



Institutional Animal Care and Use Committee Guidelines and Policies

WHAT TYPE OF PROTOCOL FORM SHOULD I USE?

1. STANDARD PROTOCOL (long form)

When a new project is planned and IACUC approval has not yet been granted for the work, as well as every three years for ongoing research projects, the PI needs to file the “ANIMAL USE PROTOCOL FORM”. No animals can be ordered or used for any activities until final approval for the submitted 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. If required by the category of study, the PI also must consult with one of the attending veterinarians prior to submitting the protocol. If other adherence documents are needed (e.g. radiation safety and/or biohazards), these must be obtained prior to protocol review. The PI then submits the forms to the IACUC coordinator electronically, and also supplies one printed copy that contains the PI’s signature. Animal use protocols, when approved, are good for 3 years, contingent upon filing annual reviews (only 2 annual reviews are allowed).

The Triennial Renewal

A separate “triennial renewal” animal use application doesn’t exist. Federal regulations require that IACUC to perform a complete review of the project every third year. Thus, even though the PI’s grant may be funded for 5 or more years, a complete new animal protocol application must be filed every 3 years. The form used for this purpose is the same as the standard protocol form for a new project (see #1 above). The IACUC is not allowed to administratively extend approval for a protocol beyond the expiration date at the end of the third year.

2. ANNUAL REVIEW (short form)

Once approval for an animal protocol has been granted by the IACUC, federal regulations require the IACUC to conduct ongoing review of each protocol on an annual basis. The purpose of monitoring is to ensure that no changes have taken place that might require further review by the IACUC, and 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 the “ANNUAL RENEWAL FORM” in a timely manner. If no changes or 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 additional form (“SIGNIFICANT CHANGE TO APPROVED PROTOCOL”)

3. CHANGES TO PROTOCOL. Minor changes to a protocol can be addressed either on the annual renewal form or in a letter to the IACUC (typically both). What is meant by a “minor change” vs. a “significant change” in the protocol?



Institutional Animal Care and Use Committee Guidelines and Policies

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 number of animals (if <20% of that originally approved)
- Change in genetic background or strain within a species of animal
- Change in treatment that involve small adjustments in timing, dose, route of administration (only if this does NOT alter the degree of invasiveness or specific objectives)
- 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 species.
- Change in study objectives.
- Change in the approximate number of animals used that is >20% of the original request.
- 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.

If one or more such changes are proposed, the PI must file the “SIGNIFICANT CHANGE TO APPROVED PROTOCOL FORM” as well as obtain any other compliance documents which may now be needed depending on changes (e.g. Radiation Safety, Biohazards Committee approval).