

## Modifications to Approved Animal Use Proposal

### Request for Approval of Modifications in Study Procedures

The process for modifying (or amending) an existing IACUC application varies depending on the nature of the desired modification. Some modifications are considered routine, or minor, and can be reviewed and approved by the IACUC Chairperson and Attending Veterinarian. Other proposed revisions are substantive, or major, and must be reviewed either by a Designated Reviewer, or by the Full Committee, using the same process as a new approval. Regardless of the nature of the proposed modifications, all revision in study procedures must be approved by the IACUC in advance of being implemented by the investigator.

Modifications requiring approval include, but are not limited to, the following kinds of changes:

- A. **Funding:**
- B. **personnel:** investigators, including principal investigator, may change, as may other authorized personnel, or such relevant information as an investigator's contact telephone number;
- C. **population:** the size of the study population may change, or a new population may be included;
- D. **procedures:** interventions, or other approved procedures, instruments;
- E. **purpose:** involving, for example, changes in the time over which the study is conducted.

### Definitions and Examples

#### Major or significant change

The following are examples of major changes that are to be presented to the entire IACUC and the procedure is followed as outlined under the IACUC Review Process. If several major changes occur, it may warrant submission of a new Clearance form.

- A. A change in the overall aim or objective of the study which supports the need to perform the animal work.
- B. A change which may involve an increase in the level of pain, distress, and/or discomfort so as to categorize it in a different USDA category.
- C. An increase in mortality over levels that were either specified or presumed to occur when the protocol was originally reviewed.
- D. A change from non-surgery to surgery; from minor to major surgery; from non-survival to survival surgery, or from single to multiple survival surgery.
- E. A change involving the need for euthanasia, where none had originally been anticipated.

- F. A large (>20%) increase in the number of animals to be used.
- G. A change in the genus.
- H. The addition of a hazardous agent used in the animal procedure.
- I. A change in Principal Investigator.

Minor change

The following are examples of minor changes and may be approved by the Attending Veterinarian and IACUC Chair.

- A. Additions or changes in the personnel who will be performing procedures involving animals, other than the PI.
- B. A small ( $\leq 20\%$ ) increase in the number of animals to be used.
- C. A minor change in technique, drug, diet, and the like which is not inconsistent with the intent of the original Clearance form, nor does it change the level of discomfort, distress, or pain (remains in the same USDA category).

# Request for Modification to Approved Animal Use Proposal

**Principal User/Investigator:** \_\_\_\_\_

**Department** \_\_\_\_\_ **Faculty** \_\_\_\_\_ **Graduate Student** \_\_\_\_\_ **Undergraduate** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Phone:** \_\_\_\_\_ **Email:** \_\_\_\_\_

**Animal (Species) Used:** \_\_\_\_\_

**IACUC # and Title of Original Proposal:** \_\_\_\_\_

**Date of Approval Letter:** \_\_\_\_\_

**Anticipated Duration of Study/Use:** \_\_\_\_\_

**Select one: Major modification(s)** \_\_\_\_\_ **or Minor modification(s)** \_\_\_\_\_

**Nature of the change** (personnel, drug, procedure, etc.) \_\_\_\_\_

**Signatures:**

**Principal Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Faculty Supervisor (student research):** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Printed or typed name:** \_\_\_\_\_

**Department Chair:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Printed or typed name:** \_\_\_\_\_

**For Committee Use Only**

**Full Committee Review Required: Yes No**

**Comments:**

<b>Rec'd:</b> _____ <b>Sent to ACUCM:</b> _____ <b>Approved:</b> _____
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**IACUC Member Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

In preparing your request for modification, please consider the following questions answered upon your initial submission. **Modification requests do not require that all questions be completed as per the initial review, only that you address in a detailed fashion the changes being made in the animal study and provide an explanation or justification.**

1. In lay terms, explain the scientific objective of the proposed study, describe methods to be used, and expected results. **Have the scientific objectives or methods changed?**
2. Indicate the kind and number of animals to be used. Rationalize the use of these animals including the species chosen and the number required. **Has there been a change in the kind and number of animals used? If so, provide a justification.**
3. Describe procedures to be used to minimize discomfort, distress, and pain. Document in writing alternatives that have been considered to procedures causing pain and duress or alternative species that could be utilized (Contact the Animal Welfare Information Center for alternative suggestions). **Describe any changes in procedure.**
4. Describe the use of sedation, analgesia, or anesthesia if the procedures may cause more than momentary or slight pain or distress. Describe outcome or consultation with the Committee veterinarian. **Describe any changes in the use of sedation, analgesia, or anesthesia.**
5. Indicate the method of euthanasia if the animals are to be sacrificed or other means of disposition used upon completion of the research or educational use. **Describe any changes to euthanasia procedures, or other disposition.**
6. If animals are not to be euthanized at the end of the study, what will be done with them? **Describe any changes in this area.**
7. Describe the housing, feeding, and non-medical care of the animals and who will be responsible for their care. **Describe any changes in this area.**
8. Describe the provisions for medical care and the use of a veterinarian if necessary. **Describe any changes in this area.**
9. Describe the qualifications and training of the personnel who will be conducting procedures on the animals. **Note any changes in personnel and describe their qualifications and training.**
10. Provide a written assurance that the research and use activities are non-duplicative; otherwise provide a justification for duplicity. **Do the modifications**

**impact the duplicative or non-duplicative status of the original proposal? If so, describe how and justify any new duplicity.**

11. Completed request for modification forms must be signed and sent to the Office of Graduate Studies and Research. Forms may also be emailed to [iacuc@cwu.edu](mailto:iacuc@cwu.edu). However, the signed coversheet must still be submitted via mail or FAX to the Office of Graduate Studies and Research.
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