



I. Purpose

To describe MSU's IACUC procedures for reviewing new Animal Care and Use Protocols, changes to existing protocols (amendments) and annual reviews (renewals).

II. Definitions

Protocol – A detailed plan or proposed scientific plan, treatment, or procedure to be conducted using animals.

Amendment – Any modification to an approved protocol that does not change the original scope of the protocol; classified as minor or significant.

Full Committee Review (FCR) – A quorum of the IACUC will review the protocol and vote to approve, return for modification to secure approval, or withhold approval.

Designated Member Review (DMR) – Following the opportunity to call for FCR, appointed IACUC member(s) reviews and determines the outcome for the assigned protocol/amendment. Possible outcomes are return for modification, approval or request for FCR.

Expedited Review – Review of a protocol/amendment in a swift and thorough process due to critical time dependent events.

Administrative Approval – For minor amendments including, but not limited to, change to protocol personnel, and animal number increases up to 10%, the IACUC Administrator and/or IACUC Chair determine the outcome.

Conflict of Interest (COI) – No IACUC member having association with the protocol under review or other COI may participate in the IACUC review or approval of a protocol/amendment, except to provide specific information requested by the IACUC. A member who has a COI cannot contribute to the constitution of a quorum.

IACUC Approval Date: 06/20/2018

Review Date: 06/20/2018

Issue Date: 07/13/2018

III. Procedure

A. Protocol Review:

Principal Investigators (PIs) are required to consult with the Attending Veterinarian (AV) for all protocols, including protocols being submitted to replace a protocol that is expiring. After consultation with the AV, protocols can be submitted to the IACUC at any time using the IACUC Online Protocol system (IACUCOP). Note: Every three years, an expiring protocol must be submitted as a new protocol.

Depending on the nature of the protocol, some protocols can be reviewed soon after they are received by the IACUC office using the designated member review (DMR) process. Any IACUC member may request FCR of a protocol at any time during the review process.

1. Veterinary/Administrative Review

- a. Protocols can be processed through veterinary/administrative review prior to or concurrent with IACUC review.
Allotted time: Up to one calendar week
- b. Veterinary/administrative review of the protocol may be returned for Modification (RFM) to the PI by email notification prior to committee review. PI's can revise and resubmit protocol.
- c. If the PI chooses not to address reviewer comments, a response to the RFM email including an explanation/rationale may be sent to the IACUC administrator. The IACUC administrator will forward the email to the reviewer(s).

a. Full Committee Review

Typically the following protocols will undergo FCR:

- Category E animals
- Survival surgeries
- Animal housing areas that are not part of the animal program overseen by the IACUC
- Impact to personnel safety
- Protocols involving USDA covered species

- 1) Protocols scheduled for FCR are placed on the IACUC meeting agenda. Committee members receive electronic notification.
- 2) All members have access to the protocol. Comments/questions on the protocol may be submitted electronically.

- 3) The protocol may be RFM to the PI via email prior to the meeting.
- 4) The PI may be asked to present the protocol to the IACUC during a convened meeting (quorum required). The presentation should include a brief overview of the study objective and address the recommended modifications/questions suggested by the committee. At this time, the IACUC has the opportunity to ask the PI any additional questions/concerns, after which and the PI is excused from further meeting deliberation.
- 5) The protocol will be discussed by the quorum of the IACUC. After discussion the IACUC has the following voting options:
 - Approve
 - Return for Modification (RFM) and send to DMR (see process below) when resubmitted
 - Return for Modification and review during convened meeting
 - Withhold approval

b. Designated Member Review

- 1) The full committee will be notified that a protocol will be assigned to DMR. All IACUC members are given two business days to view/assess and comment on the protocol and the opportunity to request FCR.

Allotted time: Two business days

- 2) An IACUC member(s) will be assigned as the DMR(s) by the IACUC Program Manager on behalf of the Chair. The DMR(s) is selected from a review assignment list approved by the Chair. The review assignment list is maintained in an electronic document shared folder. IACUC member(s) who are associated with the protocol or have a conflict of interest will not be assigned as the DMR(s).
 - a) The DMR(s) is required to review the protocol. If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications. Once the review of the protocol has been completed, the DMR(s) has the following voting options:
 - Approve

- Return for Modification (to secure approval). When a protocol is Returned for Modification, the following process occurs:
 - i. PI is notified via e-mail of requested modification(s).
 - ii. PI revises and resubmits the protocol.
 - iii. Protocol is reassigned to the DMR(s) to verify the requested modification(s) have been addressed appropriately. The DMR(s) may RFM the protocol as many times as necessary to secure approval, or may call for FCR (see IVA.2.b above).
Allotted time: Two business days

B. Amendment Review:

Amendments may be submitted at any time. Amendments are reviewed in context to the original approved protocol which may necessitate review of the entire protocol, but is not required to secure approval. Amendments may be reviewed by FCR (See x) DMR (See IV.A.2.b), IACUC Administrator Review, or Expedited Review.

a. Administrative Approval

Minor amendments may be approved by the IACUC Administrator for the following changes:

- Addition or deletion of protocol associates
- Up to 10% increase in non USDA covered species

Allotted time: Two business days

NOTE: This list is not inclusive. IACUC leadership (Chair and Attending Veterinarian) may determine an amendment addressing other minor changes is acceptable for administrative approval.

b. Expedited Review

Expedited review of an IACUC protocol amendment may be necessary, due to critical time-dependent events.

- 1) The PI must obtain Department Head approval to request expedited review (email).

To ensure that the expedited review process is executed in a swift and thorough fashion, the following items **must be addressed prior to protocol amendment submission:**

- a) If the proposed changes involve an increase in pain and distress, an appropriate literature search for alternatives to painful/distressful procedures must be conducted and included in the submission, and a consultation with the Attending Veterinarian or designee is required.

- b) When applicable, corresponding biohazard, particularly hazardous substances (PHSs) and radiation safety protocols must be in place and verified by Environmental Health & Safety.
- 3) An email describing the rationale for expedited review; including the Department Head authorization memo must be submitted to the IACUC Chair.
- 4) The IACUC Chair will notify the PI if the protocol amendment will undergo expedited review process as described below.
 - a) Notification is sent to all committee members that the protocol will be assigned to DMR. All IACUC members will be given the opportunity to view/assess and comment on the protocol, and the opportunity to request FCR.
Allotted time: 24 hours
 - b) Concurrently a DMR will be required to review the protocol.
Allotted time: 24 hours

C. Annual Review:

Protocols should be submitted for annual review as a 'renewal' at least 30 days prior to protocol expiration to allow sufficient time for review and approval.

The IACUC provides reminder notifications of protocol renewals/amendments/expiration coming due at approximately 90, 60 and 30 days. If a protocol has not been submitted 14 days prior to the protocol renewal date, the PI will receive a final reminder notification that if the protocol is not approved by the renewal date animal work described in the protocol cannot occur.