



INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

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IACUC GUIDELINE: SIGNIFICANT PROTOCOL CHANGES
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The Public Health Service Policy on Humane Care and Use of Laboratory Animals¹ and *Guide for the Care and Use of Laboratory Animals*², as well as the United States Department of Agriculture Animal Welfare Act Regulations³ require the Institutional Animal Care and Use Committee (IACUC) to review and approve proposed significant changes in ongoing activities involving animals, though the word "significant" is not defined. Recently, however, the NIH has provided the following guidance: "significant changes include changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant."⁴ This NIH guidance document has also established criteria for reducing administrative burden by allowing IACUC to administratively handle some significant changes (see #2 and 3 below).

Principal Investigators (PIs) are responsible for ensuring that members of the research team who work with animals are familiar with relevant procedures and details specified in their protocol(s), including procedure changes introduced through protocol modification(s). In addition, supervision of work performed on animals must be adequate and ensure that approved protocols are being followed and that significant changes are not implemented prior to IACUC approval.

To better ensure compliance with this regulatory requirement, and following the new NIH guidance, the IACUC has established the following mechanism for reviewing significant changes in an animal research activity on a case-by-case basis. However, the IACUC retains the discretion to define what it considers a significant change.

1. The following significant changes must be reviewed by Designated Member Review (DMR). The outcome of the DMR may be approval of the protocol amendment, require revision of the protocol amendment to secure approval, or refer the protocol amendment for Full Committee Review (FCR).
 - Any change that results in greater pain, distress, or degree of invasiveness.

- Any change that impact on personnel safety.
 - Changing a surgical procedure from nonsurvival to survival, or adding a new surgical procedure.
 - Adding a new animal housing or use location that is not part of the animal program overseen by the IACUC.
 - Changing the species of animal used in the protocol, or adding a new species of animal to the protocol.
 - Changing the study objectives.
 - Changing the Principal Investigator.
2. The IACUC Coordinator in consultation with the Attending Veterinarian may handle the following significant changes administratively according to IACUC-reviewed and -approved policies. The veterinarian may refer any request to the IACUC for review (i.e. DMR or FCR) for any reason, and must refer any request that results in greater pain of distress.
- Changing the anesthesia, analgesia, sedation, or experimental substances.
 - Changing the euthanasia method to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#)
 - Changing the duration, frequency, type, or number of procedures performed on an animal.
3. The IACUC Coordinator, without additional consultation or notification, may handle the following significant changes administratively.
- An increase in the previously approved animal numbers, if the increased number of animals requested is $\leq 10\%$ of the approved number. The cumulative total of all changes in animal numbers within a given year should not exceed 10% of the originally approved animal number.
 - Correction of grammatical or typographical errors in the protocol.
 - Updating personnel contact information.
 - Adding new personnel, if the personnel are appropriately identified, appropriately trained and qualified, and enrolled in applicable occupational health and safety programs.
 - Adding a new funding source.

REFERENCES:

1. PHS Policy IV.B.7. <http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>
2. *Guide for the Care and Use of Laboratory Animals* 8th Edition. Page 25.
<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>
3. United States Department of Agriculture Regulations (9 CFR, Subchapter A) issued under the Animal Welfare Act, 1998 edition, § 2.31(c)(7).
4. Guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on significant changes to animal activities - See more at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>