Policy Statement

This policy applies to revisions made to a protocol through an amendment during the IACUC approval process. A subset of significant changes may be processed administratively and in consultation with a veterinarian, and in accordance with the IACUC’s approval, as described in NOT OD 14-126. 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.

In accordance with IACUC-review and approval procedures, proposed revisions to an approved study may be processed administratively and in 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.

Veterinarians using the administrative veterinary review process have been authorized by the IACUC to do so. Veterinary staff review the proposed amendment with the PI and communicate in-person, by phone call, or email.

Changes to a protocol that may be processed by administrative veterinary amendment include:

- **In purpose-bred mice:**
  - Addition of veterinary-approved vendor.
  - Refinement of technique description (depilatory application, von Frey, etc.) of currently approved study activities.
  - Transfer of animals between IUB IACUC approved protocols.
  - Add option of using nonpharmaceutical grade substance (analgesics, neuromuscular blockers) in terminal procedures.
  - Addition of inhalation anesthesia as an option for anesthesia.
  - Addition of non-invasive sample collection.
  - Decrease in frequency of sample collection.
- A change in bedding or feed, which does not include feed or water restriction.
- Extension of feed shelf-life in accordance with manufacturer’s specifications.
- Addition of testing a compound of similar drug class as previously approved.
- Change in antibiotics or analgesics, in accordance with IACUC-approved LAR formulary.
- Change in dose range of injectable agent for anesthesia/sedation.
- Addition of identification methods (toe clipping, tattooing, microchipping, nonpermanent marker, and ear punch), as described in IACUC policy.

• **In purpose-bred rats:**
  - Addition of veterinary-approved vendor.
  - Refinement of technique description (depilatory application, von Frey, etc.) of currently approved study activities.
  - Transfer of animals between IUB IACUC approved protocols.
  - Add option of using nonpharmaceutical grade substance (analgesics, neuromuscular blockers) in terminal procedures.
  - Addition of inhalation anesthesia as an option for anesthesia.
  - Addition of non-invasive sample collection.
  - Decrease in frequency of sample collection.
  - A change in bedding or feed, which does not include feed or water restriction.
  - Extension of feed shelf-life in accordance with manufacturer’s specifications.
  - Addition of testing a compound of similar drug class as previously approved.
  - Change in antibiotics or analgesics, in accordance with IACUC-approved LAR formulary.
  - Change in dose range of injectable agent for anesthesia/sedation.
  - Addition of identification methods (toe clipping, tattooing, microchipping, nonpermanent marker, and ear punch), as described in IACUC policy.

• **In hamsters:**
  - Clarification of currently approved study activity.
  - Transfer of animals between IUB IACUC approved protocols.
  - Add option of using nonpharmaceutical grade substance (analgesics, neuromuscular blockers) in terminal procedures.
  - Addition of non-invasive sample collection.
  - Decrease in frequency of sample collection.
  - A change in bedding or feed, which does not include feed or water restriction.
After the veterinarian and PI agree on the amendment content and have established that the content is in accordance with the related IACUC policy and relevant references, the veterinarian may choose to verify the change requested if:

- It is consistent with eligible significant changes in this IACUC approved Policy;
- There is an appropriate reference for the veterinarian to verify against the change being requested; and
- The change is appropriate for animals in the context of the protocol.
- Or, the veterinarian may choose to send the protocol back to the IACUC for DMR or FCR.

If the administrative veterinary amendment is authorized for approval, then this is processed and documented by the IACUC Manager. Approval is communicated to the PI by electronic communication.
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/their administrative review.

Contacts

<table>
<thead>
<tr>
<th>Subject</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIACUC Policy</td>
<td>BIACUC Manager</td>
<td>855-5138</td>
<td><a href="mailto:Biacuc@indiana.edu">Biacuc@indiana.edu</a></td>
</tr>
<tr>
<td>LAR Veterinarian</td>
<td>Laboratory Animal Resources</td>
<td>855-2356</td>
<td><a href="mailto:Lar@indiana.edu">Lar@indiana.edu</a></td>
</tr>
</tbody>
</table>

Web Address for this Policy

https://research.iu.edu/policies/bloomington-animal-care-and-use.html