

Guidelines Regarding Changes to Animal Study Proposals

Background: The Animal Welfare Act Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) require that Animal Care and Use Committees (ACUCs) review and approve changes to previously approved animal activities described in an Animal Study Proposal (ASP).

In accordance with Office of Laboratory Animal Welfare (OLAW) Guidance on Significant Changes to Animal Activities¹, the NIH intramural research program Animal Research Advisory Committee (ARAC) recognizes that the individual Institute/Center (IC) ACUCs have the option to establish and approve IC-specific policies and guidance documents for the review and approval of proposed changes to ASPs. Without an IC-ACUC-specific policy, approval of significant changes can only be granted after full committee review (FCR) or designated member review (DMR).

Several categories of proposed changes are outlined in OLAW guidance. These categories allow IC ACUCs some discretion to use internal policies and guidance documents to define what constitutes a significant change or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS Policy.

OLAW defines the following categories of proposed changes:

1. Significant changes that must be approved by FCR or DMR:

a) Changes from non-survival to survival surgery
b) Changes resulting in greater pain, distress, or degree of invasiveness
c) Changes in housing to a location not part of the program overseen by the IC ACUC
d) Changes in species
e) Changes in study objectives
f) Changes in Principal Investigator (PI)
g) Changes that impact personnel safety

2. Significant changes that may be handled *administratively* according to an IC-ACUC-approved policy and in consultation with an IC-ACUC-authorized veterinarian:

a) Changes in anesthesia, analgesia, sedation, or experimental substances
b) Changes in euthanasia to any method approved in the <i>AVMA Guidelines</i>
c) Changes in duration, frequency, type, or number of procedures performed on an animal

These significant changes may be handled administratively through the optional process of veterinary verification and consultation (VVC). VVC allows an IC-ACUC-authorized veterinarian to verify that a proposed significant change to an already approved procedure is within the scope of an IC-ACUC-approved policy, consistent with an IC-ACUC-approved guidance document, and appropriate for the animals and circumstance. The veterinarian is not

conducting DMR but is serving as a subject matter expert and may refer any significant change to the IC-ACUC for FCR or DMR for any reason. Any significant change that does not meet the parameters of the IC-ACUC-approved policy must be referred to the IC-ACUC for FCR or DMR.

This process is contingent upon an IC-ACUC-approved policy that defines the scope of each type of significant change by listing a concurrent IC-ACUC-approved guidance document (e.g., SOP, formulary, guideline, etc.) upon which the change can be verified by the IC-ACUC-authorized veterinarian. The consultation with the veterinarian must be documented. The approved change must be documented in the ASP; must be sent to the appropriate animal facility staff; and the IC-ACUC must be kept informed of changes made through this process.

3. Significant changes that may be handled *administratively* according to an IC-ACUC-approved policy without additional consultation:

a) Increase in previously approved animal numbers
b) Addition of stock or strain with no anticipated adverse phenotypes

This process is contingent upon an IC-ACUC-approved policy that defines the scope of changes (e.g., allowable number or percentage of animals to be added) and designates the individual(s) responsible for verifying that the change is within the scope of the policy. No additional consultation is required. The approved change must be documented in the ASP, must be sent to the appropriate animal facility staff, and the IC ACUC must be kept informed of changes made through this process.

PIs may use fewer animals than approved. This does not require IC ACUC approval, notification, consultation, or administrative handling.

4. Other changes that may be handled *administratively* without an IC-ACUC-approved policy, consultation, or notification:

a) Correction of typographical errors
b) Correction of grammar
c) Contact information updates
d) Change in personnel, other than the PI (provided all criteria required by the IC ACUC is met)
e) Changes in housing to a location that is part of the program overseen by the IC ACUC

This process does not require an IC-ACUC-approved policy or additional consultation. The approved change must be documented in the ASP and must be sent to the appropriate animal facility staff. For personnel changes, there must be an administrative review to ensure that all personnel are appropriately identified; adequately trained and qualified; enrolled in occupational health and safety programs; and meet other criteria as required by the IC ACUC. Any other changes that do not meet the above parameters must be reviewed by FCR or DMR.

The IC ACUC policies and guidance documents must be reviewed by the IC ACUC at intervals of no less than once every three years to ensure they are appropriate and accurate. It is the IC ACUC's responsibility to clearly define and communicate its policy for determining significance to PIs.

References:

- NIH OLAW Notice Number: NOT-OD-14-126, August 26, 2014 – Guidance on Significant Changes to Animal Activities: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>
- [OACU Example IC ACUC Policy on Changes to Animal Study Proposals](#)

Approved - 06/16/1992

Re-approved - 05/08/1996

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