any minority views shall also be recorded in the minutes. All Committee members except for the Authorized Official who serves in an Ex-Officio manner and non-University consultants are voting members of the Committee.

C. Conflict of Interest

An IACUC member should not vote on protocols in which he/she is listed as an investigator. The member may provide information to the Committee, if the Committee so desires. However, the Chair shall excuse the member during these deliberations if no further information is required, or if another Committee member requests such action and before a vote is taken.

D. Subcommittees

The IACUC Chair may appoint subcommittees, as deemed appropriate, to facilitate the business of the Committee. All members of subcommittees shall consist of members in good standing. Subcommittees shall report directly to the IACUC with recommendations or reports. No actions may be taken by the subcommittee without prior approval of the majority of the quorum present at a convened IACUC meeting.

V. Protocol Review Procedures

The Federal Animal Welfare Act and Animal Welfare Regulations (AWAR), the Institute of Laboratory Animal Resources (ILAR) Guide for the Care and Use of Laboratory Animals, the Guide for the Care and Use of Agricultural Animals in Research and Teaching, and the PHS Policy on the Care and Use of Laboratory Animals shall be used as basis for review.

A. Principal Investigator (PI)

The PI conducting research or teaching involving live vertebrate animals shall submit a typed and signed protocol for the use of live vertebrate animals. Protocols requiring full review received less than five (5) working days before the scheduled IACUC meeting shall be reviewed at the next scheduled meeting.

Animals may not be procured until the protocol has been approved by the IACUC. Research involving animals may not begin until the PI is notified in writing that the protocol has been approved. Only those persons listed on the protocol are authorized access to the animal facilities. Additions or substitutions to this list require a protocol amendment, and subsequent approval.

B. IACUC Committee Chair

The completed protocol is submitted using the University's online submission site (i.e., Microsoft Forms or IRB Manager) and is initially reviewed by the Research and Scholarship Council to ensure that all the components of the application have been completed. Once the application has been completed, the Research and Scholarship Council submits the new application to the IACUC Committee Chair and asks if a DMR or Full Committee Review (FCR) will be required. If the protocol is eligible for DMR, the IACUC Chair identifies the Committee member that will be conducting the review. The completed protocol is submitted electronically to all Committee members for review at least five days in advance of the next scheduled meeting in preparation of discussion at the Committee meeting. If upon review the protocol is incomplete or unclear, the IACUC Committee Chair notifies the PI of the clarifications/modifications that are required.

C. Veterinarian

The attending veterinarian will perform the veterinary review and present any concerns regarding the research at the next scheduled Committee meeting.

D. Protocol Review

All research involving animals should be brought to the attention of the IACUC.

D.1. Exemptions

There are areas of research are exempt from IACUC protocol submission and review. Investigators do not make the determination that animal use is exempt from an IACUC protocol submission. Using animals in teaching situations does not automatically exempt the activity from IACUC review and approval. Some areas that may be exempt include but are not limited to: work with invertebrates, observational field research involving no manipulation, research on vertebrate eggs, commercially obtained tissues, or tissues from colleagues with approved animal protocols in place at their facility, and others. The IACUC will discuss a project and vote (simple majority of the quorum) to approve an exemption. If an exemption is granted, the investigator will receive an exemption letter from the IACUC for that specific activity or area. The exemption letter is only valid for that specific situation. If the investigator changes or modifies the activity, then it is

subject to reexamination by the IACUC, and the exempt status may change and necessitate a protocol and review.

D.2. DMR of a Protocol (Only allowed for research that falls under Category A, B, or C as defined in the FranU IACUC Protocol Form).

The IACUC Committee Chair determines if a protocol is eligible for DMR. If the protocol qualifies for DMR, each IACUC committee member is provided with a copy of the cover page and the non-technical summary. Copies of the complete protocol shall be available to any member who requests it, and any committee member may request FCR within 5 days. If FCR is not requested, at least one committee member is designated by the IACUC Committee Chair to review the research project. The designated individual is qualified to review the research project and has authority to approve, require modifications or request FCR. The designated individual does not have the authority to disapprove the research project. Disapproval can only be done by a majority vote of a quorum at a convened meeting of the IACUC.

If approved, an approval letter will be emailed to the PI. Protocols are approved for a maximum of three years, although the PI will need to undergo annual review yearly. After three years, the PI will rewrite and resubmit the protocol for review.

D.3. FCR

If an FCR is required, full copies of the protocol are submitted to all Committee members for review at least 5 days prior to the regularly scheduled meeting. A quorum of the Committee must be present at the meeting. The Committee will discuss the proposed research project(s) and determine if approval can be given or if modifications are needed before approval can be granted. If the research project is ready for approval, an approval vote by the majority of the quorum present is required.

When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, a quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

The IACUC Committee Chair will communicate the required modifications directly to the researcher. The revised protocol will be resubmitted to the IACUC Committee Chair and distributed to the designated member for review and approval. Protocols are approved for a maximum of three years, although the PI will need to undergo annual review yearly. After three years, the PI will rewrite and resubmit the protocol for review.

D.4. Procedures to Request an Expedited Review of Protocols

Under unusual circumstances a PI may request an Expedited Review. An Expedited Review may be requested when any of the above review activities must take place sooner than would occur under the normal review processes. This process must be justified beyond a convenience for the PI. The Expedited Review process follows these steps:

- **Written Request** – A completed protocol application to the IACUC must be submitted. In addition, the PI must formally request, in writing, an expedited review along with a clearly articulated justification for its need.

- Determination – Upon receipt of an Expedited Review request, the IACUC Chair, the Veterinarian and another member of the IACUC will determine if the request has merit and notify IACUC and the PI of the determination. If the request for Expedited Review is not granted, the review activity will take place via the standard procedures.
- Emergency Meeting – If the request has merit and is granted, the IACUC Chair will convene an emergency meeting of the IACUC. The application and other relevant materials will be given to all IACUC members prior to the meeting. The proposal will then be reviewed in the Full Committee and undergo normal voting procedures.

E. Procedures for the Annual Review of Protocols

- Approved protocols must be reviewed at least annually. Therefore, at least four (4) weeks prior to the anniversary date of an approved protocol, the IACUC Chair shall send to the PI an Annual Review of Protocol for Use of Live Vertebrates Form indicating that the annual review form must be completed and submitted to the IACUC Committee Chair before the first day of the anniversary month.
- The annual reviews are approved by the IACUC Committee Chair on behalf of the Committee and will be listed on the agenda and minutes of the next scheduled meeting.
- Annual reviews consisting of minor changes may be approved administratively or administratively with veterinary consult. Significant changes require a revision in writing will be reviewed at the regularly scheduled convened monthly meeting.
- Protocols are approved for a maximum of three years. After three years, the PI must rewrite and resubmit the protocol and undergo either expedited or FCR.

F. Procedures for the Review of Modifications of Approved Protocols

F.1. Significant Changes

Significant changes to an IACUC-approved protocol must be reviewed and approved through FCR or DMR before they occur. FranU interprets significant changes to mean those that have the potential to impact substantially and directly on the health and well-being of the experimental animals. Examples of significant changes include, but are not limited to, changes:

- from non-survival to survival surgery;
- resulting in greater pain, distress or degree of invasiveness;
- in species;
- in study objectives;
- in PI;
- that impact personnel safety; and
- in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC
- in increases in animal numbers greater than 10% of the originally approved number. Proposed significant changes require FCR or DMR and approval prior to initiation. See the FranU IACUC Request for Significant and Administrative Changes Form.

F.2. Administrative Changes

FranU interprets administrative changes to mean those that do not have the potential to impact substantially and directly on the health and well-being of the experimental animals. Examples of non-significant changes include but are not limited to changes:

- that correct typographical errors and/or grammar;
- in the funding source;
- in contact information;
- in personnel (other than the PI)

Proposed administrative changes may be approved administratively or administratively with veterinary consult prior to initiation. See the FranU IACUC Standard Operating Procedure for Significant and Administrative Changes.

VI. Program and Facilities Review

A. Program Review and Site Inspection

The IACUC shall review the Animal Care and Use Program and all University animal facilities, as defined in the PHS Policy and the Animal Welfare Act, at least once every six months. A subcommittee of the IACUC may conduct the inspection, but any member wishing to participate may not be excluded and the program review and inspection report must be reviewed and approved by the majority of the quorum present of the Committee and include any minority views.

The subcommittee conducting the review and inspection must include at least two members. The subcommittee shall use the ILAR Guide for the Care and Use of Laboratory Animals as a standard for evaluating all laboratory animal facilities. Other guidelines and recommendations will be used as appropriate. The Guide for the Care and Use of Agricultural Animals in Research and Teaching shall be used as a standard for the non-PHS supported research and teaching activities involving production agricultural animals.

B. Program Review and Site Inspection Report

After review and inspection, a written report (including any minority views) shall be submitted to the Institutional Official or delegate. The report shall contain a description of the extent of each facility's adherence to the Federal Animal Welfare Regulations and shall distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, in the judgment of the IACUC and the appropriate Institutional Official and in accordance the Animal Welfare Regulations, may be a threat to the health or safety of the animals. The IACUC shall include a plan of action with specific dates for correcting any deficiencies. Any failure to adhere to this plan that results in a significant deficiency remaining uncorrected shall be reported within 15 business days through the appropriate Institutional Official.

C Laboratory Animal Veterinary Observations

The veterinarian will make in-person checks to all laboratory animal facilities to assess the health status and environmental conditions of the housed animals. The in-person checks will be conducted at a frequency deemed medically appropriate by the veterinarian based on the needs of the housed species. Any issues of concern noted during these checks will be reported to the associated principal investigator and the chair of the IACUC committee. The veterinarian will work with the principal investigator to correct any problems or deficiencies and report progress and outcomes to the IACUC chair as needed.

VII. Training

A. Committee Members

Committee members shall review these bylaws, the Animal Welfare Regulations, the PHS Policy, and other documents, as well as copies of individual policies developed by the IACUC regarding specific animal use issues. Committee members will complete the CITI courses including: Essentials for IACUC Members and Post-Approval Monitoring (PAM) (others on a case-by-case basis).

In order to stay current with the ever-changing regulatory environment, Committee members will be required to complete the CITI Working with the IACUC – Refresher course at a minimum of once every three (3) years.

B. Scientists, Research Assistants, and Animal Technicians

All scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment and use must be qualified to perform their duties. All scientists, research technicians, animal technicians, and other personnel will be required to take the CITI Working with the IACUC basic course and any other modules that can be identified at the time of protocol submission that align with their specific research project.

In order to stay current with the ever-changing regulatory environment, all scientists, research technicians, animal technicians, and other personnel involved in animal care and use will be required to complete the CITI Working with the IACUC-Refresher course at a minimum of once every three (3) years.

VIII. Noncompliance, Adverse Events, and Animal Welfare Concerns

Definitions

Non-compliance: deviations from established policies or procedures applied to animals in research or teaching without prior IACUC approval. Such deviations may be intentional or accidental.

Animal welfare concern: A condition or situation that could jeopardize the health or well-being of animals used in research or teaching, including suspected misuse or mistreatment.

Adverse event: An unexpected incident that negatively affects the health or welfare of animals used in teaching or research. Adverse events may, or may not, be associated with research experiments (ex: acts of nature, equipment failure)

Unexpected outcome: An unanticipated result of IACUC-approved animal activities (ex: higher than expected animal morbidity/mortality, experimental procedures resulting in unanticipated levels of pain or distress).

A. Posted Procedures for Reporting Non-Compliance

Everyone involved in animal care and use at the University shall be made aware of the procedures for reporting non-compliance. These procedures will be posted in all laboratory facilities and on the IACUC website.

B. Procedure for Reporting Noncompliance with Laboratory Animal Care and Use Guidelines

Concerns or complaints regarding animal usage within FranU should be brought directly to the attention of the people involved whenever possible. If the concern or complaint cannot be handled directly, it may be handled in one of two ways:

- If an emergency exists, the Veterinarian should be contacted immediately.
- If the situation is not an emergency, the concern or complaint should be submitted to the IACUC Chair. The Chair will assign an ad hoc committee to investigate the concern or complaint and prepare a report for the IACUC. The IACUC will review the concern or complaint during the next regularly scheduled meeting. The IACUC will determine what action will be taken and the Chair will notify the PI of such action.

A written reply to those primarily involved and to the appropriate Institutional Official will follow each written concern or complaint submitted to the IACUC. No facility employee, student, IACUC member or laboratory personnel will be discriminated against, or be subjected to any reprisal for reporting suspected noncompliance, according to the FMOLHS Duty to Report and Non-Retaliation Policy COMP 08 003. 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.

C Procedure for Reporting of Animal Welfare Concerns

Any individual who has a concern about the care and use of animals in research or teaching within FranU [or has observed a procedure not covered under an approved IACUC protocol (noncompliance – see section B)] should report those concerns immediately. Concerns may be reported anonymously, or the individual may request confidentiality

- If an emergency exists, the Veterinarian should be contacted immediately. The Veterinarian will investigate the concern and report the findings to the IACUC chair.
- If the situation is not an emergency, the concern or complaint should be submitted to the IACUC Chair. The Chair will assign an ad hoc committee to investigate the concern or complaint and prepare a report for the

IACUC. The IACUC will review the concern or complaint during the next regularly scheduled meeting. The IACUC will determine what action will be taken and the Chair will notify the PI of such action. A written reply to those primarily involved and to the appropriate Institutional Official will follow each written concern or complaint submitted to the IACUC. No facility employee, student, IACUC member or laboratory personnel will be discriminated against, or be subjected to any reprisal for reporting suspected noncompliance, according to the FMOLHS Duty to Report and Non-Retaliation Policy COMP 08 003. 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.

D. Procedure for Reporting Unexpected Outcomes

Principal investigators or research personnel must notify the Attending Veterinarian or IACUC Chair of any facility issue or unanticipated research outcome, animal injury or animal illness as soon as possible, and within 12 hours of the event or outcome. Animal emergencies should be immediately reported to the Attending Veterinarian.

The Attending Veterinarian and IACUC chair will investigate the event/outcome. In consultation with the PI, the Attending Veterinarian will develop a resolution plan including any animal treatment or euthanasia decisions and alterations/stoppage or experimental procedures.

Following a full investigation, findings will be presented to the IACUC committee (at either a regularly scheduled meeting or an emergency meeting), and a determination of corrective measures will be made. Corrective measures may include, but are not limited to, a temporary halt of work or protocol suspension. If the adverse event or unexpected outcome is found to be due to noncompliance of an IACUC protocol, additional corrective measures may be taken.

E. Suspension of Activity

If the IACUC suspends an activity due to continuing significant deficiencies in animal care and use, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report the action with a full explanation to USDA, Regulatory Enforcement of Animal Care, OPRR, and any agency funding that activity. Any proposal for animal use approved by the IACUC may be subject to further approval by the Institutional Official. However, the Institutional Official may not approve activities involving the care and use of animals that have not been approved by the IACUC.

F. Investigator Appeal

The PI of any activity that has been disapproved or suspended by the IACUC may appeal that action to the IACUC and request another review based on the correction of misinformation or additional information not available at the time of the initial review.

IX. Amendments

Any member may request a review of any part of these bylaws. The review shall be conducted by an ad hoc subcommittee appointed by the Chair. The IACUC may amend these bylaws by a two-thirds vote at any meeting at which a quorum is present, providing that all IACUC members receive notification of the pending vote 10 working days prior to the meeting.