

Policies and Procedures
Marquette University Institutional Animal Care and Use Committee (IACUC)

I. Committee Membership

A. Composition

1. Veterinarian
2. Public member not affiliated with Marquette University
3. Non-scientist scholar
4. More than one tenured, animal-using scientist from Marquette University—attempt should be made to balance the representation of various animal-using units but with no more than three members from any one administrative unit
5. Non-voting members: Research Compliance Officer and Animal Facility Director and Biosafety; Animal Care Supervisor; Animal and Biosafety Research Analyst

B. Alternate Members

1. Alternates to members of categories 1-4 above may be appointed to receive training as eventual replacements and to substitute for the absent regular member of the same category.
2. Alternate members are non-voting unless substituting for the absent regular member of the same category.

C. Appointments

1. Institutional Official (IO) nominates individuals and the Chief Executive Officer (CEO) appoints with a letter.
2. Appointments are made for three years. Members may be re-appointed for additional terms.
3. Alternate members will be nominated and appointed in same manner.

D. Officers

1. Chair
 - a. The Chair will be appointed by the IO for a 3-year term.
 - b. The IO may re-appoint the Chair for additional 3-year terms.
2. Vice Chair
 - a. The Vice Chair will be elected by the IACUC members for a 3-year term and may be re-elected for additional terms.
 - b. The Vice Chair will substitute for the Chair in the latter's absence.

II. Meetings

- A. Frequency: at least quarterly.
- B. Quorum: more than 50% of voting members.
- C. Minutes will be taken, subject to approval at the next meeting, and kept on file for three years.

III. Duties of IACUC

- A. Oversight and evaluation of the Marquette University animal care and use program and its components. IACUC will make recommendations to the IO regarding any aspect of Marquette University's animal program, facilities, and personnel training.
- B. Semi-annual inspections of animal care and use facilities at Marquette University.
- C. Semi-annual evaluation of animal programs at Marquette University.
- D. Review of animal use protocols.
- E. Provide a mechanism for receipt and review of animal care and use concerns.
- F. All protocols, protocol modifications, reports, minutes, and correspondence of the IACUC will be kept for at least three years after end of the study.

IV. Facilities Inspection

- A. Frequency: every six months.
- B. Requires two IACUC members. The public member is strongly encouraged to attend.
- C. An adaptation of the Office of Laboratory Animal Welfare (OLAW) inspection checklist is used.
 - 1. Checklist will be used to identify departures from regulations or standards.
 - 2. Checklist will distinguish significant from minor deficiencies.
- D. Results of inspection are presented to the IACUC at next scheduled meeting for review.
 - 1. Quorum of members signs the final report indicating agreement with the findings.
 - 2. Minority views, if any, will be included in final report.
 - 3. Final report will provide a reasonable and specific plan and schedule for corrections of deficiencies.
 - 4. Final report will be forwarded to IO, Office of Research Compliance, and the Animal Facility Director.
 - 5. The Animal and Biosafety Research Analyst will be responsible for updating the IACUC at the regularly scheduled meetings regarding the progress toward correcting any deficiencies.
 - 6. The meeting minutes will reflect the ongoing efforts to correct any deficiencies and the Animal and Biosafety Research Analyst is responsible for maintaining a log detailing when each deficiency has been corrected.
- E. Non-adherence to a plan of correction for significant deficiencies will be reported within 15 business days to Animal and Plant Inspection Service (APHIS) of the United States Department of Agriculture (USDA) and/or the Office of Laboratory Animal Welfare (OLAW) of the Department of Health and Human Services (DHHS).

V. Program Review

- A. Frequency: every six months at a meeting of the IACUC.
- B. Checklist for program evaluation will include:

1. IACUC membership and functions
 2. IACUC records and reporting requirements
 3. Veterinary care
 4. Personnel qualifications and training
 5. Occupational health and safety of personnel
- C. Quorum of members signs the final report indicating agreement with the findings.
1. Minority views, if any, will be included in final report.
 2. Final report will provide a reasonable and specific plan and schedule for corrections of deficiencies.
 3. Final report will be forwarded to IO.

VI. Protocol Review

- A. New Protocols.
1. New protocols will be reviewed at an IACUC meeting.
 2. All IACUC members will be provided with the protocol prior to the meeting.
 3. IACUC members reviewing and voting on the protocol must have no conflict of interest with the protocol.
 4. Principal Investigator (PI) is encouraged to attend the meeting to answer questions, but will leave the room for the vote regarding his/her protocol.
 5. If deemed helpful, non-voting consultants may be used in the review process.
 6. A primary reviewer will be assigned to each protocol.
 - a. The primary reviewer will be responsible for presenting the protocol at the IACUC meeting.
 - b. Prior to the meeting, the primary reviewer may contact the PI to seek clarification and have questions answered regarding the protocol.
 7. Upon completion of review of the protocol at the IACUC meeting, there will be a motion to approve, disapprove, or approve with contingencies.
 - a. A majority of the convened quorum voting in favor of the motion will pass the motion.
 - b. Protocols will be approved for one year starting with the date of approval or contingent approval.
 8. Contingent Approval.
 - a. When a protocol is in large part acceptable but has minor, correctable problems, it is eligible for contingent approval, meaning that approval will be granted only after specified changes have been satisfactorily made.
 - b. At the time of the vote for contingent approval, the IACUC Chair will designate one or more IACUC members to review the resubmission of the protocol to evaluate whether the changes were made satisfactorily. If all members of the IACUC are not present at a

meeting, the committee may use designated review subsequent to full committee review if the quorum of members present at a convened meeting decides by unanimous vote to use designated review 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 full committee review of the protocol.

- c. If given contingent approval, the PI of the protocol will be informed in writing of the specific changes that must be made to the protocol before approval can be granted. No animal work on the protocol may be done until the resubmission has been received, final approval given by the designated reviewer(s), and the PI has been notified in writing of the approval.
 - d. Normally, the PI will be given no more than two months to submit the modified protocol. If this time limit expires with no resubmission, the protocol must be resubmitted for full IACUC review.
9. No study may begin before final approval is granted.
10. The following are examples of issues to be considered in review:
- a. Rationale and purpose of the proposed use of animals.
 - b. Justification for species and numbers of animals.
 - c. Consideration of alternatives (e.g., in vitro, computer simulation).
 - d. Adequacy of training of personnel in proposed techniques.
 - e. Unusual housing and husbandry requirements.
 - f. Appropriateness of methods for sedation, analgesia, and anesthesia.
 - g. Unnecessary duplication of experiments.
 - h. Conduct of multiple major operative procedures.
 - i. Criteria for intervention, removal, or euthanasia of animals from study.
 - j. Appropriateness of euthanasia methods.
 - k. Safety of working environment for personnel.
- B. Annual Review.
1. New protocols have a maximum duration of three years, but are approved for one-year intervals.
 2. All approved protocols will be reviewed at an IACUC meeting at least annually.
 3. Procedures for full committee review are similar to those for new protocols.
 4. If approval of the annual review cannot be given before the expiration date of the protocol, the PI will be notified in writing by the Office of Research Compliance that animal activities associated with the protocol must stop after the expiration date and that any animals currently in the facility will be maintained by ARC staff until the annual review protocol is reviewed and approved by the IACUC. If the annual review submission is not received prior to the expiration date, the PI must submit a new protocol for review and approval.

5. After three years from initial approval date (three-year renewal), a new protocol must be submitted by the investigator. If the new protocol cannot be approved before the expiration of the previous protocol, the PI will be notified in writing by the Office of Research Compliance that animal activities associated with the previous protocol must stop until the new protocol is approved.

C. Modification of Protocols.

1. Investigators must submit amendments to protocols for changes in animal activities.
 - a. Major changes will be reviewed via the designated review process..
 - b. Minor changes will be reviewed by the Chair or the Veterinarian.
2. The Chair or the Veterinarian will make the determination as to whether a modification is major or minor.
3. Examples of major (significant) changes.
 - a. changes in the objectives of a study
 - b. proposals to switch from non-survival to survival surgery
 - c. changes in the degree of invasiveness of a procedure or discomfort to an animal
 - d. changes in species or in the number of animals used by more than 10%
 - e. changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia
 - f. changes in the duration, frequency, or number of procedures performed on an animal

D. Designated Review.

1. Designated review is a protocol review procedure conducted by one or more reviewers, rather than by the full committee.
2. Designated reviewers are IACUC members who are appointed by the IACUC Chair.
3. The designated reviewer assumes the responsibility of the full committee in granting approval, requiring modification, or sending the protocol for full committee review.
4. The designated review and approval has equal validity to full committee approval and does not require subsequent re-approval by the full committee.
5. Designated review is the default review process for all continuing reviews and protocol modifications unless the IACUC determines otherwise. Full review is the default review process for all new protocols and three-year reviews.
6. The following procedures will be followed when a protocol is received by the ORC
 - a. The ORC will send a copy of the protocol to all IACUC members for initial review.
 - b. Members will have five (5) business days to review the protocol. If any IACUC member objects to designated review, the protocol will go to full review. A non-response at the end of the five days is considered agreement with the designated review process.

- c. If no member objects to designated review, the protocol will be sent either electronically or via mail to designated reviewer(s) chosen by the Chair or Chair's designee.
- d. The designated reviewer(s) will have five (5) business days to review the protocol and respond to the ORC with a determination.
- e. The designated reviewer(s) can approve the protocol as written, require revisions, or bring the protocol to full review. Designated review may not result in withholding of approval.
- f. If multiple reviewers are assigned, the reviewers must be unanimous in decision and must review identical versions of the protocol. If revisions are requested by one or more of the reviewers, then the other reviewer(s) must be aware of and agree to the revisions. If reviewers do not agree, the protocol will be reviewed by the full committee.

7. The IACUC will be informed of the outcome of all designated reviews.

E. Deferred Review.

- 1. Deferred Review is a review process for protocols from Marquette University PIs that have been approved at another institution for work being conducted at the other institution.
- 2. The Marquette IACUC does not need to review the protocol, but must keep the protocol and the other institution's approval letter on file.
- 3. The Marquette IACUC must be informed of any problems encountered during the other institution's semi-annual inspections related to the protocol.
- 4. The Marquette IACUC must be informed of the outcome of annual reviews of the protocol at the other institution.
- 5. It will be the responsibility of Marquette University Principal Investigator to obtain these documents from the other institution and provide copies to the Office of Research Compliance.

VII. Mechanism for receipt of concerns regarding animal use

- A. Anyone from the public, facility personnel, or those using animals may report concerns regarding animal care or use.
- B. Reports of concern should be directed to either the ORC or the IACUC.
- C. The reported concerns will be investigated by the ORC and the IACUC and, if needed, action will be taken by the ORC and the IACUC to address the concerns.
- D. A report of the original concern, the investigation, and the actions taken will be submitted to the IO. The IO will report any significant, ongoing non-compliance activity to APHIS, OLAW and any Federal agency funding the activity.

- E. The IACUC can suspend an approved protocol with a majority vote of a convened quorum. Suspensions will be reported to APHIS, OLAW and any Federal agency funding the activity.

VIII. Suspension of Activities

- A. The IACUC is authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6 in the event of an animal health emergency.
- A. The veterinarian has the authority to euthanize an animal if necessary.
- B. The veterinarian may temporarily (until the IACUC convenes) suspend animal experimentation if animals are in distress.
- C. The IACUC can suspend a protocol with a majority vote of a convened quorum.
- D. Suspensions will be reported to PHS, APHIS (if applicable), and any federal agency funding the activity.