



IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Initial Review of IACUC Protocols

Policy/Procedure ID: 05-02-002 **Effective:** February 18, 2005

A. Background

BGSU policy requires IACUC review of all research, research training, experimentation, biological testing, and related activities, involving live, vertebrate animals. The review is guided by the ethical principles regarding all research involving vertebrate animals, as set forth by the Animal Welfare Act and the PHS Policy.

Review and approval must occur before any animals can be used and includes the following considerations from the federal regulations (9 CRF 2.31d):

- Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.
- The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals.
- The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments.
- Procedures that require more than momentary pain and distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, involve consultation with the attending veterinarian, and not include the use of paralytics without anesthesia.
- Animals that would otherwise experience severe or chronic pain or distress that can not be relieved will be painlessly euthanized at the end of the procedure.
- The animals' living conditions will be appropriate for their species.
- Medical care will be available for all animals by a qualified veterinarian.
- Personnel conducting procedures will be appropriately qualified and trained in those procedures.
- Activities that involve surgery must include appropriate provision for pre-operative and post-operative care of the animals. All survival surgery will be performed using aseptic procedures.
- No animal will be used in more than one major operative procedure from which it is allowed to recover unless justified by scientific reasons, required as routine veterinary procedure, or in special circumstances as determined on an individual basis.
- Methods of euthanasia must be acceptable, recommended methods (e.g., included in the most current version of the AVMA Euthanasia Report).

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B. Procedure

1. The researcher completes an IACUC protocol form and submits a copy to the Attending Veterinarian and the Office of Research Compliance (ORC) by the appropriate deadlines (the IACUC meeting calendar and associated deadlines can be found at <http://www.bgsu.edu/offices/spar/orc/iacuc/MeetingCalendar.html>).
2. The ORC reviews the application for completeness and checks to make sure the principal investigator (P.I.) and all participants listed on the protocol have completed the appropriate level of animal training based upon their proposed roles on the protocol. If training is required or the application is incomplete (e.g., signatures, incomplete answers or missing literature search information) the P.I. will be contacted, and the application held from the review process until training has been acquired and/or required materials/information is provided.
3. The ORC assigns a protocol number and logs the protocol information into the active protocol database.
4. The ORC designates an appropriately qualified primary presenter.
5. If the protocol is complete it is included in the IACUC meeting packets, with all of the relevant materials. IACUC meeting packets are assembled and distributed to IACUC members seven days prior to the monthly meeting.
6. The Committee meets, discusses the protocol within the context of the review considerations identified above, and determines a review outcome. Possible outcomes are:
 - a. Approved
 - b. Clarifications / Modifications Required - researcher must provide clarification or make changes before final approval can be given
 - c. Deferred - the Committee does not have sufficient information to make a decision. Additional information is required from the researcher before the Committee will review the application.
 - d. Approval Withheld - the project cannot be conducted as proposed. Substantial changes must be made before the project can be re-submitted for review by the Committee.
7. The ORC notifies the P.I., in writing, of the Committee's decision and the PI is provided the opportunity, if the protocol review result is not "approved", to address the Committee's concerns.