

University at Buffalo Animal Care and Use Program

Policy on the Review and Approval of Animal Use Protocols and Amendments

Introduction

The University at Buffalo is committed to ensuring the humane care and use of vertebrate animals in research, instruction, and testing through the adherence to all applicable Federal and State laws, regulations, policies, principles, and standards (including accreditation standards) affecting such use. Approval by the Institutional Animal Care and Use Committee (IACUC) is required prior to the involvement of a vertebrate animal in any institutional research, testing, or teaching procedure.

Policy

This policy defines the procedures for IACUC review and approval of animal use protocols and amendments to previously approved animal use protocols.

Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) and the United States Department of Agriculture (USDA) Animal Welfare Regulations permit only two methods for IACUC review of proposed animal use protocols and significant changes to previously approved protocols:

- 1) Full Committee Review (FCR) by a convened meeting of the IACUC
- 2) Designated Member Review (DMR) in lieu of a convened meeting of the IACUC

Full Committee Review (FCR)

Proposals undergoing Full Committee Review are reviewed by the IACUC through the deliberative process during convened meetings in which a quorum of committee members is present. Committee meetings are held on at least a monthly basis. Proposal documents are provided to IACUC members for review prior to the convened meeting. During the meeting, proposals are presented and discussed. Proposal information is considered potentially confidential and is discussed in executive session. The final recommendations of the IACUC are voted on in open session.

Possible IACUC recommendations after FCR include:

- 1) *Approval*
- 2) *Require Modifications to Secure Approval* – By unanimous agreement of all committee members and alternate members, the IACUC has adopted the practice of allowing DMR subsequent to FCR when substantive additional information is required to properly evaluate proposals that require modifications to secure approval. DMR subsequent to FCR may only occur by the unanimous vote of all members at a convened meeting. The IACUC Chair will assign the designated reviewer(s).
- 3) *Withhold Approval* – The IACUC may, by a majority vote at a convened meeting, withhold approval for a proposal which generally has serious flaws requiring extensive

rewriting. Investigators will be notified in writing of the IACUC's decision and the committee's concerns and questions to be addressed. The investigator is also provided an opportunity to respond to the IACUC's decision and guidance in resubmitting the proposal for future consideration. Proposals for which approval has been withheld must undergo FCR at another fully convened meeting.

Designated Member Review (DMR)

Proposals determined to be eligible for review by the DMR method are circulated to all committee members for review on a rolling basis, as they are received by the IACUC Office. IACUC members are given three business days to review the proposal and provide any comments on the proposal for the consideration of the designated reviewer(s). All members also have the opportunity to call the proposal for Full Committee Review (FCR) during this timeframe. If no member calls the proposal for FCR after three business days, the proposal may be reviewed via DMR. A non-response by an IACUC member is considered their acceptance of the designated review process.

Following the three business day waiting period, in the absence of a call for FCR, the designated reviewer(s) is assigned by the Chair. The Attending Veterinarian or designee is included in the review process to provide a veterinary care/use perspective.

Possible IACUC recommendations after DMR include:

- 1) *Approval*
- 2) *Require Modifications to Secure Approval* – Investigators will be notified in writing of the IACUC's decision and the committee's concerns and questions to be addressed. The investigator is also provided an opportunity to respond to the IACUC's decision and guidance in resubmitting the proposal for future consideration.
- 3) *Call the proposal for FCR* – If any committee member calls the proposal for FCR, it will be placed on the agenda for discussion at the next scheduled IACUC meeting.

If multiple designated reviewers are assigned, they must each review the same version of the proposal. Approval can only be granted if their recommendation for approval is unanimous. The designated reviewer(s) cannot disapprove or withhold approval, as that decision can only be rendered by a majority vote of the committee at a fully convened meeting. If modifications are required to secure approval, upon receipt of a revised version of the proposal from the investigator, the IACUC Office will circulate the revised proposal to the designated reviewer(s) for review on a rolling basis.

Procedures for Review of Animal Use Protocols

The PHS Policy states that the IACUC shall conduct continuing review of approved activities at appropriate intervals which is to be determined by the IACUC, but *de novo* (triennial) review cannot occur less than once every three years. Protocols that included pain category E procedures, and protocols funded by the Department of Defense (DOD) must have an annual review, in addition to the three years *de novo* (triennial) review. The annual review must be

submitted in Click and the PI must answer questions regarding the progress of the study over the previous year.

The standard method for review of new animal use protocols, annual reviews, and triennial renewals by the IACUC is Full Committee Review (FCR).

Investigators will be given sufficient notice by IACUC Office staff prior to the protocol's expiration or annual review date in order to allow adequate time for submission and IACUC review to ensure that the study remains in compliance and approval does not lapse.

All approvals will be reported to the IACUC at the next scheduled meeting. Any approved activity may be called for reconsideration by the IACUC at any time if any member determines that review of an approved protocol is necessary.

Any protocol or amendment that has not had edits submitted to the IACUC for review within 6 months of the initial submission date will be withdrawn from the review process. The submission will need to be resubmitted to the IACUC review and approval process.

Procedures for Review of Amendments to Previously Approved Animal Use Protocols

Amendments must be submitted by the investigator with changes clearly identified and contrasted with the previously approved protocol.

Certain proposed changes may be reviewed administratively by IACUC Office staff and approved on behalf of the IACUC. These types of changes include:

- The correction of typographical errors or grammar
- Changes to personnel contact information
- Changes in personnel (other than the PI)
- An increase in animal numbers for non-USDA regulated species, of less than 10% over the number currently approved
- The addition of another strain of the same species, if the strain has no inherent health/welfare concerns
- Changes in the sex of animal used
- Reducing or eliminating a previously approved water or food restriction
- The addition of an animal housing/use location that is already part of the animal program as currently overseen by the IACUC
- The deletion of an animal housing/use location

The standard method for review of significant changes to previously approved protocols is Designated Member Review (DMR), however committee members are given the opportunity to call such proposals for Full Committee Review (FCR). Significant changes include:

- Changes in study objectives
- The addition of a new species
- Changes in Principal Investigator (PI)
- An increase in animal numbers for USDA-regulated species

- An increase in animal numbers for non-USDA regulated species, of greater than 10% over the number currently approved
- The addition of a survival surgery
- The addition of a painful or distressful procedure
- The addition of a new procedure or changes to a currently approved procedure
- Changes to euthanasia procedures
- An increase in the overall pain, distress, or invasiveness of a procedure
- Description of an unanticipated increase in clinical signs or animal deaths
- The addition of or change in anesthetic or analgesic, or a change in dosage
- Changes in or the addition of hazardous agents, or requirements for BSL-2
- The addition of a neuromuscular blocking agent
- A request to add PI-managed satellite housing (animals housed for 24+ hours outside a vivarium)
- A request to add housing of a USDA-regulated species outside the vivarium for more than 12 hours
- The addition of an animal housing/use location that is not already part of the animal program as currently overseen by the IACUC
- The description of any exemptions to the *Guide for the Care and Use of Laboratory Animals*, or other regulatory agent

Upon approval of the amendment, the investigator will be notified. All approvals will be reported to the IACUC at the next scheduled meeting. Any approved activity may be called for reconsideration by the IACUC at any time if any member determines that review of an approved amendment is necessary. The classification of proposed amendments as either significant or able to be reviewed administratively will be determined by the IACUC Chair or designee.