### Objective:

To provide guidance on classifications and IACUC review processes of amendments to IACUC-approved protocols.

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### Version

1.3

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The IACUC is required by federal regulations\(^1\) to review proposed significant changes to a previously approved application. IACUC approval for all proposed changes to an approved application is required prior to the 1) procurement of animals; 2) commencement of activities and 3) the implementation of proposed changes to the approved protocol.

### AMENDMENT CLASSIFICATIONS

**Minor** – A minor amendment is a change that is unlikely to reduce animal welfare or may decrease the potential for pain/distress (i.e. a refinement). Examples of minor amendments include:

- addition or substitution of qualified personnel;
- title change;
- change in funding source;
- small increase in animal numbers ≤10%;
- addition of another strain of same species;
- change in sex of animal used;
- addition of collaborator(s)

**NOTE:** Changes in personnel (other than the Principal Investigator) are not considered significant and may be processed by the Office of Research Compliance IF it can be documented 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.

**Significant** – Examples of changes that would qualify for review as a significant amendment and therefore may require Full Committee Review include:

- changes in purpose or specific aim of study;
- changes in principal investigator;
- changes in the species or approximate number of animals to be used;
- large increase in animal numbers >10%;
- changes resulting in greater discomfort, pain, or in a greater degree of invasiveness;
- changes in the duration, frequency, or number of procedures performed on an animal
- changes from non survival to survival surgery;
- addition of survival surgery;
- changes in method of anesthesia (either the use of or withholding of);
- changes in post-operative care; or
- changes in method of euthanasia.

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\(^1\) Regulations include: PHS Policy, the Animal Welfare Act regulations, and the *Guide for the Care and Use of Laboratory Animals*. 
**AV Consultation:** Prior to submitting an amendment to the IACUC, the principal investigator must consult with the Attending Veterinarian regarding the category of the proposed change. If the proposed change is not in either of the categories above, the Attending Veterinarian will make the determination regarding the category on a case-by-case basis. The principal investigator must consult with the Attending Veterinarian regarding potential painful procedures as well as changes in anesthesia, analgesia and euthanasia.

**Review Procedures:** Minor amendments may be reviewed by the Committee Chair and/or the Attending Veterinarian and do not require full committee review unless either party requests it.

All significant amendments require full committee review. The IACUC Coordinator will distribute a copy of the amendment to the IACUC. The Committee will perform an initial review to determine whether a significant amendment can be further reviewed using the Designated Member Review process or Full Committee Review at the next convened meeting.

**NOTE:** A maximum of three (3) significant amendments can be approved by the IACUC without requiring submission of a new protocol. More than three significant amendments require submission of new protocol.

**AMENDMENTS WHICH MAY BE HANDLED ADMINISTRATIVELY**

Per guidance from OLAW (NOT-OD-14-126: 08/26/2014), if an institution has defined IACUC-reviewed – and – approved policies, guidelines, and/or SOPs for the conduct of animal activities, those may be used in conjunction with consultation by the Attending Veterinarian to administratively handle the following categories of significant changes to a protocol without the need for full IACUC review (i.e. Designated Member Review or Full Committee Review):

- Anesthesia, analgesia, sedation, or experimental substances;
- Euthanasia to any method approved by the AVMA Guidelines for the Euthanasia of Animals; and
- Duration, frequency, type, or number of procedures performed on an animal

**NOTE:** Per the OLAW guidance these categories of significant changes to a protocol can be reviewed administratively as long as AV consultation has occurred AND that consultation is documented.

**References**


