Major vs. Minor Protocol Modifications

In an attempt to help Iowa State University investigators determine what course of action is necessary when making modifications to an existing animal protocol, we have generated two lists of examples. These lists are in no way complete and are shown here only as a guide to help investigators make informed decisions when modifying existing protocols.

Please note: Per the Research Compliance Advisory Committee, a change in Principal Investigator (PI) is not a modification, but rather requires submission of a new Protocol Review Form (PRF).

Major Modifications

The following is a list of modifications that the Institutional Animal Care and Use Committee (IACUC) deems as major. As such, they require submission of a Continuing Review and/or Modification Form by the PI (via email to iacuc@iastate.edu) and review and approval by the IACUC:

1. Changing the Principal Investigator.
2. Applying the protocol to a new species. (However, PRFs in which several species are already studied are exempt [i.e., survey studies]).
3. Changing the number or age of animals used on the study.
4. Changing the humane use category.
5. Changing when an intervention will be administered to an animal on trial.
6. Changing the duration, frequency, or number of procedures to be performed on an animal.
7. Changing from terminal to survival or repeat surgery.
8. Changing to a different surgical approach or medical treatment.
9. Changing the dosage or dose of hazardous agent or an infectious or biohazardous material already in the protocol.
10. Addition of a new hazardous agent (e.g., betamercaptoethanol).
11. Addition of a new biohazardous material or new infection protocol (e.g., adenovirus vs. lentivirus).
12. Changing or adding objectives to the study.
13. Changing the anesthetic agent(s) or the use or withholding of analgesics. PIs should give an acceptable range so that a modification is not needed.

Please note: If the changes are considered significant enough, the IACUC may require submission of a new PRF.

Minor Modifications

The following is a list of modifications that the IACUC deems as minor. As such, they require submission of a Continuing Review and/or Modification Form by the PI (via email to iacuc@iastate.edu) for approval by the IACUC Chair:

1. Changes in personnel other than the Principal Investigator. When adding personnel, list their role/duties on the project and list their training.
2. Changing the sex of animals used on a protocol.
3. Changing the supply source of animals.
4. Changing the campus housing location.
5. Changing the disposal of animals.
6. Changing the amount of blood drawn, if within guidelines.
7. Changing the person monitoring anesthesia (if person is properly trained).