

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
Policy #27

Veterinary Administrative Approval for Significant Protocol Changes (VVC)

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, Veterinary Verification and Consultation (VVC) 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 VVC at TTUHSC El Paso.

Overview

It is the policy of the IACUC that the certain specific significant protocol changes (outlined in OLAW Guidance #NOT-OD-14-126 and further specified in this policy) may be approved by the Clinical or Attending Veterinarian, with proper consultation and review of the approved protocol.

Protocol changes that can be approved by VVC:

- Anesthesia, analgesia, or sedation, provided that animal welfare is not compromised.
- Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals.
- Duration, frequency, type, or number of procedures to be performed on an animal as long as those procedures are already approved in the protocol.

Protocol changes that cannot be approved by VVC:

- Change a surgery from a non-survival to a survival
- Increase pain, distress, or degree of invasiveness
- Change housing or use of animals to a non-LARC location
- Change species
- Change study objectives
- Change Primary Investigator
- Make changes that will impact personnel safety
- Add new procedures to a protocol.

Veterinary Accountability and Documentation

During VVC, the veterinarian is not conducting a designated review, but is serving as a subject matter expert to allow specific procedural changes that maintain the intent of the IACUC-reviewed and approved protocol while providing appropriate veterinary care for the animals listed therein.

- Consultation with the veterinarian will be documented by having the Veterinarian send iRIS correspondence approving the change to the PI, IACUC Chair, and IACUC Coordinator.
- The PI can then begin the modified work.
- The protocol will be updated by PI and submitted in IRIS within 5 business days to document the change.
- The IACUC coordinator will assign the protocol to the IVET for review and approval.

The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC reviewed and approved policies and/or procedures.

Reviewed and Approved by the TTUHSC IACUC: 11/08/2019

Reporting to IACUC

All VVC amendments will be placed on the agenda for the next scheduled meeting of the IACUC, for informational purposes.

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 20: Administrative Approvals of Amendments

References

NIH Guide Notice NOT-OD-14-126

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>

OLAW Webpage Significant Changes

http://grants.nih.gov/grants/olaw/significant_changes.htm

OLAW Special Seminars: Guidance on Significant Changes to Animal Activities: Recording, transcripts and resources

http://grants.nih.gov/grants/olaweducational_resources.htm#a_08212014

AVMA Euthanasia Guidelines –

<https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>