Animal Care and Use Program
Policies & Procedures

Modifications to an Animal Research Protocol

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I. BACKGROUND & SCOPE

The purpose of this policy is to describe the process for approving modifications to an IACUC-approved animal research protocol. Public Health Service Policy requires that significant modifications to animal research protocols undergo IACUC review while minor changes may be approved administratively. The Office of Laboratory Animal Welfare explains that the IACUC has discretion to define what it considers to be a significant change, or to establish a mechanism for determining significance on a case-by-case basis. It must become institutional policy that no one may implement modifications categorized as significant prior to IACUC review and approval.

II. POLICY

Significant modifications to an approved animal research protocol must be reviewed and approved by the IACUC. Minor modifications may be reviewed and approved administratively. In either case, approval must be obtained prior to implementing the change.

III. PROCEDURES

Proposed modifications to an approved animal research protocol must be submitted to the IACUC office. Initial categorization of a modification as significant or minor will be made by an IACUC analyst in consultation as needed with the IACUC chair. Significant modifications will be reviewed by the IACUC by designated member review or at a convened meeting of the IACUC. Minor modifications may be reviewed and approved administratively by the IACUC office, or by the IACUC office on recommendation of approval from a Department of Comparative Medicine veterinarian (Central/Waterfront Campus) or a Department of Animal Resources veterinarian (West Campus).

IV. EXAMPLES

The table below lists examples of significant changes that require IACUC review and approval. Also listed are examples of minor changes that may be approved administratively by the IACUC office*, or by that office following a recommendation of approval from a Department of Comparative Medicine veterinarian (Central/Waterfront Campus) or a Department of Animal Resources veterinarian (West Campus).

NOTE: This list is not exhaustive. For questions about the level of review required for a change, please contact the IACUC Office at 503-494-8408 (Central and Waterfront) or 503-690-5289 (West Campus).

PROPOSED CHANGE	SIGNIFICANT CHANGE (REQUIRES IACUC REVIEW & APPROVAL)	OTHER CHANGES (REQUIRES VET & IACUC OFFICE APPROVAL*)	MINOR CHANGE (REQUIRES IACUC OFFICE APPROVAL ONLY)
Number of animals used	Increases >10% of currently approved total	Increases ≤10% of currently approved total for NHP	Increases ≤10% of currently approved total (excluding NHP)
Animal use areas (not in DCM/DAR facilities)	Any change in animal use area that does not meet the requirements for a minor change		Animal use <8 hours + noninvasive procedures + animals not returned to DCM/DAR** (excluding NHP)
Study objectives	Addition of new aims that are not extensions of existing aims		Addition of new aims that are extensions of existing aims (with agreement of IACUC Chair or Co-Chair)
Personnel	Change in PI		Change in personnel other than the PI
Grant			Addition of a new grant or extension of an existing grant already on the protocol (with assurance of grant:protocol congruency by the PI and verification of congruency by the Analyst)
Change in species, addition of new species, or change in strain	• Change in species • Addition of new species • Addition of strain that is more susceptible to pain or discomfort		Addition or change in strain of approved species that is equivalent in susceptibility to pain or discomfort
Type of surgery	Change made to an approved surgical procedure from non-survival to survival	Change made to an approved surgical procedure from survival to non-survival	
Timing of endpoint	Increase in level or duration of discomfort	Less / shorter discomfort	
Change to an already-approved procedure (including blood collection)	More invasive / more discomfort	Less invasive / less discomfort	
New Procedure	All procedures that are new to the protocol		
Anesthetic or analgesic regimen	Change in anesthetic or analgesic	Change in anesthetic or analgesic regimen (i.e., dose; frequency) that will be equally effective and reliable	
Route of administration of approved test article or agent	Change in route that is more invasive or may cause more discomfort	Change in route that is less invasive or causes less discomfort	
Euthanasia method	Always a significant change		
Test articles or agents (e.g. diet components; antigens; pharmaceuticals)	Substantively different from test articles or agents already approved	Nonhazardous agents and/or substantively similar to test articles or agents already approved	

Duration, frequency, or number of procedures performed on an animal	Any change that increases the level or duration of discomfort	Any change that has no effect or decreases the level or duration of discomfort	

*IACUC Office Approval on West Campus requires approval from the Attending Veterinarian and either the Research Integrity Officer or IACUC Chair. IACUC Office Approval on the Central/Waterfront Campus requires approval from an IACUC Analyst or the Research Integrity Officer.

**Inspection by an IACUC representative must be conducted within 30 days of approval of the modification, or at the next semiannual IACUC inspection.

V. AUTHORITY

Animal Welfare Act, 2.31: With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities. http://www.aphis.usda.gov/animal_welfare/awr.shtml

Guidance: NIH FAQs

What is considered a significant change to a project that would require IACUC review?

Examples of changes considered to be significant include, but are not limited to, changes:

- in the objectives of a study
- from non survival to survival surgery;
- resulting in greater discomfort or in a greater degree of invasiveness;
- in the species or in approximate number of animals used;
- in Principal Investigator;
- in anesthetic agent(s) or the use or withholding of analgesics;
- in the method of euthanasia; and
- in the duration, frequency, or number of procedures performed on an animal. [A4, A7, A13]

Changes in personnel other than the Principal Investigator need not be considered significant provided that an appropriate administrative review mechanism is in place to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC. See NIH Guide for Grants and Contracts NOT OD-03-046. The IACUC has some discretion to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis. http://grants.nih.gov/grants/olaw/faqs.htm#d9