Institutional Animal Care and Use Committee		UNTHSC
Title: Amendments to Approved Protocols (including Veterinarian Verification and Consultation)		
Document #: 002	**Version #:** 07	
Approved by IACUC Date: November 18, 2025		

A. BACKGROUND INFORMATION

a. The Institutional Animal Care and Use Committee (IACUC) at the University of North Texas Health Science Center has the responsibility to assure that all animal use activity meets federal law mandates, Public Health Service policy, the Guide recommendations and all accreditation expectations. Any change needed to an already approved protocol must be approved by the IACUC before the change can occur.

b. Amendments are proposed changes to an active and approved animal use protocol. The proposed change(s) must fit within the scope of the original protocol (objectives, purpose or aims should remain the same)

c. Types of amendment reviews (see attachment for specific examples)

i. Administrative Review (AR) – a review process only allowed for minor amendments.

ii. Veterinary Verification and Consultation (VVC) – an expedited review process in accordance to OLAW Guidance #NOT-OD-14-126, wherein the Attending Veterinarian (AV) or their designee approves minor changes without the need for a PI to submit a Designated Member Review or Full Committee Review amendment.

iii. Designated Member Review (DMR) – a review process allowed by the regulations, in which each IACUC member is provided with at least a list of the proposed amendment, and given a specified period to call for Full Committee Review. If no one calls for Full Committee Review, the submission is assigned to at least one IACUC Member as the Designated Reviewer. The Designated Reviewer may approve the submission, require modifications, or call for Full Committee Review.

iv. Full Committee Review (FCR) – a review process in which the proposal is reviewed at a fully convened IACUC meeting, attended by a quorum of IACUC members. The proposal must receive a majority vote of members present in order to receive full approval.

B. RESPONSIBILITIES

a. It is the responsibility of the Principal Investigator (PI) to submit an amendment when a change is needed to an approved protocol. The PI cannot implement the change until the amendment is approved.

b. It is the responsibility of the AV or their designee to use their discretion to verify and approve minor procedural changes as long as the change is: (1) a modification to an existing IACUC approved protocol, (2) will not unduly impact animal welfare, (3) does not result in greater pain, distress, or degree of invasiveness, (4) does not change overall study objectives, and (5) is consistent with current standards of veterinary practice or specifically addressed in IACUC procedure or guidance.

C. PROCEDURES

a. The PI will create the amendment (form can be found on the IACUC website) and complete all appropriate fields as necessary. Any new procedures will require an updated or new flow chart.
b. The PI shall submit the amendment electronically to the IACUC office for review.
c. The Administrator will review to assure the application is complete. If revisions are needed, the Administrator will contact the PI with necessary revisions requested.
d. After all revisions are received, the amendment will be triaged to determine which review process it qualifies for, i.e., Administrative Review (AR), Veterinary Verification and Consultation (VVC), Designated Member Review (DMR), or Full Committee Review (FCR). It will follow the review process as detailed below.
e. If an amendment exceeds the purpose of the protocol, a new protocol may be requested at any given point during its review process.

ADMINISTRATIVE REVIEW AMENDMENTS

a. Minor amendments (such as personnel changes other than PI, lab locations if already approved for animal use, title/funding changes, additional procedures during terminal surgery or post euthanasia) may qualify for administrative review. Administrative changes include changes that do not affect the welfare of the animals.
b. IACUC administrator will review the amendment, route it for a veterinary review. If accepted by AV or designee, the Chair will review it. The Veterinarian or their designee or Chair may refer any request to the IACUC for DRM or FCR for any reason.
c. The committee is provided with a list of the amendments approved by AR each month.

VETERINARIAN VERIFICATION & CONSULTATION AMENDMENTS

a. The AV or their designee may verify changes to:
   i. Anesthesia, Analgesia, Antimicrobials and Sedation:
      1. Addition of a clinically relevant drug of the same previously approved class to induce a similar outcome. May be used to replace an already approved anesthetic, analgesic, antimicrobial, or sedative drug; or provide an alternate drug that may be used due to shortages in supply.
      2. Modify the dose, route, concentration, volume, and/or duration of an approved anesthetic, analgesic, antimicrobial, or sedative drug.
      3. Additions or modifications must be in accordance with published veterinary formularies and may not result in a change in study objectives or greater pain, distress, or degree of invasiveness. Approved veterinary formularies are listed in the Reference section below.
      4. Note: The addition of anesthesia where anesthesia is not currently used for an approved procedure and/or the addition of a non-pharmaceutical grade anesthetic, analgesic, antimicrobial, or sedative drug is not eligible for the VVC process.
   ii. Experimental Compounds or Substances
      1. Add an additional experimental compound or substance of the same drug class used to induce a similar outcome to an existing experiment that is already approved for use of such compounds or substances.
      2. Modify the timing, frequency, dose, route, concentration, volume, and/or duration of an approved experimental substance.

3. Additions or modifications may occur if the change does not result in a change in study objectives or greater pain, distress, or degree of invasiveness.

iii. Changes to duration, frequency, type, or number of approved procedures performed on an animal may be eligible for VVC, as long as the change is 1) a modification to an existing IACUC approved procedure and 2) does not result in greater pain, distress, degree of invasiveness, and/or a change in study objectives:
   1. Changes related to blood collection (e.g.: frequency, volume, vessel of access)
   2. Change in sample collection method to a method with equal or lesser pain, distress or degree of invasiveness.
   3. Revision of sample collection intervals or total samples collected.
   4. Change in route of administration for an approved compound
   5. Additional peri-mortem tissue collection or tissue collection from a new organ system or anatomical site when the animal is under terminal anesthesia.
   6. Substitution of one accepted biopsy method for another for tissue or DNA analysis (e.g.: tail snip vs ear notch)
   7. Altering the duration or interval between procedures (e.g.: lengthening an imaging episode or the time between episodes).
   8. Changing an identification means (e.g.: ear tag vs microchip).
   9. Adding or altering behavioral testing methods providing they do not involve greater pain and distress or degree of invasiveness.
   10. Change in other protocol time-points not addressed above.

iv. Modification to sex of previously approved animal species (addition of females when males are approved and vice versa, or change to opposite sex)

v. Modifications to previously approved surgical procedures that do not increase invasiveness or expected adverse outcomes (e.g., change of suture material, closure method, surgical approach, number of samples collected).

vi. A change in the source of animals as long as the new source is a previously approved DLAM vendor.

v. Increase in previously approved animal numbers up to 10%.

vi. A change in the final disposition of the animal including change from euthanasia to adoption, or transfer to another protocol.

vii. A change in euthanasia to any method approved in the current (2020) AVMA Guidelines for the Euthanasia of Animals.

b. An approval letter is then prepared by the IACUC Administrator and sent to the IACUC Chair.

c. The Committee is provided with a list of amendments approved by VVC each month.

DESIGNATED MEMBER REVIEW AMENDMENTS

a. Amendments that qualify for DMR include a select list of amendments involving significant changes such as:

i. Amendment involving additional prolonged restraint.

ii. Principal Investigator transfers, only between faculty members in good standing.

iii. Use of analgesics.

iv. Changes in duration, frequency, or number of procedures performed on an animal that results in greater pain, distress, or degree of invasiveness.

v. Change in number of animals over 10% of the approved number (rodents only).
vi. Change/addition of species (mice and rats only).
vii. Change in housing or use of animals in a location that is not part of the animal program overseen by the IACUC.
viii. Changes that impact personnel safety.

b. Amendments undergoing DMR are generally assigned to the Chair or Vice-Chair; however, the Chair may designate any IACUC member to serve as the Designated Reviewer.
c. Committee members are given five business days grace period to call for full committee review. Committee members may provide comments of the document for the Designated Reviewer to consider.

FULL COMMITTEE REVIEW AMENDMENTS

a. Full Committee Review amendments are amendments that have significant changes and may only be reviewed at a convened meeting with a quorum (simple majority) of members present such as:
i. Change/Addition of USDA covered-animal species.
ii. Changes in objectives of a study
iii. Addition of survival surgeries (when no survival surgeries are described in original application). A change from non-surgery to surgery; from minor to major surgery; or from non-survival to survival surgery.
iv. Addition of animals to which invasive procedures will be performed (i.e. stroke surgery)
v. Move to pain category E (withholding analgesics, painful procedures added, etc.).
b. Amendments that qualify for FCR, are placed on the next month's meeting agenda. The PI is notified of the meeting date in which the amendment will be reviewed.
c. Two Committee Members will be assigned as reviewers for the amendment and will present the amendment at the IACUC meeting. A majority vote of the quorum present is needed to approve, require modifications (to secure approval), or withhold approval of an amendment.

D. REFERENCES & ATTACHMENTS

Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.
PHS Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised 2015.
NOT-OD-14-126 Guidance on Significant Changes to Animal Activities
Guide for the Care and Use of Laboratory Animals, Eighth Edition. National Academy Press, Washington, D.C. 2011.
UNT Health Protocol Amendment Form
AVMA Guidelines for the Euthanasia of Animals (2020)