1. Purpose

To describe the submission and review process for Agricultural Animal Care and Use Protocols.

1. 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

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 AACUC 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 AACUC member(s) reviews 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, change to protocol personnel, animal number increases up to 10%, the AACUC Program Manager and/or AACUC Chair/AV determine the outcome.

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

1. Procedure
2. Protocol Review:

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

1. Administrative Review
2. Protocols can be processed through /administrative review prior to or concurrent with AACUC review.

**Allotted time**: One calendar week

1. 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 the protocol.
2. If the PI chooses not to address review comments, a response to the comment(s) should be added to the protocol.
3. Full Committee Review

Typically, the following protocols will undergo FCR:

Category E animals

Survival surgeries

Impact to personnel safety

1. Protocols scheduled for FCR are placed on the AACUC 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 returned for modification to the PI prior to the meeting.
4. The PI may be asked to present the protocol to the AACUC 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 AACUC can ask the PI any additional questions/ concerns, after which the PI is excused from further meeting deliberation.
5. The protocol will be discussed by the quorum of the AACUC. After discussion the AACUC 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

1. Designated Member Review
2. The full committee is notified that a protocol will be assigned to DMR. All AACUC 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

1. AACUC member(s) will be assigned as the DMR(s) by the AACUC Program Manager following consultation with the Chair. AACUC 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:

1. PI is notified via e-mail the protocol has been returned for modification
2. PI revises and resubmits the protocol.
3. 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).
4. 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 III.A.2) DMR (See III.A.3), Administrative Review or Expedited Review.

1. Administrative Review

Minor amendments may be approved by the AACUC Chair for the following changes:

● Addition or deletion of protocol associates

**Allotted time**: Two business days

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

1. Expedited Review

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

1. The PI must obtain Department Head approval torequest 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:**
2. 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.
3. When applicable, corresponding biohazard, particularly hazardous substances (PHSs) and radiation safety protocols must be in place.
4. An email describing the rationale for expedited review, including the Department Head authorization memo must be submitted to the AACUC Chair.

c. The AACUC Chair will notify the PI if the protocol amendment will undergo an expedited review process as described below.

1. Notification is sent to all committee members that the protocol will be assigned to DMR. All AACUC members will be given the opportunity to view/assess and comment on the protocol, and the opportunity to request FCR.

**Allotted time**: 24 hours

1. Concurrently a DMR will be required to review the protocol.

**Allotted time**: 24 hours

1. 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 that are sent the month before they are due.

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

1. 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).

1. Suspension

The AACUC 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 AACUC may suspend an activity only after a review of the matter at a convened meeting of a quorum of the AACUC and with the suspension vote of a majority of the quorum present.

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

\*Will be implemented when protocols are migrated to TOPAZ.