

IACUC Guidelines for Major versus Minor Protocol Modifications at UWM

Last Review: 4/2022

Revision History:

Major modifications include: changes in the objectives of the study; proposals to switch from non-survival to survival surgery; changes in the degree of invasiveness of a procedure or discomfort to an animal; changes in species or in the approximate number of animals used; and changes in anesthetic agents, the use or withholding of analgesics, and methods of euthanasia. Additional factors may involve changes in the duration, frequency or number of procedures performed on animals.

Minor modifications include: changes in title or funding agency with the animal protocol being the same, and changes in personnel other than the Principal Investigator.

OLAW Frequently asked question:

1. **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 (greater than 10% change);
- 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.

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. 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. Because significant changes require IACUC approval it is critical that the IACUC clearly define and communicate to investigators its policy and mechanism for determining significance.