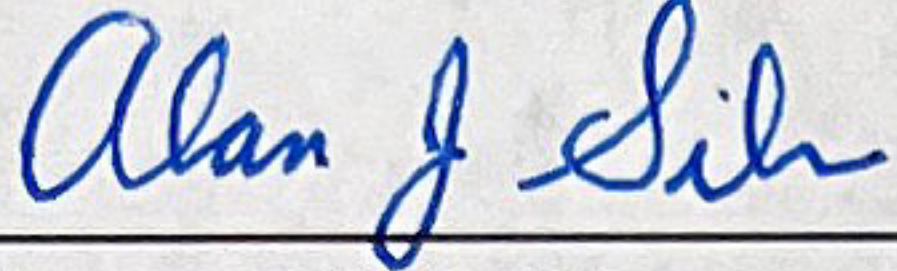
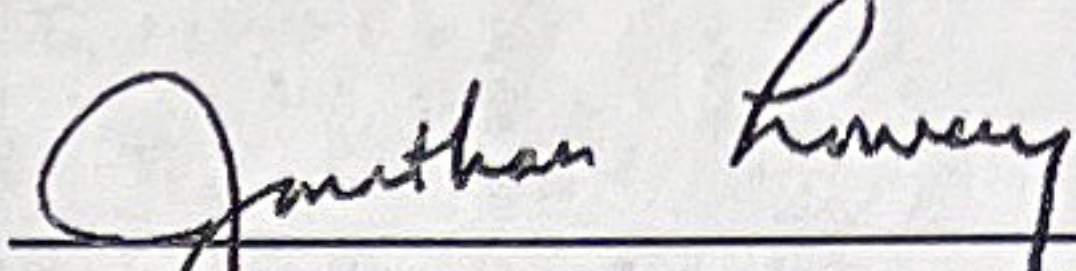


Marian University Indianapolis
Institutional Animal Care and Use Committee Bylaws
Version 5.0

Approved by:

 Date: 11/07/2023
Alan J. Silva, PhD
Institutional Official

 Date: 11/9/2023
Jonathan W. Lowery, PhD
Assistant Provost for Research & Scholarship

I. Establishment and Purpose

A. Pursuant to federal guidelines (Federal Animal Welfare Act, Chapter 54:2143(b) and Public Health Service Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals (hereafter, the "Guide")), an institution using vertebrate animals, or whose representatives are using vertebrate animals, in teaching and/or research, is required to establish an animal care and use committee. The name of this committee is the Marian University Indianapolis (MU-Indy) Institutional Animal Care and Use Committee, hereafter referred to as "IACUC."

B. The IACUC will ensure the appropriate care and treatment of all vertebrate animals used in teaching and/or research activities in facilities under of the oversight of Marian University (except on the campus at Marian University's Ancilla College (MUAC), which is under the oversight of the MUAC-IACUC). Additionally, the IACUC will oversee activities involving vertebrate animals carried out by representatives of Marian University (faculty, staff, students, volunteers, etc.) at field sites or locations where another IACUC does not have oversight. Specific responsibilities of the IACUC include the following:

- Review, at least semiannually, the institution's program for the humane care and use of animals;
- Inspect, at least semiannually, the institution's animal facilities (including satellite facilities);
- Prepare reports to the Provost (hereafter "Institutional Official" (IO)) of the IACUC evaluations;
- Review animal welfare concerns;
- Make recommendations to the IO on any aspect of the animal program, facilities, or personnel training;
- Review and approve research and teaching activities related to the care and use of animals;
- Review and approve, proposed significant changes to the use of animals in ongoing activities; and
- Be authorized to suspend an activity involving animals.

II. Committee Membership and Organization

A. IACUC members (standing and alternate) are to be appointed by the IO for no more than three consecutive three-year terms.

B. There are to be five standing members of the IACUC as follows, each of whom shall have voting rights:

1. A chairperson, who must be a member of the Marian University faculty. The following qualifications are preferred but not required for the chairperson: have been granted tenure; prior or current experience in research involving vertebrate animals; previous service on an IACUC. The MU-IACUC chair will have the following responsibilities:

- i. Call all meetings.
- ii. Prepare agendas for all meetings.
- iii. Appoint the vice-chair to preside at meetings for which she/he has a conflict of interest or otherwise unable to preside as chair.
- iv. Prepare semiannual reports of MU-IACUC activities for the IO and to regulatory agencies as required.

2. A veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution. This member does not have term limits. The MU-IACUC veterinarian will have the following responsibilities:

- i. Consult with investigators during the planning phase for proposed procedures that may cause more than momentary pain or distress (such as surgery, infectious or inflammatory disease models, and food or water restriction).
- ii. Ensure an adequate system of health records. Notably, the USDA requires health records be kept for all animals that are members of covered species.
- iii. Decide when necropsies (autopsies) of animals should be performed to investigate health problems in the organization.
- iv. When dogs must be exercised, determine the frequency, method, and duration of exercise in consultation with and approval by the IACUC.
- v. Direct the required environmental enrichment plan for non-human primates.

3. At least one member from the Marian University faculty with experience in animal research.

4. One member who does not utilize laboratory animals, has no affiliation to Marian University outside of IACUC involvement, and whose immediate family members (spouse/domestic partner or dependent children) have no such affiliation with Marian University. The nonaffiliated member will provide representation for general community interests in the proper care and treatment of animals. Financial compensation of the nonaffiliated member is permitted for expenses such as travel, parking, meals, and participation in national or regional training courses on IACUC-related topics, as long as the compensation meets the following:

- i.* Is not so substantial as to be considered an important source of income.
- ii.* Does not influence the member's voting on the IACUC.
- iii.* Does not qualify the member as an employee of the organization.

5. One member whose primary concerns are in a non-scientific area (for example but not limited to an ethicist, lawyer, member of the clergy).

6. A single individual may serve as both the non-scientific and as the non-affiliated person.

7. No more than three members may be from the same administrative unit.

C. One member (standing, alternate, or *ex officio*) may be appointed by the IO as vice-chair for scenarios in which the chairperson is unable to serve due to incapacity or conflict of interest. When replacing the chairperson, the vice-chair shall stand in for and perform all duties of the chairperson (except voting). As a non-voting participant, the vice-chair does not count toward quorum.

D. Federal regulations allow any number of *ex officio* or alternate members of the IACUC appointed by the IO. Specific *ex officio* members are detailed in the IACUC charter and may attend all meetings of the IACUC and participate in all discussions but may not vote. Alternate members may attend all meetings of the IACUC and participate in all discussions but may only vote or poll when, with permission of the IACUC Chair, acting as a replacement of a standing member in situations such as particularly germane expertise, absence, conflict of interest, or ineligibility due to noncompliance with required trainings. *Ex officio* and alternate members are not to be considered towards quorum except when an alternate member stands in for a standing member. Alternate members of the IACUC must hold the qualifications (e.g., animal research experience, non-scientist, non-affiliated, etc.) of the standing member they are replacing, may replace only one standing member at a time, and are expected to vote their consciences rather than representing the positions of the standing member.

E. Removal of Members

1. Any member may resign their position on the committee at any time.
2. A member may be removed by the IO from the committee for any of the following:
 - i. Animal use protocol violations
 - ii. Disclosure of confidential information
 - iii. Missing three consecutive meetings
 - iv. Failure to comply with training requirements
 - v. A change in relationship status with Marian University such that the composition of the IACUC no longer meets conditions stated above.

Removal will be communicated via writing within one month of decision and the former member will be provided an explanation as to the reason removal is warranted and justified.

III. Meetings and Procedures

A. Meetings and quorum

1. A regular meeting is to be scheduled at least every six months. In-person meetings are preferred but teleconferencing capabilities may be employed when available, provided that the following conditions are met:

- i.* All members are given notice of the meeting.
- ii.* Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting.
- iii.* All members have access to the documents and the technology necessary to fully participate.
- iv.* A quorum of voting members is convened when required by PHS Policy.
- v.* The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (in other words, members can actively and equally participate and there is simultaneous communication).
- vi.* If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. A mail ballot or individual telephone polling cannot substitute for a convened meeting.
- vii.* Opinions of absent members that are transmitted by mail, telephone, fax or email may be considered by the convened IACUC members but may not be counted as votes or considered as part of the quorum.
- viii.* Written meeting minutes are maintained in accord with the PHS Policy (IV.E.1.b.).

2. Special meetings to discuss submitted protocols are to take place no more than one month following submission of a protocol.

3. Quorum will consist of a simple majority of standing or replacement members and must be maintained for official business to occur. When standing in for the chairperson, the vice-chair does not count toward quorum.

4. Polling, described by OLAW as “sequential, one-on-one communication, either in person or via telephone, e-mail, fax, U.S. mail, or by other similar means,” is not allowed by OLAW as substitution for voting at a convened meeting, nor does OLAW allow polling as a means of suspending an approved activity. Activities for which polling may be are as follows:

- i. Providing all committee members the opportunity to call for full review of a protocol prior to initiating the designated reviewer method of protocol review.
- ii. Approving IACUC policies.
- iii. Distributing and reviewing drafts of meeting minutes and reports.
- iv. Approving semiannual program review and facility inspection reports.

B. Semiannual program reviews, inspection, and report to the IO

1. The IACUC must monitor the animal care and use program by conducting thorough reviews of the program and inspections of the animal facilities at least every 6 months, utilizing the standards in the Guide as the basis for conducting its reviews. All members (standing, alternate and *ex officio*) are eligible to participate in the semiannual review but, at minimum, the review must be performed by at least two standing members of the IACUC. No IACUC member (standing, alternate or *ex officio*) wishing to participate in an evaluation may be excluded from participating.

2. Facility reviews are a physical inspection of all buildings, rooms, areas, enclosures and vehicles (including satellite facilities in which animals are housed for more than 12 hours) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. USDA animal welfare regulations exempt areas containing free-living wild animals in their natural habitat from inspection.

- i. While semiannual inspections of field study sites are not required, and in many circumstances are impractical, the IACUC should be apprised of the circumstances under which studies are conducted so that they can consider risks to personnel and impact on study subjects. This may be partially accomplished by written descriptions, photographs, or videos that document specified aspects of the study site. The IACUC should also ensure that appropriate permits are in place.

3. After review and inspection, a written report (including any minority views) that is compiled for review and approval by signature from a majority of voting members of the IACUC. The report must include information about the status of the program including any recommendations; a description of the nature and extent of the Institution's adherence to the Guide; any departures from the Guide, identified specifically with reasons for each departure stated; any program or facility deficiencies, distinguishing significant deficiencies (i.e., a threat to animal health or safety such as the following: failures in heating, ventilating, and air conditioning systems; inoperative water systems; general power failures of sufficient duration to affect critical areas; inadequate veterinary medical or post-surgical care of animals) from minor deficiencies, and include plans and schedules for correcting each deficiency. The final report must be submitted to the IO. Failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected must be reported in writing within 15 business days by the IACUC, through the IO, to the U.S. Department of Agriculture (USDA) and any federal agency funding that activity.

C. Studies requiring IACUC approval

1. Except for certain situations (i.e., studies involving a) only tissues or other parts obtained from vertebrate animals, b) carcasses of vertebrate animals except when the animal was sacrificed for the purposes of the study, or c) non-invasive observational studies of wild animals not classified as “threatened” or “endangered” in their natural habitat that do not materially affect the behavior of the animals), the housing and use of all vertebrate animals for teaching and/or research performed by or under the supervision of Marian University faculty, staff or students (either on the Marian University campus or off campus) must have a protocol approved by the IACUC for such activities. Performing such activities without prior IACUC approval may result in disciplinary action. The process for submitting an animal use protocol is described elsewhere.

D. Protocol review

1. The IACUC oversees the specific use of animals by formally reviewing animal use protocols and granting approval prior to the work commencing. The 2 valid methods of protocol review are either full committee review (FCR) or designated member review (DMR). The IACUC must complete initial review within two business weeks of receipt. It is at the discretion of the chairperson (or vice-chair in the case of incapacity or conflict of interest by the chairperson) to determine if a submitted protocol is to be reviewed by FMR or DMR. The review procedures for FMR and DMR, subject to federal guidelines, are described elsewhere.

2. IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after FCR or DMR. Protocols may be approved for a maximum of three years except protocols that involve species covered by the Animal Welfare Act and Regulations (AWAR) which may be approved for a maximum of one year. Animal work may not be administratively extended beyond the protocol expiration date.

3. The IACUC may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities. These policies must be reviewed by the IACUC at appropriate intervals of no less than once every 3 years to ensure they are appropriate and accurate.

E. Post-approval monitoring

1. Monitoring of animal care and use is required by the PHS Policy. Continuing protocol review consists of an annual update indicating the following: whether the protocol is in active use; what, if any, changes have been made to the animal activities in the protocol; and whether new personnel have been added. While the annual review should serve as an opportunity for the principal investigator to inform the IACUC of any minor changes to the protocol, it is not intended to serve as a replacement for receiving prior approval for significant changes. Animal work may not be administratively extended beyond the protocol expiration date.

i. Active protocols that are not supported by annual report are subject to disqualification at the discretion of a majority vote of the IACUC.

ii. Failure to adhere to scheduled reporting or deviance from protocol must be reported by the IACUC within 15 days of the failure to the any agency from which the protocol is receiving funding.

2. Any changes in personnel or substantive change in procedures must be communicated via a protocol addendum and approved by the IACUC prior to implementation.

F. Required training

1. The IACUC may set forth policies requiring training for individuals performing research and/or teaching involving live vertebrate animals. Additionally, the IACUC may establish training requirements for IACUC members, IO, and other individuals in order to carry out its duties.

G. Addressing animal welfare concerns

1. The IACUC has a mandate to evaluate concerns regarding the care and use of animals. Concerns may be raised by staff or employees of the institution, individuals in the community, or even members of the IACUC. The IACUC is cognizant of the rights of whistleblowers under the AWA, which prohibits discrimination against or reprisal for reporting violations of regulations or standards under the AWA.

H. Suspension of animal activities

1. The IACUC is empowered to suspend a project if it finds noncompliance with, deviation from, or goes beyond the approved protocol, organizational guidelines, PHS Policy, *Guide*, Assurance, or violations of the Animal Welfare Regulations. 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. Further, the IACUC must notify the IO regarding the reasons for the suspension. The IO must, in consultation with the IACUC, review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the U.S. Department of Agriculture (if regulated species are involved), OLAW (if PHS funds are involved), any other federal agency funding the activity, AAALAC (if applicable) and any other appropriate funding agency/agencies.

2. The IO and/or certain administrators including the respective dean, IACUC chair, and IACUC veterinarian may halt any animal activity for any reason without IACUC concurrence, particularly when there is concern about animal welfare. Notably, in these instances, the official is acting for the University not the IACUC. Additionally, these officials do not have the authority to approve an animal activity in the absence of IACUC approval.

I. Reports and Recordkeeping

1. Annual Reports to OLAW

i. Each year, federally-assured institutions must submit a report to OLAW that includes the following:

- changes in the institution's program of animal care and use or facilities (PHS Policy IV.A.1.a.-i.)
- changes in the Institutional Official (IO)
- changes in the Institutional Animal Care and Use Committee (IACUC) membership
- dates that the IACUC conducted its semiannual evaluations of the program and facilities
- minority views filed by members of the IACUC

- changes in the institution's accreditation status

2. The reporting period is the calendar year (January 1 - December 31) and the annual reports are due the end of the following month (January 31).

J. Maintaining IACUC Records

1. The institution is responsible for maintaining these records:

- Assurance approved by OLAW (if applicable);
- minutes of IACUC meetings;
- records of IACUC attendance, activities, and deliberations;
- documentation of protocols reviewed by the IACUC and proposed significant changes to protocols, and whether approval was given or withheld;
- report of semiannual IACUC evaluations and recommendations to the IO, including minority views; and
- accrediting body determinations.

2. All records are to be kept for a minimum of 3 years, with the exception of records that relate directly to protocols which must be kept for the duration of the activity and for an additional 3 years after completion of the activity. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

3. Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the *Guide* and with commonly accepted professional standards.

K. Reporting Noncompliance, Guide Deviations, and Suspensions

1. For federally-assured institutions, circumstances that must be reported to OLAW by the IO, without delay, are:

- serious or continuing noncompliance with the PHS Policy;
- serious deviations from the *Guide for the Care and Use of Laboratory Animals*; and
- IACUC suspensions.

i. NIH Guide Notice NOT-OD-05-034 provides examples of reportable situations, situations that don't normally need to be reported, plus guidance on when and what to report.

ii. In some cases, it may be necessary to submit a preliminary report until an investigation and corrective plan have been completed. Preliminary reports can be made by calling the OLAW Division of Compliance Oversight by phone, fax or email.

iii. A final report should include a detailed explanation of the situation and actions taken. Final reports must be signed by the IO and sent to the OLAW Division of Compliance Oversight by fax or email.