

IOWA STATE UNIVERSITY
Institutional Animal Care and Use Committee

Major, Minor, or VVC Protocol Amendments

In an attempt to help Iowa State University investigators determine what course of action is necessary when making amendments to an existing animal protocol, we have generated the following lists of examples. These lists are in no way complete and are shown here only as a guide to help investigators make informed decisions when modifying existing protocols.

Please note: A change in Principal Investigator (PI) is not an amendment, but rather requires submission of a new Protocol Review Form (PRF) for review and approval by the IACUC.

Changes to Protocols/Activities: The PI must submit information that completely explains the proposed changes to the approved animal care and use activity. The Chair or their designee will make the determination whether a proposed change to an activity or protocol is major or minor using the following guidelines.

- a. Major Amendments:** The proposed major amendment will be reviewed by DMR unless it is referred to the full IACUC committee. If the IACUC determines the proposed changes are significant enough, it may require submission of a new protocol.

Those amendments considered major include:

- 1) Applying the protocol to a new species (However, PRFs in which several species are already studied are exempt [i.e., survey studies].)
- 2) Increasing the number or changing stage of life of animals used on the study
- 3) Changes resulting in greater pain, distress or degree of invasiveness
 - a. Ex. withholding of analgesics
- 4) Changing the duration, frequency, or number of procedures to be performed on an animal, if procedures are not included in the existing approved protocol
- 5) Changing from non-survival to survival surgery
- 6) Changing to a different surgical approach or medical treatment
- 7) Adding or changing a hazardous or infectious agent or material
- 8) Adding or changing the dosage of a hazardous or infectious agent or material
- 9) Changing or adding study objectives
- 10) Adding anesthesia or analgesia to the protocol when it wasn't already approved.
- 11) Changing the method of euthanasia to a non-AVMA approved method.
- 12) Changes that impact personnel safety
- 13) Changes in housing and/or use of animals in a location that is not part of the animal program overseen by the ISU IACUC

- b. Minor Amendments:** Amendments that are determined to be minor can be approved by the IACUC Chair.

Those Amendments considered minor include:

- 1) Changes in personnel other than the principal investigator (When adding personnel, list their role/duties on the project and list their training.)
- 2) Changing the sex of animals used on a protocol
- 3) Changing the supply source of animals
- 4) Changing the housing location between facilities that are inspected by the ISU IACUC
- 5) Changing the disposal of animals

- 6) Changing personnel duties
 - i. Ex: the person monitoring anesthesia (if person is properly trained)
 - ii. Ex: person performing euthanasia

The following is a list of amendments that the IACUC deems can be reviewed using the Veterinarian Verification and Consultation (VVC) mechanism. This requires submission of an IACUC Amendment.

- c. **Veterinary Verification:** The Attending Veterinarian or the AV designee may administratively verify changes through Veterinary Verification and Consultation (VVC) when using ISU IACUC Guidance documentation (OLAW's Guidance on Significant Changes to Animal Activities Notice Number NOT-OD-14-063).
 - 1) Anesthesia, analgesia, sedation, or experimental drugs
 - 2) Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
 - 3) Duration, frequency, type, or number of procedures performed on an animal, if already included in the IACUC-approved protocol. Examples include:
 - a. Blood collection frequency, sites, and volumes
 - b. Dosage administration site
 - c. Genotyping procedures utilized (tail snips, ear punches)
 - d. Making a change to a surgical procedure
 - e. Changing the animal identification method

The following is a list of amendments that the IACUC deems are administrative changes.

- d. **Administrative Changes:** IACUC administrators may contact PIs to change the following. These are synonymous with OLAW NOT-OD-14-063 defined administrative changes.
 - 1) Correction of typographical errors
 - 2) Correction of grammar
 - 3) Contact information

Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.