University at Buffalo Animal Care and Use Program

Policy on the Review and Approval Procedures for Animal Use Protocols and Amendments

Introduction

The University is committed to ensuring the humane care and use of vertebrate animals used in research, instruction, and testing adhere to applicable Federal and State laws, regulations, policies, principles, and standards (including accreditation standards) affecting such use.

Policy

Approval by the University’s Institutional Animal Care and Use Committee (IACUC) is required prior to the involvement of a vertebrate animal in any University research, testing or teaching procedures.

Guidelines for Review and Approval of Animal Use Proposals

Public Health Service Policy on the Humane Care and Use of Laboratory Animal (PHS Policy) and the USDA Animal Welfare Regulations (AWR) permit only two methods of review of animal use proposals and proposed 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) –

The standard method of review and approval of the Animal Care and Use Application form by the IACUC is through the deliberative process during convened meetings of the IACUC. For those meetings, held monthly, a quorum must be present for the IACUC to conduct business. Copies of new or renewal Animal Use Applications or proposed significant changes are distributed to the IACUC members for their review prior to the convened meeting.

At the IACUC meeting, proposals are presented by the IACUC Chair and opened for discussion. All protocol discussions are considered potentially confidential and are considered in executive session. The final recommendations of the IACUC are voted in open session.

IACUC actions include:

1) Approval
2) Require Clarifications/Modifications to secure Approval – By unanimous agreement of all voting members and alternate members, the IACUC has adopted the practice of allowing DMR following FCR when substantive additional information is required to properly evaluate proposals that requires modification to secure approval. DMR can only occur in these situations by the unanimous vote of the members at a properly convened meeting. If this method is chosen, the IACUC chair and Committee generally assign the designated reviewer.
3) Deferral (tabled) – Proposals deferred at the meeting generally have serious flaws requiring extensive re-writing. Investigators are provided with a list of concerns, comments, and questions for response and guidance in resubmitting the proposals for consideration. Deferred proposals must be reviewed at another full IACUC meeting before approval may be granted.

4) Withhold Approval – The IACUC may, by a majority vote, withhold approval for a proposal. In these cases the investigator is notified in writing of the IACUC’s decision and their reasons for the decision. The investigator is provided an opportunity to respond to the IACUC decision. The IACUC may reconsider its decision following the investigator’s response.

Designated Member Review (DMR) –

Proposals or proposed significant changes determined to be eligible for approval by the DMR method are circulated to all committee members. IACUC members are given three work days to respond back to the IACUC Chair or IACUC Administrator and indicate one of two dispositions for the proposal or significant change:

1) Members respond to the request and have no objections to that particular proposal or proposed change being reviewed and potentially approved by the DMR process.
2) One or more members call for full committee review (FCR).

Following receipt of responses from the IACUC members, and in the absence of a call for FCR, the designated reviewer(s) are assigned by the Chair to review the proposal or proposed significant change. The designated reviewers either approve the proposal or change, request further information in order to secure approval, or direct the proposal or change for FCR. The designated reviewers cannot disapprove a proposal or proposed change. That decision can only be rendered by the full committee at a convened meeting.

**Amendments**

Amendments to protocols are submitted to the IACUC office. Based on the criteria listed below, amendments are classified as either minor or major (significant). Major amendments require IACUC review as detailed above, as required by PHS Policy and AWR.

Significant protocol amendments are reviewed by the Designated Member Review (DMR) method. Amendments are completed by the investigator with changes clearly delineated, i.e., identified and contrasted with previously approved protocol. After submission to the IACUC Office, the amendment request is made available to all IACUC members for review and comment. If no member requests full committee review during the period of review (as above), the amendment is reviewed and approved by the DMR process.

Examples of Major (significant) amendments may include the following:

1) Change in purpose or specific aim of the study
2) Change or addition in species
3) Increase in animal numbers of any USDA regulated species
4) An increase in animal number greater than 10% over the number approved on the
initial protocol

5) Addition of a survival surgery
6) Addition of a painful/distressful procedure
7) Increase in overall invasiveness of a procedure
8) Unanticipated increase in clinical signs or animal deaths
9) Addition or change in anesthetic or analgesic or a change in dosage
10) Change in or addition of hazardous agents, or requirements for BSL-2
11) Change in Principal Investigator
12) Addition of a neuromuscular blocking agent
13) Request for PI-manged housing or greater than 12 hours in lab
14) Exemptions to the Guide, or other regulatory agent.

Minor Changes with Veterinary Review.
This type of amendment requires a UB Attending Veterinarian or designee to review and approve the requested change from a veterinary care/use perspective. This veterinary approval is required prior to approval of the proposal by the DMR. Generally, the IACUC Chairperson, the Attending Veterinarian, and one other IACUC member will serve as the DMR, although Full committee review can be requested. The approval of the amendment is immediate, with the signature of the Chair. The PI will be notified of the approval and a copy of the approved amendment will be maintained in the PI’s IACUC master protocol file. All approvals will be reported to the IACUC at the next scheduled meeting. Any approved activity may be called for re-consideration by the IACUC if any member determines that such as review of an approved amendment is necessary.
Examples include:

1) Changes in anesthetic drug regimens
2) Changes in analgesic drug regimens.
3) Addition of surgery or procedure that is less invasive than already on the approved protocol, or decreased proportion of expected animal deaths.
4) Changes in animal care and monitoring practices.
5) Changes in humane endpoints.
6) Addition of sample collection times.
7) Repetition of an already approved experiment.
8) Addition of noninvasive sampling/analysis.
9) Change in or addition of euthanasia procedures
10) Requests for delayed weaning of rodents or single housing of aggressive male rodents for animal welfare purposes.
11) Addition of another strain/stock of the same animal species.

Minor amendments not having direct animal welfare/well-being impact) may be reviewed by a DMR, and may be approved by the IACUC Chairperson or IACUC member designee (DMR procedure). The approval of the amendment is immediate, with the signature of the DMR. The PI will be notified of the approval and a copy of the approved amendment will be maintained in the PI’s IACUC master protocol file. All approvals will be reported to the IACUC at the next scheduled meeting. Any approved activity may be called for re-consideration by the IACUC if any member determines that such a review of an approved amendment is necessary.
Examples include:
1) Transfer of animals to another protocol where animals (same stock/strain) are already approved on that study.
2) Increase in animal numbers ≤20% of the approved animal numbers of species other than USDA regulated species.
3) Addition of a location for PI managed housing if an approved scientific justification has already been approved and all policies are followed for facility inspection of the new area.
4) Addition of or change in dosage of an experimental drug in the same class as one previously approved
5) Need to repeat an experiment, or addition of experimental groups

Classification of proposed amendments that are not described herein will be determined as either significant or minor by the IACUC Chairperson or designee.

Some Minor amendments are processed through the IACUC Office as administrative changes, and are approved by the Chair. Minor amendments may include the following:

1) Addition or deletion of study personnel
2) Addition of another strain of the same species
3) Change of sex in the animal to be used
4) Changes to contact information
5) Training updates of PI or study personnel
6) Addition of faculty collaborator
7) Reducing or eliminating previously approved water or food restrictions
8) Addition or deletion of location of animal usage

Continuing Review of Animal Research

The PHS Policy states the IACUC shall conduct continuing review of activities at appropriate intervals as determined by the IACUC but not less than once every three years. The USDA regulations use similar language, except that continuing review must be performed not less than annually.

The IACUC requires a full Animal Care and Use Application form be submitted for review every three years, whether or not changes have been made to a protocol. Changes that were previously made by amendment during the previous three years would need to be incorporated into the renewal Animal Care and Use Application form if those changes will continue to be done.

For annual reviews, a short questionnaire must be completed for submission to the IACUC to ensure animal activities are being conducted in accordance with the approved protocol.

Notification renewal notices are sent to the Principal Investigator two months prior to the expiration date in order to provide adequate time for review to ensure that the study remains in compliance, that the activities have been conducted in accordance with the approved protocol, that significant modifications receive prior IACUC approval, and to ensure that any new requirements of PHS, USDA, and/or SUNY Buffalo are conveyed to the Principal Investigator.
The first renewal notice is due the month prior to the protocol expiration date. If there is no response to the first notice, a second renewal notice will be sent indicating the date IACUC approval will expire and that the investigator will not be allowed to use or purchase animals if current approval expires. These are the only two notices that will be sent. Federal regulations prohibit the use of animals without current IACUC approval.

**Expired Protocols**

The CMLAF is notified when approval for a protocol has expired. If there are still animals covered under the protocol, the Facilities Manager will notify the IACUC Administrator and will post the animal room door and/or cages with a notice that indicates that no research associated with the expired protocol is to be conducted.

The IACUC Administrator will contact the Principal Investigator and notify him/her of the protocol expiration, consequences (i.e., euthanasia or transfer of animals), the process for correction, and a deadline for process of correction. Animals will be maintained and cared for by the CMLAF during this time period, but no experimental procedures are permitted. The per diem charges will continue to be the responsibility of the Principal Investigator until the disposition of the animals has been determined.

Animals may be transferred to another approved protocol provided no procedures have been done on the animals.

**Suspended Protocols**

The procedure for protocols whose approval has been suspended by the IACUC is outlined in the IACUC’s Policy for Non-Compliance.

IACUC administration will notify Sponsored Project Administration (SPA) when approval for a funded protocol has been suspended by the IACUC indicating that the grant should not be billed for any animal related costs while the protocol is suspended. SPA will be notified when approval for a suspended protocol has been re-instated.

In addition, when the IACUC notifies the investigator that their protocol has been suspended, the letter will include a statement indicating that the funding agency will be notified of the suspension along with a statement that no further animal related costs can be made against the grant while the protocol is suspended. Alternative sources of funding must be sought.