Policy Statement

This policy applies to changes made to a protocol and the approval process. Any changes to an already approved IACUC protocol must be approved by the IACUC prior to implementation. If a change is implemented prior to approval, it is considered protocol non-compliance.

Background

NIH released a Notice on August 26, 2014, which provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs), on significant changes to animal activities.

The USDA Animal and Plant Health Inspection Service has reviewed and concurs with the guidance provided in the NIH Notice.

Policy

The IU Bloomington and School of Medicine IACUC have adopted the direction provided in the NIH Guide Notice NOT-OD-14-126 for review of proposed changes to a previously approved animal study.

Significant changes must be approved by one of the valid IACUC approval methods described in the PHS Policy IV.C.2., that is FCR or DMR. These review process are described in the IACUC SOP.

The specific significant changes described below, may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies.

This includes changes in:

- anesthesia, analgesia, sedation, or experimental substances;
- euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
- duration, frequency, type, or number of procedures performed on an animal.

Other changes considered by the IACUC to be Minor or Administrative are defined in the IACUC SOP. The following chart summarizes the type of review and categories of changes.
<table>
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<th>Examples of Significant Amendments</th>
<th>Examples of Minor Amendments</th>
<th>Administrative Amendments</th>
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<tr>
<td>Change from non-survival to survival surgery</td>
<td>Request to repeat an experiment</td>
<td>Changes in title of protocol</td>
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<tr>
<td>Changes resulting in greater pain, distress, or degree of invasiveness</td>
<td>Addition of a minor surgery (if already approved for Survival Surgery)</td>
<td>Change in funding source</td>
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<td>Change in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC</td>
<td>Addition of a procedure to be performed on an already anesthetized animal</td>
<td>Addition of a qualified student or technician</td>
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<td>Change in species</td>
<td>Addition of non-invasive sampling</td>
<td>Change in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals</td>
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<td>Change in study objectives</td>
<td>Addition of sample collection times or change in timing of sample collection</td>
<td>Change in duration, frequency, type, or number of procedures (already approved in the protocol) performed on an animal</td>
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<td>Change in Principal Investigator</td>
<td>Change in administration of treatment/observation as it relates to timing, dose, route of administration, and/or specific chemical composition</td>
<td>Change in veterinary recommended medication for animal health purpose</td>
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<td>Change in the impact of personnel safety</td>
<td>Addition of testing compound of similar drug class as previously approved</td>
<td>Other changes not listed above may fall into this category</td>
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<td>Change in sex of animal to be used</td>
<td>Refinement in techniques</td>
<td>Veterinary Consult Review Timeframe</td>
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<tr>
<td>Other changes not listed above may fall into this category</td>
<td>Change in another strain or genetic background of the same animal species that is not exempt from IBC review.</td>
<td>36 hours for review</td>
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**DMR or FCR Review Timeframe**

- 24 hours to call for FCR
- 2 weeks for IACUC review

**DMR Review Timeframe**

- 24 hours to call for FCR
- 72 hours for IACUC review

Note: Addition of several Minor Changes may cause amendment to become Significant.

Note: At any time during the Minor Amendment review, the Reviewer(s) can call for the amendment to be reviewed by FCR.

**IACUC Office Timeframe**

- 24 hours for review

Note: At any time during the Veterinary Consult review, the Veterinarian can call for the amendment to be reviewed by either DMR or FCR.

**Administrative Amendments**

- Change in administration of treatment/observation as it relates to timing, dose, route of administration, and/or specific chemical composition
- Change in veterinary recommended medication for animal health purpose
- Other changes not listed above may fall into this category

**Veterinary Consult Review Timeframe**

- Change in administration of treatment/observation as it relates to timing, dose, route of administration, and/or specific chemical composition
- Change in veterinary recommended medication for animal health purpose
- Other changes not listed above may fall into this category

Note: At any time during the Veterinary Consult review, the Veterinarian can call for the amendment to be reviewed by either DMR or FCR.

**Veterinary Consult Review Timeframe**

- 36 hours for review

Note: At any time during the Veterinary Consult review, the Veterinarian can call for the amendment to be reviewed by either DMR or FCR.

**IACUC Office Timeframe**

- 24 hours for review

Note: At any time during the Minor Amendment review, the Reviewer(s) can call for the amendment to be reviewed by FCR.