EXAMPLE IC ACUC Policy
Changes to Animal Study Proposals

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 reviewed 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.

Significant changes require full committee review (FCR) or designated member review (DMR) by the IC ACUC. These changes include, but are not limited to, the following:

a. Change from non-survival to survival surgery;
b. Changes resulting in greater pain, distress, or degree of invasiveness;
c. Change in housing and/or use to a location not currently under the authority of 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. Increases in animal numbers greater than 10% of the currently approved amount.

The following **significant changes** *may* be handled via the administrative route following review and concurrence by the authorized ACUC Attending Veterinarian (ACUC AV). The ACUC AV will consult guidance documents [IC ACUC approved references, appendices, and standard operating procedures (SOPs)] to verify compliance and has the authority to request FCR or DMR for any significant change. Significant changes that may be handled via the administrative route with *veterinary verification and consultation* (VVC) include, and are limited to, the following:

a. Changes in anesthesia, analgesia, or sedation that are included in CMS SOPs 6410 & 6430 (rodents), 6420 & 6435 (rabbits), and 6422 & 6423 (NHPs);
b. Changes in experimental substance: diluent. Specifically, 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 Euthanasia *and* included in CMS SOP 6600;
d. Change in duration, frequency, type, or number of procedures performed 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).

Commented [SH([1]: Programs can add to the list of changes requiring FCR/DMR, but cannot remove OLAW-defined items a. – g.

Commented [SH([2]: Authorized veterinarian(s) identified by title.

Commented [SH([3]: Explicit acknowledgement that the authorized veterinarian(s) can refer any request for FCR or DMR at any time, for any reason, even if the request meets the criteria for VVC.

Commented [SH([4]: Each acceptable category is listed along with an associated guidance document or inclusive list.

The following **significant changes** *may* be handled via the administrative route by the ACUC AV or ACUC coordinator and do not require FCR, DMR, or VVC:

a. Increases in animal numbers that are less than 10% of the currently approved amount (given that requested increases are *not* due to animal deaths or unexpected events); and
b. Addition of a strain or stock with no anticipated adverse phenotypes.

Other changes *may* be handled via an administrative route by the ACUC AV or ACUC Coordinator and do not require FCR, DMR, or VVC. These changes include:

a. Correction of typographical or grammatical errors;
b. Updates to contact information; and
c. Addition or removal of personnel other than the PI (provided all required IC-ACUC criteria is met).

Procedure:

Proposed changes to approved ASPs must be submitted electronically into the IASP System as ASP amendments as well as delivered (signed paper copy) to the ACUC Coordinator. The ACUC AV will review the requested change and evaluate it to determine if it is significant; and, if significant, whether it must be reviewed by FCR/DMR; or may be reviewed 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.

Commented [SH([5]: Procedure includes how changes are incorporated into the existing ASP (submitted as an amendment), how others are notified of the change (email), and how administratively processed changes are documented (ACUC meeting agenda)

It is recommended that the original ASP be sufficiently broad with parameter ranges where appropriate to help avoid unnecessary post-approval modifications.

References:

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