Institutional Animal Care & Use Committee (IACUC)

PROTOCOL AMENDMENT POLICY

What is the purpose of an amendment?* An amendment must be filed whenever there is a modification of a previously approved animal use protocol at any time other than at the annual review. All animal procedures, manipulations, and actions must be documented and receive IACUC-approval prior to instituting the modification.

When should an amendment be completed? PI’s need to notify the IACUC and receive approval of these intended changes prior to beginning the work. As you are formulating the experimental plans, be sure to contact the IACUC Administrator to initiate the amendment.

Why is an amendment necessary? Any changes or deviations from the approved protocol need to be approved by the IACUC prior to implementing the desired changes because the USDA Animal Welfare Act and the Public Health Service Policy on Humane Care and Use of Laboratory Animals mandate that all activities involving animals receive IACUC review and approval.

*The requested amendment must fit with the objectives, purpose or aims stated in the original protocol. If this requirement is not met, the IACUC will require submission of a new protocol.

I. Minor Amendment

What changes are considered as Minor?*
- Change in the animal numbers < less than 20% of the original request
- Change in acclimation period
- Change in diet
- Change in housing
- Change in strain of animal species
- Change in sex of animal to be used
- Change in age of animal to be used
- Change in title
- Addition of faculty collaborator
- Addition or change in student or technician
- Addition or deletion of a procedure that is less invasive than the approved
- Transfer of animals to another protocol where the same stock/strain are already approved on that study

Minor Amendment Format
Minor changes to your approved protocol are submitted on the Minor Amendment Form (http://www.uml.edu/research/forms.html)
Review of Minor Amendments*
Minor amendments may be approved by the IACUC Chairperson, their designee or the IACUC Veterinarian.

- Upon approval, a copy of each minor amendment will be returned to the Principal Investigator. The original will remain in the master protocol file.
- All minor amendments are reported to the IACUC at the next scheduled meeting, and may be revisited by the IACUC if any member determines this appropriate.
- A minor amendment may be determined to be major depending on the information contained in the description.

II. Major Amendment

What changes are considered as Major?*

- Objectives of the study have changed
- Non-survival to survival surgery
- Degree of invasiveness
- Increased pain, discomfort, or distress to animal
- Increased proportion of expected animal deaths
- Addition of USDA regulated species
- Anesthetic agents
- Hazardous agents administered to animals
- Use or withholding of analgesia
- Duration, frequency of number of procedures performed
- Change in PI
- Change species
- Change method of euthanasia
- Change in number of animals > greater than 20% over the original approved animal number

Major Amendment Format
The amendment can take the form of a letter/memo (email is preferable). It should include complete descriptions and justification of the requested changes. These changes include items from the list below:

- Purpose for the protocol amendment - how does the amendment relate to the originally approved protocol?
- Addition/deletion of personnel - make certain to enter them into the proper training program prior to allowing them to begin working with the animals.
- Change of species, sex or strain - include justification for changes.
- Specialized housing requirements - include justification for housing changes
- Need to increase number of animals - include a justification for the increase
- Addition of minor surgical procedures - use of analgesia
- Additional sampling of body fluids or tissues - indicate the frequency, the amount and the route used
- Addition of new procedure - describe in the same level of detail as is required by a new protocol.
- Change in method of anesthesia, analgesia or euthanasia
- Addition of hazardous agents - make certain of Environmental Health & Safety approval.
- Change surgical plans from minor to major, multiple major survival

*Major changes may require submitting a new animal activity protocol if any member determines this to be appropriate.
Review of Major Amendments*

- Major Amendments require full IACUC approval. A Primary Review will be performed by the IACUC Protocol Pre-Review Committee.
- If the IACUC decides to withhold approval of a proposed major amendment, the PI will receive written notification that includes justification for withholding approval. At this time, the PI may address the IACUC concerns in person or in writing. The IACUC may reconsider in light of additional information provided by the PI.
- Committee approval of all amendments will be documented in the committee minutes.

*If you are in doubt as to whether a ‘minor’ or ‘major’ amendment should be filed, please contact the Office of Research Services Supervisor or the IACUC secretary.