

University of Notre Dame Institutional Animal Care and Use Committee (IACUC) Policy
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Title: Amendment of Approved IACUC Protocols	
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Effective Date: 7/20/24	Last Revised Date: 7/20/24
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I. Purpose

Animal care and use regulations require that the IACUC review and approve significant changes regarding the use of animals on approved protocols.

II. Policy

1. Significant Changes

- a. Most significant changes to previously approved animal activities are reviewed by Full Committee Review (FCR) or Designated Member Review (DMR), including changes:
 - i. from non-survival to survival surgery
 - ii. resulting in greater pain, distress, or degree of invasiveness
 - iii. in housing and/or use of animals in a location that is not part of the animal program currently overseen by the IACUC
 - iv. in species
 - v. in overall study objectives
 - vi. in Principal Investigator (PI)
 - vii. that impact personnel safety
 - viii. through the addition of new study procedures
- b. A significant change that can be reviewed administratively without proceeding to FCR or DMR is an increase in animal numbers that equals or is less than ten percent (10%) of the total number of animals last approved on a protocol through DMR or FCR. If an increase in animal numbers requires a change in species, study objectives, or impacts animal welfare, it cannot be reviewed administratively and will be assigned for FCR.

2. Veterinary Verification and Consultation (VVC)

- a. Proposed significant changes not listed in (1)(a) above may be eligible for review that does not require FCR or DMR. A documented and IACUC-approved consultation with the Attending Veterinarian (AV) may be sufficient for implementation of changes:

- i. in anesthesia, analgesia, sedation, or experimental substances
 - ii. in euthanasia using any method approved in the most current version of the AVMA Guidelines for the Euthanasia of Animals
 - iii. in duration, frequency, type, or number of procedures performed on an animal as described in an approved IACUC Policy (e.g., the IACUC Policy on the Frequency of Blood Sampling in Rodents)
 - iv. in strain/line of animals (but not species)
 - v. in source of animals
 - vi. in location of animal housing
 - b. Consultation with the AV is initiated through the existing protocol amendment form. If all significant changes proposed in an amendment fall within the VVC-eligible categories identified above, the amendment may be sent to the AV for consultation and verification. No proposed changes may be implemented until approval of the amendment is received in the electronic protocol system.
 - c. The IACUC Chair or the AV retains the authority to determine that a significant change be reviewed by FCR or DMR.
 - d. Changes to research supported by the U.S. Dept. of Defense require FCR, even if the changes proposed fall under the categories identified above for VVC review.
- 3. Non-significant Changes
 - a. Revisions to approved IACUC protocols that are not considered significant changes include changes to:
 - i. personnel, excluding the PI
 - ii. contact information
 - iii. title of IACUC protocol
 - iv. funding
 - v. protocol content limited to correction of typographical or grammatical errors that don't substantively alter the research description
 - vi. update attachments
 - b. Non-significant changes may be approved by IACUC-designated staff through administrative review in lieu of FCR and DMR. In all cases, investigators must submit an amendment in the electronic protocol system describing the proposed changes and obtain approval before implementing any changes to previously approved activities.
- 4. Recommendations
 - a. Investigators are encouraged to build flexibility into their protocols to minimize the likelihood that significant changes must be made to the protocol (e.g., including a maximum volume of blood to be collected, alternate methods of blood collection, etc.).
 - b. Some changes to the original study objectives may require the submission of a new separate protocol.

III. References

1. Public Health Service (PHS) Policy IV.C.1.a.-g.
2. 9 CFR 2.31(d)(1)(i)-(xi)
3. National Institutes of Health NOT-OD-14-126, issued August 26, 2014