IACUC Policy 20: Administrative Approvals of Amendments

1. Background
The Assurance between TTUHSC and Public Health Services for the IACUC allows administrative approval for protocol amendments that are solely to:

A. Add, delete, or change a title of a study;
B. Add, delete or change personnel other than the Principal Investigator;
C. Add and/or delete location(s);
D. Add and/or delete animals of species (rats and mice only) approved to be used on the protocol when the increase is no greater than 10% of the approved number of animals;
E. Add, delete or change a funding source.

The Principal Investigator (PI) is responsible for the submission of the completed and signed amendment form to the IACUC staff. Final approval of an amendment for addition of personnel will not be given until all personnel have received appropriate training and have enrolled in the Employee Health program (EHP).

2. Addition of Personnel (other than PI)
Once the IACUC staff receives an amendment that includes addition of new personnel, the person(s) listed in the amendment and the PI will be notified of the following items:

A. Personnel shall not work with animals until they have completed the required on-line training course(s) at www.citiprogram.org and this has been verified by the IACUC Administrator and/or his/her designee. Required training includes completing the Investigators, Staff and Students course and the appropriate species-specific modules (dependent upon each individual protocol).

B. Personnel also shall not work with animals until they have enrolled in OHS/EHP. The IACUC Administration and/or his/her designee must receive verification of this enrollment from the EHP nurse on the campus the personnel will be working.

3. Addition of Location
Addition of new location(s) for the use of animals may be administratively approved after the PI has submitted an amendment indicating a request for location change. This location shall be verified in writing by the Institutional Veterinarian or designee as allowable before the site may be used to conduct animal work. All non-LARC locations are subject to IACUC approval and must be inspected by the IACUC before animal work may commence. The Institutional Veterinarian (or designee) shall have 24/7 access to all locations where animal work is carried out.

4. Addition of Animal Numbers
An increase of up to 10% in the number of rats and/or mice (but not other species) approved in the original protocol may be approved administratively after the PI has submitted an amendment indicating a request for additional animals. This number must be verified by IACUC as allowable before additional animals may be put onto the protocol by purchase or transfer.

5. Addition of Funding Source
Addition of a new or different funding source may be administratively approved. However, if the funding source requires a grant/protocol comparison, then the change may be administratively approved only after the assigned reviewer provides written verification that the comparison is satisfactory.
6. **VVC – Veterinary Verification and Consultation**

Certain specific significant changes (outlined in OLAW Guidance #NOT-OD-14-126 and further specified in this policy) may be approved by the Institutional Veterinarian (IVet), with proper consultation and review of the approved protocol.

The IVet is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and IACUC–approved policy is appropriate for the animals in various circumstances. Consultation with the IVet will be documented. The IVet may refer any request to the IACUC for full-committee review. Documentation of the Consultation will be forwarded to the IACUC Administrator for attachment to the protocol. The PI shall submit a protocol amendment within one month of the Consultation. This amendment may be approved by Designated Member Review. The following changes may be handled administratively through the IVet and IACUC staff:

A. Anesthesia, analgesia, sedation, or experimental substances;
B. Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and,
C. Duration, frequency, type, or number of procedures performed on an animal.

VVC cannot be used to add new procedures or study objectives to a previously approved protocol. In addition, modifications to existing procedures with the possibility that animal welfare will be compromised must undergo committee review. In particular, the following changes require committee review:

A. Change from non-survival to survival surgery;
B. Changes resulting in greater pain, distress, or degree of invasiveness; and,
C. Changes that affect personnel safety.

**Reporting to IACUC**

All administratively approved amendments will be placed on the agenda for the next scheduled meeting of the IACUC for informational purposes. All administrative approvals take effect when verification of all requirements is completed and written notification from the IACUC or their designee is sent to the PI.