

## EXAMPLE/TEMPLATE IC ACUC Policy: Changes to Animal Study Proposals

*[Note: Remove highlighted and boxed text prior to finalization. Once approved, this policy must be reviewed by the IC ACUC at least triennially]*

Background: The Public Health Service Policy requires that the Institutional Animal Care and Use Committee review and approve, require modifications to, or withhold approval of significant changes regarding the use of animals in previously approved activities (IV.B.7.). In accordance with the NIH ARAC [Guidelines Regarding Changes to Animal Study Proposals](#), this policy outlines how changes to an Animal Study Proposal (ASP) are categorized and subsequently handled by the Institute/Center Animal Care and Use Committee (IC ACUC). No changes in animal use may be implemented without prior review and approval by the IC ACUC.

The following **significant changes** require full committee review (FCR) or designated member review (DMR):

- a. Change from non-survival to survival surgery;
- b. Changes resulting in greater pain, distress, or degree of invasiveness;
- c. Change in housing to a location not currently part of the program overseen by the IC ACUC;
- d. Change in species;
- e. Change in study objectives;
- f. Change in Principal Investigator (PI);
- g. Changes that may impact personnel safety; and
- h. *[The IC ACUC may define additional types of changes that require FCR or DMR but cannot remove OLAW-defined items a. – g.]***

### ***[Only include this section if VVC is used]***

The following **significant changes** to an already approved procedure *may* be handled via the administrative route of veterinary verification and consultation (VVC). The ***[IC ACUC must list the position or title of the authorized veterinarian(s) (e.g., Animal Program Director, Facility Veterinarian, etc.)]*** is authorized by the ACUC to verify that a proposed significant change to an already approved procedure is consistent with an ACUC-approved guidance document [e.g., formulary, guideline, or standard operating procedure (SOP)] and is appropriate for the animals and circumstance. The authorized veterinarian has the authority to request FCR or DMR for any significant change at any time. **Significant changes** that *may* be handled via the administrative route of VVC include, and are limited to, the following:

*OLAW only allows VVC for the following types of significant changes:*

- a. A change in anesthesia, analgesia, sedation, or experimental substances;*
- b. A change in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals;*
- c. A change in duration, frequency, type, or number of procedures performed on an animal.*

***[The IC ACUC must decide which of the above types of changes can be handled by VVC. The list below is an example of how these are to be defined in this policy. Each type of change must be accompanied by a guidance document or inclusive list.]***

- a. Changes in anesthesia, analgesia, or sedation that are considered equally effective and reliable; and are included in IC SOPs 6410 & 6430 (rodents), 6420 & 6435 (rabbits), or 6422 & 6423 (NHPs);
- b. Changes in experimental substance, specifically, diluents that are not expected to increase pain or distress, impact the approved endpoint criteria, or impact personnel safety. These diluents include: PBS, normal saline, water, corn oil, DMSO, and ethanol;
- c. Change in method of euthanasia if approved in the AVMA Guidelines for the Euthanasia of Animals *and* included in IC SOP 6600;
- d. Change in duration, frequency, type, or number of already-approved procedures that have no effect or decrease level of discomfort/distress of the animal *and* are described in an approved SOP or ACUC Appendix, as follows:
  - i. Blood collection method – frequency and type (SOP 5500);
  - ii. Genotyping method – frequency and type (SOP 1200); and
  - iii. Behavioral assessments – frequency and type (ACUC Appendix 314).

The following **significant changes** may be handled via the administrative route by the **[IC ACUC must define the responsible individual(s) (e.g., ACUC Chair, APD, or ACUC Coordinator)]** and do not require FCR or DMR:

*OLAW only allows this type of administrative handling for the following types of changes:*

- a. An increase in previously approved animal numbers;
- b. The addition of a stock or strain with no anticipated adverse phenotypes.

**[The IC ACUC must decide which of the above types of changes can be handled by this type of administrative process. The list below is an example of how these are to be defined in this policy]**

- a. Increases in animal numbers that are less than 10% [**← this number or percentage must be defined by the IC ACUC**] of the currently approved amount; and
- b. Addition of a strain, stock, or genotype with no anticipated adverse phenotypes.

The following **other changes** may be handled via an administrative route by the **[IC ACUC must define the responsible individual(s) (e.g., ACUC Chair, APD, or ACUC Coordinator)]** and do not require FCR or DMR:

**[Items cannot be added to the following list]**

- a. Correction of typographical or grammatical errors;
- b. Updates to contact information;
- c. Addition or removal of personnel other than the PI (provided all required IC ACUC criteria is met);
- d. Changes in housing to a location that is part of the program overseen by the IC ACUC.

Procedure:

**[The IC ACUC must describe how changes are incorporated into the existing ASP, how others are notified of the change, and how administratively processed changes are documented]. Example:** Proposed changes to approved ASPs must be submitted electronically into the ASP System as

amendments as well as delivered to the ACUC Coordinator. The authorized veterinarian will review the requested change and evaluate it to determine if it must be reviewed by FCR/DMR; or may be handled via an administrative route. Significant changes that are handled administratively are documented on the agenda for the next ACUC meeting. Other persons impacted by the changes are notified by email.

References:

***[Links to suggested references are listed below]***

ACUC Appendices: [LINK](#)

SOPs: [LINK](#)

AVMA Guidelines for the Euthanasia of Animals: [LINK](#)

ARAC Guidelines Regarding Changes to Animal Study Proposals: [LINK](#)

OLAW NOT-OD-14-126 – Guidance on Significant Changes to Animal Activities: [LINK](#)

PHS Policy on Humane Care and Use of Laboratory Animals: [LINK](#)