



INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Policy# 20

ADMINISTRATIVE APPROVALS OF AMENDMENTS

In concurrence with
TTUHSC El Paso Assurance #D19-01056
and Federal Regulations and Guidelines

Purpose

Significant changes to a protocol must be approved either by a majority vote of a convened quorum of the IACUC (full committee review) or by designated member review. However, OLAW encourages institutions to develop review policies that reduce the administrative burden on the PI and IACUC reviewer. Under specific circumstances, administrative approval allows amendments to the IACUC protocol without full committee or designated review in specific circumstances that do not significantly impact animal welfare. The intent of this policy is to describe the use of Administrative Approval at TTUHSC El Paso.

Overview

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

- Add, delete or change personnel other than the Principal Investigator;
- Add and/or delete location(s);
- Increase the number of animals on the protocol when the increase is no greater than 10% of the original approved number (rats and mice only);
- Add, delete or change a funding source.
- Add, delete, or make slight changes to the title of a study

The Principal Investigator (PI) is responsible for the submission of the completed and signed amendment form through IRIS. 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).

1. 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 by the IACUC coordinator:

- Personnel **shall not work** with animals until they have completed the required on-line training course(s) at www.citiprogram.org, and have been approved on a protocol. This list includes, but is not limited to, the following:
 - Working with the IACUC Course
 - Reducing Pain and Distress in Laboratory Mice and Rats Course
 - Working with (Species) in Research Settings Course (Species will vary i.e. mice, rats, ferrets, fish)
 - Conflict of Interest Course
 - Additional training as applicable: Antibody Production in Animals/Aseptic Surgery
- Personnel also **shall not work** with animals until they have enrolled in OHS. The IACUC Administration and/or his/her designee must receive verification of this enrollment from the OHS program.

2. Addition of Location

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

3. 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.

4. 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.

5. Changes to the title of a study

Addition or deletion or slight change in the title of the study, without altering the core concept or introducing prohibited elements, may be acceptable under administrative approvals.

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 is sent to the PI.

Related policies

Investigators must comply with all other institutional policies at TTUHSC El Paso and Federal Guidelines. This list includes, but is not limited to, the following:

IACUC Policy # 2: Veterinary care

IACUC Policy # 7: Designated reviews

IACUC Policy # 27: Veterinary Verification and Consultation