Policy Statement

This policy applies to revisions made to a protocol through an amendment during the IACUC approval process. A subset of veterinary-related, significant changes may be processed administratively. The BIACUC will review at least annually the LAR formulary and other recommended resources related to this policy.

Background
In August of 2014, the National Institutes of Health (NIH) issued notice number NOT-OD-14-126:

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on significant changes to animal activities. The IACUC has some discretion to use IACUC-reviewed and –approved policies to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis... In support of the use of performance standards and professional judgment and to reduce regulatory burden, IACUC-reviewed and –approved policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities may be used for the administrative handling of some significant changes...

Procedure

The Bloomington IACUC has adopted the direction provided by the NIH Guide Notice NOT-OD-14-126 for reviewing proposed revisions to an animal-related study.

Significant revisions must be IACUC-approved by Designated Member Review (DMR) or Full Committee Review (FCR) as described in the PHS Policy IV.C.2.

In accordance with IACUC-review and approval procedures, proposed revisions to an approved study may be processed administratively and in documented consultation with a LAR veterinarian. The veterinarian serves as a subject matter expert to verify that the modification is appropriate for the animal(s) and is in compliance. The veterinarian may refer any consultation to the IACUC and must refer any request that does not meet the parameters of the IACUC-review and approval procedures.

Significant revisions include:

- A change in or addition of anesthesia, analgesia, sedation, or experimental substance(s);
- A change in the method of euthanasia to a method currently approved by the most recent AVMA Guidelines for the Euthanasia of Animals;
- A change in the duration, frequency, or number of procedures performed on an animal, which includes:
  - Addition of a procedure to be performed on an already anesthetized animal;
  - Addition of a non-invasive sample collection method;
  - Addition of sample collection times or change in timing of collection;
  - Addition of testing a compound of similar drug class as previously approved;
  - Refinement of techniques; or
  - Change in feed or bedding.
Communication about the revision must be routed through the IACUC Office by the LAR Veterinarian or the PI, prior to the veterinarian completing his/her administrative review.

Contacts

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Web Address for this Policy

http://researchcompliance.iu.edu/iacuc/iub/biacuc_policies.html