SUBJECT:	Institutional Animal Care & Use Committee				
POLICY:	1001.1 Institutional Animal Care & Use Committee				
PROCEDURE:	1001.1.2 Protocol Review Process				
EFFECTIVE:	April 2024	**REVISED:**		**REVIEWED:**	September 2026

Introduction and Purpose

The purpose of this procedure is to describe the submission and review process for animal care and use protocols.

Procedure

A. Protocol Review:

Principal Investigators (PIs) are required to consult with the Attending Veterinarian (AV) before submission of all protocols. After consultation with the AV, protocols can be submitted to the IACUC at any time. Every three years, an expiring protocol must be submitted as a Renewal.

Protocols are reviewed by Full Committee Review (FCR) or by Designated Member Review (DMR).

1. Veterinary/Administrative Review

   a. Protocols can be processed through veterinary/administrative review prior to or concurrent with IACUC review.
   Allotted time: 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. The PI should revise and resubmit protocol.

   c. If the PI chooses not to address review comments, a response to the comment(s) should be added to the protocol.

2. Full Committee Review (FCR)

   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

   a. Protocols scheduled for FCR are placed on the IACUC meeting agenda. Committee members receive electronic notification.
   Allotted time:

   b. All members have access to the protocol. Comments/questions on the protocol may be submitted electronically.

   c. The protocol may be returned for modification to the PI prior to the meeting.

d. 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 can ask the PI any additional questions/ concerns, after which the PI is excused from further meeting deliberation.

e. 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

3. Designated Member Review (DMR)

a. The full committee is 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

b. IACUC member(s) will be assigned as the DMR(s) by the IACUC program manager following consultation with the chair. IACUC member(s) who is associated with the protocol or has a conflict of interest will not be assigned as the DMR(s).
Allotted time: One calendar week

1) 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 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:
  a) PI is notified via e-mail the protocol has been returned for modification
  b) PI revises and resubmits the protocol.
  c) Protocol is reassigned to the DMR(s) to verify the requested modification(s) has been addressed appropriately. The DMR(s) may RFM the protocol as many times as necessary to secure approval or may call for FCR (see above).

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:

1. Administrative Review
Administrative Review items include minor amendments including but not limited to changes to protocol personnel, animal number increases up to 10% in non-USDA covered species, the IACUC Program Manager and/or IACUC Chair/AV determine the outcome.
Allotted time: Two business days

NOTE: The list above is not inclusive. IACUC leadership (chair and/or attending veterinarian) may determine whether an amendment addressing other minor changes is acceptable for administrative approval.

2. Veterinary Verification and Consultation (See Veterinary Verification and Consultation Policy)

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

   a. 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:**

      1) 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.

      2) When applicable, corresponding biohazard, particularly hazardous substances (PHSs) and radiation safety protocols must be in place.

   b. An email describing the rationale for expedited review, including the Department Head authorization memo, must be submitted to the IACUC Chair.

   c. The IACUC Chair will notify the PI if the protocol amendment will undergo expedited review. A DMR will be assigned simultaneously at the call for review by FCR or DMR.

      1) 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

      2) Concurrently a DMR will be required to review the protocol.
         Allotted time: 24 hours

C. Interim Review:

Interim Review (annual review) should be submitted at least 14 days prior to the meeting date of the month they are due, to allow sufficient time for review.

The IACUC provides interim review notifications are sent the month before they are due.

Interim Reviews may be reviewed by FCR (See III.A.2), DMR (See III.A.3), VVC, or Administrative Review.

D. Protocol Expiration/Renewal:

Protocols that are expiring must be submitted as a "Renewal" protocol at least 30 days prior to protocol expiration to allow sufficient time for review. Protocols submitted later than 30 days prior to expiration may not secure approval in time.

Expiring protocol notifications are sent approximately 60 and 30 days prior to expiration. If a renewal protocol has not been submitted approximately 14 days before the expiration, the PI will receive a final reminder notification. If a renewal protocol is not approved prior to expiration, animal work described in the protocol cannot occur.

Renewal protocols may be reviewed by FCR (See III.A.2) or DMR (See III.A.3).

E. Suspension

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of the activity by the principal investigator as approved by the committee. The IACUC may suspend an activity 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.

If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal Agency funding that activity (if applicable).

Definitions

Protocol: A detailed plan or proposed plan, treatment, or procedure to be conducted using animals for the purposes of teaching.

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

Interim Review Protocol: An annual submission and status update. An interim review protocol may include amendments to the protocol.

Renewal Protocol: A protocol that has been renewed following expiration.

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) review and determines the outcome for the assigned protocol/amendment. Possible outcomes are return for modification to secure approval, approve or request FCR.

Expedited Review: Review of an amendment in a swift and thorough process due to critical time dependent events.

Administrative Review: Minor amendments including but not limited to changes to protocol personnel, animal number increases up to 10% in non-USDA covered species, the IACUC Program Manager and/or IACUC Chair/AV determine the outcome.

Veterinary Verification and Consultation (VVC): Review of an amendment with significant changes that may be handled administratively in consultation with the AV.

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.