Guiding Principle

The IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals. This Guiding Principle pertains to all protocols, proposed significant changes, and re-reviews of approved protocols related to the care and use of animals.

The PHS Policy and the animal welfare regulations recognize two methods of protocol review: Full Committee Review (FCR) and Designated Member Review (DMR). However, it should be noted that any IACUC member, at any time, for any reason can request FCR of any protocol. Protocols classified as pain category B or C generally qualify for DMR. However, protocols that use USDA-regulated animals, use animals for education or training, use a large number of animals or have other identified concerns may not qualify for DMR as determined by the IACUC Chair on a case by case basis. Category D and E protocols require FCR at a convened meeting. Significant changes to a protocol already classified as a D or E also require FCR. Changes that increase the pain category from a B or C to a D or E required FCR with few exceptions as determined by the IACUC Chair on a case by case basis.

The investigator should carefully examine all procedures to be applied to animals and determine his or her best estimation of the level of pain, discomfort, and distress and designate the appropriate pain category. The pain category will be assessed by the IACUC Chair or IACUC Administrator to determine the type of review, but final determination will be made by the IACUC following review.

All personnel proposing to use a live animal in research, teaching, testing or for related purposes must submit a completed IACUC Application form to the IACUC Office. Submissions are reviewed by either FCR or DMR as described previously.

A significant change is based upon guidance provided by OLAW. Significant changes include changes that have, or have the potential to have, a negative impact on animal
welfare. In addition some activities that may not have a direct impact on animal welfare are also considered to be significant.

Significant changes listed below must be approved by one of the valid IACUC approval methods (DMR or FCR).

- From nonsurvival to survival surgery;
- Resulting in greater pain, distress, or degree of invasiveness;
- In housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- In species
- In study objectives;
- In Principal Investigator (PI); and
- That impact personnel safety e.g. change in biosafety level).

The specific significant changes below may be handled administratively in consultation with a veterinarian (AV and/or any veterinarian serving on the IACUC) authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC –reviewed and –approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameter of the IACUC –reviewed and –approved policies.

- Anesthesia, analgesia, sedation or experimental substances maybe changed in accordance with the following formularies;
  - Veterinary Drug Handbook/Plumb’s Veterinary Drugs by Donald C. Plumb
  - Laboratory Animal Anesthesia by Paul Flecknell
- Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
- Duration, frequency, type, (e.g. blood collection site or volumes, route of administration, volumes, and dosages) of procedures performed on an animal.
  - Blood Collection site or volume
  - Route of administration, volumes, and dosages
  - Increasing food/fluid restriction prior to a procedure to more than 12 hours with adequate justification
- Number of procedures performed on an animal, excluding surgical procedures contingent upon them not exceeding IACUC guidelines.
- Additional strains or sources of animals
- Changes to space requirements if restriction is justified and not excessive based on veterinary consultation.
• A significant change that may be handled administratively without additional consultation or notification is
  o an increase in the previously approved animal numbers; not to exceed 10% of the originally approved number of animals.

The changes below will be handled administratively without consultations or notifications.

• Correction of typographical errors;
• Correction of grammar;
• Contact information updates; and
• Change in personnel, other than the PI. (Administrative review will ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in the Occupational Health and Safety (OHS) Program and meet any other criteria required by the IACUC.)
• In housing and or use of animals in a location that is part of the animal program overseen by the IACUC

All proposed significant changes must be submitted to the IACUC by completing and submitting the Request for Change Form.

The approval of significant changes are communicated to the IACUC at the IACUC meetings.

The IACUC will re-review all protocols of each previously approved, ongoing activity no less than annually via the annual update process. In addition investigators will be required to submit a new protocol application in accordance with the expiration dates set by the IACUC. Annual updates are reviewed administratively by the IACUC Chair and Attending Veterinarian. A list of annual updates is provided to the IACUC on a monthly basis. Three-year reviews will be reviewed via the DMR or FCR based on the pain category as described above.

Requirements

The Public Health Service (PHS) Policy in accordance with IV.C. 1-8 and the United States Department of Agriculture AWA USDA 2.31 (d) In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with this policy. In making this determination, the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applied to the research project and that the research project is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the
research project conforms to the institutions Animal Welfare Assurance and meets the requirements contained in these regulations.

**Office of Laboratory Animal Welfare (OLAW)** *Guidance NOT-OD-09-035 IACUC Actions Following Full Committee Review.*

**Office of Laboratory Animal Welfare (OLAW)** *Guidance NOT-OD-14-126 Significant Changes to Animal Activities.*

**PROCEDURE:**

1.0 Designated Member Review (DMR)

1.1 Each eligible protocol is distributed to the entire IACUC with specific instructions regarding the designated member review process and a deadline to call for FCR which is generally 5 business days. Affirmation from all IACUC members is not required.

1.2 Under extenuating circumstances, the deadline can be reduced by the IACUC Chair/designee to a minimum of one day with affirmation required from all members regarding their decision whether or not to call for FCR.

1.3 At least two members of the IACUC are assigned by the chair as the designated reviewers (DR) who are qualified to conduct the review. The DR decisions must be unanimous; if not, the protocol will be referred for FCR.

1.4 Any member of the IACUC can make the decision to send the protocol for FCR at any time during the set deadline period. If no member of the IACUC refers the protocol to full committee review at a convened meeting, at the end of the set deadline period the assigned IACUC DRs have the authority to approve, require modifications in (to secure approval) or request full committee review.

1.5 The DRs do not have the power to withhold approval.

1.6 The IACUC minutes contain notification of all actions approved by DMR.

2.0 Administrative Review in Consultation with a Veterinarian(s)

2.1 The Request for Change form will be forwarded to the Attending Veterinarian and/or Designee.

2.2 The AV or Designee will make a determination on the change request or refer the change request to DMR or FCR.

3.0 Administrative Review

3.1 The Request for Change form will be reviewed by IACUC Office personnel.

3.2 IACUC Office personnel will make a determination or refer the change request to DMR or FCR.

4.0 Full Committee Review (FCR)
4.1 Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. A simple majority of the membership of the IACUC constitutes a quorum and is required in order to convene a meeting for the review of protocols. For a protocol to be approved, it must receive the approval of the majority of those members present at the convened meeting.

4.2 Protocols scheduled for full IACUC review are distributed to all members of the IACUC at least one week prior to the meeting. The IACUC usually meets once per month with additional meetings to address extenuating circumstances convened when necessary.

4.3 The IACUC chair, or his/her designee, assigns at least two members to serve as technical reviewers. The technical reviewers present their findings to other member of the committee at a properly convened IACUC meeting for discussion.

4.4 When it is determined that consultants or experts will be required to advise the IACUC in its review of a protocol, the protocol shall also be distributed to the consultants or experts prior to the meeting, and if necessary the consultant or expert may be invited to the Full Committee Meeting. Consultants may not approve or withhold approval of any activity or vote with the IACUC.

4.5 No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g. is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. At the beginning of each meeting the Chair of the IACUC reminds investigators to declare any conflicting interest not previously disclosed.

5.0 IACUC Actions Following Full Committee Review

5.1 Following review of the protocol, a motion is made and vote taken to either: 1) approve, 2) require modification to secure approval, or 3) withhold approval.

5.2 If the motion is to require modifications (to secure approval), the motion must include how those modifications will be reviewed: 1) Designated Member Reviewers assigned or 2) FCR. When the motion is to review the modifications by DMR, the vote must be unanimous. Reviewers are then assigned by the IACUC Chair. At any time prior to or during the full committee meeting any member can request FCR of the revised protocol or request to see the revised protocol when it is sent to the assigned reviewers. Providing no one requests FCR, the assigned reviewers are authorized to approved or require further modification to secure approval and their decision must be unanimous.

6.0 Notification Following Review
6.1 Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding the protocol review are as follows:

6.1.1 The IACUC Chair or his/her designee shall notify the investigator in writing of the IACUC’s decision to approve the protocol, require modification in (to secure approval), or withhold approval (disapproval). In order to secure approval the investigator must revise the IACUC application and/or respond to other conditions set by the IACUC.

6.1.2 The IACUC Chair and/or designee shall provide the investigator with reasons, in writing, for the IACUC’s decision to withhold approval of a protocol and shall provide an opportunity for the investigator to respond and appeal.

6.1.2.1 All appeals are required to be in writing.

6.1.3 In addition to the written appeal, investigators are provided an opportunity to appear, in person, before a full convened quorum of the IACUC.

6.1.4 Applications and proposals that have been approved by the IACUC may be subject to further review by officials of the institution who can overturn an IACUC approval. However, those officials may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the IACUC.

6.1.5 A copy of IACUC meeting minutes, which record all decisions regarding protocol review and activities, is available to the IO.