



WHICH PROTOCOL FORM SHOULD I USE?

1. Application for New Animal Use Protocol (long form)

When a new project is planned and IACUC approval has not yet been granted for the work the PI needs to file a full new protocol form along with any necessary adherence documents. No animals can be ordered or used for any activities until final approval of the animal protocol is obtained from IACUC. The PI should download the current version of the form from the IACUC web site and carefully complete the form. As needed, the PI can consult with one of the veterinarians during the preparation phase. If other adherence documents are needed (e.g. radiation safety and/or biohazard approvals, SOPs, etc.), these must be obtained prior to protocol approval. Once approved, an animal use protocol is valid for 3 years, contingent upon filing annual reviews.

The IACUC is not allowed to administratively extend approval for a protocol beyond its 3 year approval date.

2. Annual Renewal Application (short form)

After approval of an animal protocol has been granted by the IACUC, federal regulations require that the IACUC to conduct ongoing review of activities done under that protocol. The purpose of monitoring is to ensure that no changes have taken place that might require further review by the IACUC, and to ensure that any new requirements of the PHS, USDA, or the institution are transmitted to the investigator. All investigators with IACUC-approved activities need to file an annual renewal application in a timely manner. If no changes, or only minor changes, in activities are proposed for the following year, this can be done using this short form. However, significant changes are proposed, the PI must file an application for a Significant Change to Animal Protocol Form, described below.

3. Longer Term Studies

Some granting agencies such as the NIH may fund a PI's grant project for 5 or more years. In that case, the animal protocol that IACUC approves needs to be re-done every 3 years. There is no "triennial renewal" application. Federal regulations require that IACUC to perform a *complete review* of the project every third year. Thus, regardless of the funding period, a complete new animal protocol application must be filed with the IACUC every 3 years. The form used for this purpose is the same as the new protocol application form discussed in item 1 above.

4. Changes to an Approved Animal Protocol.

Minor changes to a protocol can be addressed either on the annual renewal form or in a letter to the IACUC Chair (typically both). Significant changes require the submission, review and IACUC approval of any major change/s before they can be implemented. What is meant by a "minor change" vs. a "significant change" in the protocol?

The following are examples of *Minor Changes* in proposed animal activities:

- Change in funding source for, or title of, a project
- Change in personnel (except for PI)
- Change in treatment that involve small adjustments in timing, dose, route of administration (not involving anesthesia or analgesic agents, and only if this will not alter the degree of invasiveness or specific objectives of the study)
- Change in the disposition animals/carcasses at the end of an experiment

The following are guidelines for identifying *Significant Changes* in proposed animal activities:

- Switch from non-survival to survival surgery.
- Change in the degree of invasiveness of a procedure or discomfort to an animal.
- Change in study objectives.
- Change in the species, strain or increase in any number of animals (even if only one additional animal is requested)
- Change in PI
- Change in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia.
- Change in the duration, frequency, or number of procedures performed on an animal.
- Other change that the IACUC may deem significant (established on a case-by case basis)

If one or more significant changes are proposed, the PI must file an Application for Significant Change to Animal Protocol as well as any other compliance documents which may now be needed depending on changes (e.g. Radiation Safety, Biohazards Committee approval). Significant changes require IACUC approval before they can be implemented.