



Title: Veterinary Administrative Verification for Significant Protocol Changes

Policy Number: 18

Policy Intent: The intent of this policy is to describe the use of Veterinary Verification and Consultation or VVC at TTU.

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1. Purpose

- a. 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, in the following specific circumstances (3.a-c below), may be handled administratively by consultation with and verification of any Animal Care Services veterinarian.
- b. Definition of a Significant Change- changes that have, or have the potential to have, a negative impact on animal welfare.
 - i. Some activities that may not have a direct impact on animal welfare are also considered to be significant.
- c. Significant changes must be approved by one of the valid IACUC approval methods, FCR or DMR, including changes:
 - i. From nonsurvival to survival surgery;
 - ii. resulting in greater pain, distress, or degree of invasiveness
 - iii. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
 - iv. in species
 - v. in study objectives
 - vi. in Principal Investigator (PI); and
 - vii. that impact personnel safety

2. IACUC Policy

- a. 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 (including appropriate amendments).

3. Defined Changes

*** See attached chart 1) What Changes Qualify for Which Reviews; 2) Significant Changes**

Process Flow

****Not all IACUC approved policies, SOPs or guidance documents are listed, but may be used for verification**

- a. Anesthesia, analgesia, or sedation. Please refer to the following documents:
 - i. Policy 4 Analgesic Use



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- ii. SOP020 Surgical Anesthesia
- iii. SOP061 Pain, Distress, Analgesia, and Anesthesia
- iv. <http://www.depts.ttu.edu/iacuc/Analgesics.php>
- b. Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals.
 - i. Policy 19 Euthanasia of Teaching and Research Animals
- c. Duration, frequency, type, or number of procedures to be performed on an animal as long as those procedures are either approved in the protocol or are approved TTU IACUC SOP's.
 - i. Policy 07 Acceptable Methods of Blood Collection

4. **Veterinary Accountability**

- a. The veterinarian is not conducting DMR but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance.
- b. Consultation with the veterinarian will be documented by having the veterinarian send an email (or appropriate documentation verifying the change to the IACUC Chair/Coordinator. The PI will still submit an amendment form outlining the changes, but the amendment will not go through the review process.
 - i. This email will be appended to the protocol for which the change is authorized
 - ii. The protocol will be updated by the IACUC Chair/Coordinator staff
 - iii. The IACUC chair/coordinator staff will forward a copy of the approved changes to the Post Approval Monitoring Coordinator
- c. 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.

5. **References**

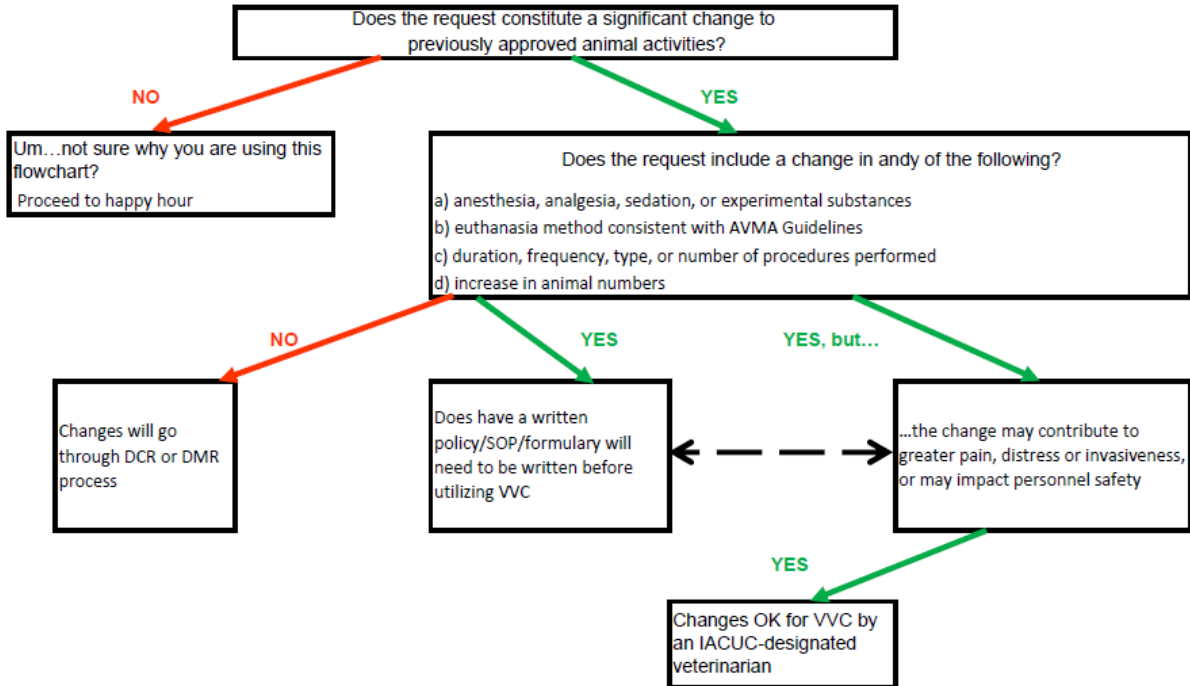
- a. NIH Guide Notice NOT-OD-14-126
 - i. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>
- b. OLAW Webpage Significant Changes
 - i. http://grants.nih.gov/grants/olaw/significant_changes.htm
- c. OLAW Special Seminars: Guidance on Significant Changes to Animal Activities: Recording, transcripts and resources
 - i. http://grants.nih.gov/grants/olaweducational_resources.htm#a_08212014
- d. AVMA Euthanasia Guidelines –
 - i. <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

What Changes Qualify for Which Reviews?

FCR or DMR	*V V C	Admin Review
From non-survival to survival surgery	Anesthesia, analgesia, sedation or experimental substances	An Increase in previously approved animal numbers
Resulting in greater pain, distress or degree of invasiveness	Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals	Correction of typographical errors
In housing and or use of animals in a location that is not part of the animal program overseen by the IACUC	Duration, frequency, type, or number of procedures performed on an animal	Correction of grammar
In species		Contact information updates
In study Objectives		Change in personnel, other than Principal Investigator
In Principal Investigator		
That impact personnel safety		

* IACUC reviewed and approved Policies (e.g. guidance documents, SOP's and drug formularies) must be in place

Significant Changes Process Flow



Adapted from Group B, August 2016 Train the Trainer Institute Module