

IACUC Policy on the Review of Animal Use Protocols

Requests for animal use are made by submitting an Animal Use Proposal (AUP) form to the IACUC via software accessible through the University website. De novo AUPs may either undergo Designated Member Review (DMR) or Full Committee Review (FCR). Amendments to approved AUPs may undergo Administrative Review (AR) or Veterinarian Verification and Consult (VVC), DMR, or FCR.

The following situations require FCR:

1. De novo protocol involving procedures with pain and distress category E.
2. De novo protocol involving procedures with survival surgery.
3. De novo protocol involving procedures with USDA Species.
4. Changes that result in greater pain, distress, or invasiveness.
5. Change in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC (excluding field studies).

The following situations are eligible for DMR:

1. De novo protocols involving procedures with only pain and distress categories B, C and/or D.
2. Change in PI.
3. Change that impacts personnel safety.
4. Change in objectives, purpose, or aim of study.
5. Change to or addition of a species

Amendments meeting any of the following criteria are eligible for VVC:

1. Changes in euthanasia methods consistent with current AVMA Guidelines.
2. Changes in anesthesia, analgesia, or sedation in a manner published in peer-reviewed literature or textbook, such as Hawk's Formulary for Laboratory Animals (https://www.aclam.org/Content/files/files/Public/Active/formulary1-pref_abbrev_dose-est.pdf).
3. Changes in experimental substances and fundamentally similar compounds that are documented in the literature regarding safety and toxicity in the same species.
4. Less than 10% increase of any one species.
5. Change in stock, strain, or genetic modification, unless such change results in abnormalities that require special support or impact the scientific objectives of the study.
6. Change in previously approved procedures involving duration, frequency, type, or number of procedures performed on an animal, in accordance with commonly-accepted practices.

Amendments meeting any of the following criteria are eligible for AR:

1. Change in personnel other than the PI.
2. Change of protocol title.
3. Addition of new funding sources with no change in procedures
4. Correction of typographical errors, grammar, and contact information updates.
5. Change in IACUC-approved animal housing/procedure room.
6. Change in animal source involving a DLAR-approved vendor

For de novo AUPs and amendments eligible for DMR, all IACUC members are provided with a copy of the AUP and allowed a reasonable amount of time to request FCR. If no member requests FCR, then the AUP or amendment undergoes DMR.

DMR

The AUP or amendment is reviewed by the IACUC Chair, the Attending Veterinarian and one or more Designated Reviewer(s) who are assigned by the IACUC Chair. After reviewing the AUP or amendment, the reviewers may (1) approve the AUP or amendment, (2) require modifications to secure approval or (3), require FCR. If there is not a unanimous decision among the IACUC Chair, the Attending Veterinarian and the Designated Reviewer(s), the AUP or amendment is referred to the IACUC for FCR.

FCR

Two committee members are assigned as principal reviewers for each AUP or amendment. The principal reviewers present their analysis of the AUP to the committee at a convened meeting. All members are afforded the opportunity to comment and/or ask questions about the AUP or amendment. Members who cannot attend a meeting may relay questions or comments via the Chairperson, another committee member, or via the electronic protocol system program. A quorum must be present at the meeting to vote on any recommended actions.

Following the committee review, the members may vote to (1) approve, (2) require modifications, or (3) withhold approval of the AUP or amendment. If by majority vote, the IACUC requires modifications to secure approval, the committee will (1) assign one or more members as designated reviewers for the modified AUP/amendment or (2) require FCR of the modified AUP/amendment.

The default process is for the modified AUP/amendment to be reviewed by a designated reviewer; however, any committee member, present or not, may request FCR of the modified AUP/amendment. If the IACUC uses a Designated Reviewer for the modified AUP/amendment, the IACUC Chair assigns one or more members who may (1) approve, (2) require additional modifications to secure approval, or (3) refer the AUP/amendment back to the IACUC for FCR. If more than one Designated Reviewer is assigned, the modified AUP/amendment is either approved unanimously by the Designated Reviewers or it must undergo FCR.

If the IACUC votes to withhold approval, the investigator may present a new AUP for de novo review.

VVC

For amendments eligible for VVC, the AV may (1) approve the amendment, (2) Require modifications to secure approval, or (3) refer the amendment to DMR or FCR, as appropriate.

AR

For amendments eligible for AR, the IACUC Administrator may (1) approve the amendment, (2) Require modifications to secure approval, or (3) refer the amendment to VVC, DMR or FCR, as appropriate.

Member attendance is documented and kept as part of the meeting minutes. A quorum is required for convening a meeting and voting on reviews or other business. A committee member who may have a conflict of interest on a specific AUP or amendment, e.g., Principal Investigator or Key Associate, is required to leave the meeting during review of that AUP and may not vote on the AUP.

All teaching or research activities that involve the use of animals require submission and approval of an Animal Use Proposal.

IACUC Policy on Significant Changes to Animal Use Proposals

Background:

The Public Health Service Policy on Humane Care and Use of Laboratory Animals and the federal regulation in Animals Welfare require that the Institutional Animals Care and Use Committee (IACUC) shall, “review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities...”

Policy:

Significant Changes include:

1. Changes in the objectives of the study;
2. Changes or additions to the species of animal to be used;
3. Changes in the approximate number of animals used;
4. Proposals to switch from nonsurvival to survival surgery;
5. Changes in the degree of invasiveness of a procedure;
6. Changes in the procedure which may change the level of potential discomfort of the animal;
7. Change in the Principle Investigator (PI) and/or Co-PI;
8. Changes in anesthetic agent(s), analgesics, and/or methods of euthanasia.

Request to make significant changes to an approved Animals Use Proposal may be made by requesting approval of an Amendment to the protocol.