

Methods for Modifying the Animal Use Protocol

Approval before implementation

An Animal Use Protocol (AUP) is considered a contract between the investigator and the Institutional Care and Use Committee (IACUC) on behalf of the institution and must be properly modified anytime a variance is needed. To avoid noncompliance, all proposed changes to an AUP must be reviewed/approved by an IACUC-sanctioned process **before** those modifications can be implemented. Mechanisms available for modifying approved animal activities are as described below.

IACUC-reviewed amendments

Significant Changes to AUPs with potential to negatively impact animal welfare must be submit for IACUC review via amendment. Examples of changes requiring this process include but are not limited to: change in species, addition of a new procedure, addition or modification of hazards, and any change resulting in greater pain, distress, or degree of invasiveness.

Review is performed by qualified IACUC member(s) appointed by the IACUC Chair (Designated Member Review [DMR]) or by a convened quorum of the members of the IACUC (Full Committee Review [FCR]). The committee receives ongoing training to locally apply the rules and regulations governing the privilege of working with animals in research.

Amendments for the same AUP are not necessarily reviewed by the same member each time, nor are they reviewed only by scientists. By law, the IACUC must also include non-scientists, and community member(s) not affiliated with the institution.

Administratively processed amendments

Minor changes such as those involving protocol personnel (other than the PI), changes in funding, and addition or modification of an IACUC approved animal housing or study location must be requested via amendment, however, can be administratively processed by the Animal Welfare Office (AWO) staff.

Veterinary Verification & Consultation (VVC)

Modifications or adjustments to existing AUP procedures with no increase in real or potential negative impact on animal welfare may be eligible for VVC. Propose your modification to the campus Attending Veterinarian (AV) or designee, who will confirm adherence to approved IACUC SOPs. Once the AV confirms and communicates that the proposed modification is eligible and appropriate, the change may be incorporated into the AUP by AWO staff. Note: VVC is not available for the Houston animal program.

Resources

- ✓ **Animal Welfare Office:** 979.845.1828 or animalcompliance@tamu.edu
- ✓ **OLAW Notice NOT-OD-14-126 Guidance on Significant Changes to Animal Activities**
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>
- ✓ **TAMU Rule 15.99.07.M1 Use of Vertebrate Animals** <https://rules-saps.tamu.edu/PDFs/15.99.07.M1.pdf>
- ✓ The following IACUC Guidance and SOPs are available here, as are other resources and tools not listed:
<https://vpr.tamu.edu/animals-in-research-and-teaching/texas-am-iacuc-guidance/#protected>
 - **TAMU-S-003 Significant and Minor Changes to Approved Animal Activities**
 - **TAMU-S-004 Veterinary Verification and Consultation**
 - **TAMU-S-005 Change to Approved Protocols by Administrative Review**
 - **AWO-O-028 VVC Explained**
 - **AWO-O-083 AUP Tool - Amending the AUP**