Marquette University Institutional Animal Care and Use Committee

Marquette University Institutional Animal Care and Use Committee Guidelines: Major vs. Minor Protocol Modifications at Marquette

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (IV.C.1.) and Animal Welfare Regulations (9 CFR 2.31 (d) (1) (i)-(iv)) define the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution’s Assurance, the US Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations, and must be consistent with the Guide unless an acceptable justification for a departure is presented. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy IV.C.1.a.-g.

1. All proposed changes to an approved animal care and use protocol must be approved by the IACUC before they are instituted.

2. The NIH and USDA require different review mechanisms for major vs. minor modification. In general:
   a. Minor modifications can be approved by the IACUC Chair
   b. Major modification must be approved at a convened full IACUC committee meeting.

**Determination of Modifications**

The IACUC has established the following guidelines to determine whether a requested modification is a minor or significant change to an active IACUC approved protocol. Contact the Consulting Veterinarian or the IACUC Chair for guidance if in doubt whether a proposed change is “minor” or is “major” from the point of view of animal welfare.

The following categorization of activities is not exhaustive but it intended as a guide to the type of changes that the IACUC might regard as major or minor changes to a protocol.

**Minor Modifications**

A minor modification is a change to the approved protocol activity that is unlikely to be a physiological cost to the animal, or the change may decrease the potential for pain/distress (i.e. a refinement).

- Reduction in the proposed number of animals
- Transfer of animals to another protocol where animals (same stock/strain) are already approved on that study
- Addition or deletion of personnel, other than the Principal Investigator
- Changes in title or funding agency with the animal protocol being the same
- Adding or changing the location where animal procedures are conducted
- One time addition of up to 10% of the total animal numbers requested (mice and rats only)
Major Modifications – Significant Changes
A significant modification is defined as any change to the approved protocol activity that is likely to be a physiological cost to the animal (i.e. there is a potential to increase pain/distress).

- Change in the study objectives and goals.
- Any procedure that has the potential to increase pain/distress.
- New or additional procedures, especially those that involve more than momentary restraint, or other surgical or invasive procedures not listed in the approved protocol activity.
- Use of hazardous agents in the animal procedures (this could mean chemical, biological or test compounds).
- Dose volume of experimental materials (increase), changes in dose route, or dose frequency (increase).
- Significant food/water restriction (not routine fasting).
- Proposals to switch from non-survival to survival surgery.
- Changes in species.
- Change in the number of animals needed over the original number approved (more than 10%)
- Changes in anesthetic agents or withholding of analgesics.
- Changes in euthanasia or methods of euthanasia.
- Extensions of the study or changes in the PI.
- Changes in the duration, frequency, or number of procedures performed on an animal.
- Change in age of animals ordered
- Protocol that would require animals to be fed, housed or cared for in any way that is not standard for that species, or does not meet that species’ minimum requirements.

Changes that may be handled administratively without IACUC approval

- Correction of typographical errors
- Correction of grammar
- Contact information updates
- Changes in personnel, other than the PI. (Using appendix G administrative review is used to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as require by the IACUC.)

For further questions or guidance please see the Frequently Asked Questions page on the OLAW Website.