



SUBJECT: Standard Operating Procedure (SOP) for IACUC Protocol and Amendment Review

DATE: March 20, 2024

The University of Toledo Standard Operating Procedure (SOP) for IACUC Protocol and Amendment Review

The University of Toledo (UToledo) IACUC must review and approve all protocols related to the care and use of animals and all significant changes to previously approved protocols (Amendments) either through Full Committee Review (FCR) or through Designated Member Review (DMR). Amendments with minor changes may be reviewed by Veterinary Verification and Consultation (VVC) or the administrative review processes. This SOP describes FCR, DMR, VVC, and Administrative procedures.

The UToledo IACUC is scheduled to meet monthly and will meet more frequently as required by workload. Members with a conflict of interest may not participate in the review or approval of a protocol or amendment except to provide information requested by the IACUC. Consultants may be used to help review complex issues, but they may not vote unless they are also members of the IACUC.

- 1. Full Committee Review (FCR)**
 - a. Most new IACUC protocols and renewals go through the FCR method. This is a review at a convened meeting with a quorum present (i.e., a majority of the IACUC voting members at a convened meeting). A majority of the quorum present at a convened meeting may grant approval of IACUC protocols via FCR only after formal review and vote.
 - b. Prior to each committee meeting, IACUC members receive copies of the protocols to be reviewed by the committee. Primary and secondary reviewers are assigned by the IACUC chair. The Attending Veterinarian and a representative of Environmental Health and Safety also review each protocol.
 - c. The primary reviewer presents the protocol in detail, giving his/her comments and recommendations; the secondary reviewer adds his/her comments and recommendations. Comments are also requested of the Veterinary and Environmental

Health and Safety Reviewers and any other committee member that wishes to comment.

- d. If the primary and/or secondary reviewer is unable to attend the convened meeting, but provides his/her comments in writing, they may be read by the IACUC chair. However, if the committee believes that the protocol cannot be given adequate and fair review due to the absence of the primary and/or secondary reviewers, the review of the protocol is deferred until a future meeting. Once assigned as a primary reviewer on one or more FCR protocol, committee members have the immediate responsibility to inform the IACUC Office when they cannot complete their review before the posted deadline. These protocols will then be re-assigned to a different IACUC member as the primary reviewer.
 - e. Following a FCR review, the UToledo IACUC has the authority to:
 1. Approve.
 2. Require modifications to secure approval via FCR. The IACUC may vote to use FCR to approve these modifications.
 3. Require modifications to secure approval –via DMR subsequent to FCR. The IACUC may vote to use DMR to approve these modifications. See explanation below.
 4. Defer
 5. Withhold approval.
 - i. In this case, the IACUC will 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.
2. Procedures for DMR subsequent to FCR
 - a. DMR subsequent to FCR is a procedure in which the IACUC designates one or more members to review information provided by Principal Investigators in response to an FCR of a protocol application. This procedure may proceed if DMR was approved unanimously by all IACUC members at the meeting at which the required modifications were developed and delineated. A quorum of members must be present at the convened meeting to use DMR subsequent to FCR to secure approval.
 - b. If, at the convened meeting, any member votes against DMR subsequent to FCR, the protocol must be re-reviewed using FCR at the next convened meeting.
 - c. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
 - d. Minor changes of an administrative nature (i.e., grammatical changes, removal of personnel from the protocol, etc.) may be confirmed by IACUC Office staff (see Section 6, below)

3. Designated Member Review (DMR)

- a. The DMR method can be used for the review of SOPs, amendments to active protocols, breeding protocols, euthanasia only protocols, protocols that do not involve analgesia, and other appropriate materials.

In such instances, notification of the protocol or amendment will be circulated via e-mail to all IACUC members. Members are requested to respond within two (2) business days or less with their request for FCR or other recommendations. Non-response to this email is considered a silent assent.

- b. The IACUC will maintain e-mail records of the polling of members to obtain concurrence to use the DMR method or a record of concurrence by silent assent after two (2) business days have passed.
- c. The IACUC chair designates the Attending Veterinarian and at least one other member of the IACUC to act as designated reviewers.
- d. After review, the reviewers have to unanimously agree to approve the material, but either can require modifications of the material, or request FCR. Withhold approval is not a possible outcome of DMR.

5. IACUC Actions

- a. If the protocol or amendment is approved, notification of approval will be sent via email. A protocol is approved for three years. Continuation of a protocol beyond this time requires submission of a new protocol.
- b. If the protocol or amendment is approved pending modification:
 1. Notification that changes are required is sent via email.
 2. Upon receipt, the revised protocol or amendment will be sent to the original primary and secondary reviewers, along with the Veterinary and Environmental Health and Safety reviewers, to determine that it is:
 - i adequate and approved, or
 - ii requires further modifications
- c. If so determined by the IACUC at the meeting, the revised protocol or amendment may return for FCR.
 1. Notification that changes are required is sent via email.
 2. Upon receipt of the revised protocol or amendment, it will be assigned to the original primary and secondary reviewers, along with the Veterinary and Environmental Health and Safety reviewers, to present at the next full IACUC meeting.
- d. A Principal Investigator (PI) has 180 days (six months) to respond to modifications requested by the IACUC for a protocol or amendment. After 120 and 150 days, the PI will be notified that the unapproved protocol may be administratively closed if there is no action. If there is still no response, the unapproved protocol or amendment will be

closed after 180 days (six months). After the protocol or amendment is closed, resubmission of the protocol or amendment will be accepted as a new submission.

6. Administrative review

The following changes may be handled by IACUC Administrative personnel:

1. Room changes, change in location for field studies
2. correction in typographical and formatting errors;
3. correction in grammar;
4. changes in personnel (except for PI)

7. Veterinary Verification and Consultation (VVC):

The National Institutes of Health have provided guidance (NOT-OD-14-126) on the allowance of certain types of significant changes to animal activities previously approved by the IACUC that may be administratively approved using Veterinary Verification and Consultation (VVC).

The Attending Veterinarian (AV) will determine if a requested change meets the criteria below for VVC review. If so, the requested change to an IACUC-approved protocol will be reviewed and acknowledged by the AV. The AV is not conducting designated member review (DMR) but is serving as a subject matter expert to verify that compliance with the IACUC reviewed and approved guidance is appropriate for the animals in the circumstance. The AV will retain the discretion to send any requested changes to either DMR or full committee review (FCR) as appropriate. All changes acknowledged by VVC will be reported to the IACUC at the next committee meeting.

VVC Criteria

Significant changes that **may** be acknowledged by VVC:

1. in the proposed method of euthanasia to an "Acceptable" or "Acceptable with Conditions" method in the AVMA Guidelines for the Euthanasia of Animals so long as the AVMA-stipulated conditions are met;
2. requests to add additional animals, provided the proposed increase is not more than 10% of the original number approved and when combined with all previously approved requests for additional animals, it does not constitute a greater than 30% increase over the original number approved
3. changes in anesthesia, analgesia, or sedation
 - a) provided that changes are only to agents listed in the formularies listed below including changes in routes, volumes, frequency, duration, and dosages of substances

Formularies

AVMA Guideline for the Euthanasia of Animals

Flecknell's Laboratory Animal Anesthesia

University of Toledo DLAR Veterinary Recommendations for Anesthesia and Analgesia

Carpenter's Exotic Animal Formulary

[ACLAM e-Formulary](#)

ACLAM, Anesthesia and Analgesia in Laboratory Animals