University at Buffalo Institutional Animal Care and Use Program
Policy on IACUC Protocol Review and Amendment Approval

Introduction:

The University at Buffalo is committed to upholding the highest ethical and regulatory Standards for the humane care and use of vertebrate animals in research, instruction, and testing. The institution complies with guidance, including the Animal Welfare Act (AWA) and its implementing regulations by the United States Department of Agriculture (USDA), the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Department of Defense (DOD) Instruction 3216.01, and the National Research Council's *Guide for the Care and Use of Laboratory Animals (The Guide)*. All research, testing, or teaching activities involving vertebrate animals (or cephalopods) must receive prior approval from the Institutional Animal Care and Use Committee (IACUC) before any such activity may begin.

Scope and Purpose:

This policy outlines the procedures for review and approval of new animal use protocols, significant changes to approved protocols (amendments), and continuing reviews (annual and triennial) in accordance with federal requirements and institutional policy.

Methods of IACUC Review:

Per PHS Policy, USDA Animal Welfare Regulations (9 CFR Parts 1–3), and DOD Instruction 3216.01, only two methods of IACUC review are permissible:

1. Full Committee Review (FCR)
2. Designated Member Review (DMR)

Full Committee Review (FCR)

Proposals reviewed by FCR are considered during a convened meeting of the IACUC, at which a quorum of voting members must be present. Proposal materials are distributed to all members in advance. The committee discusses the proposal at a fully convened meeting and reaches decisions by majority vote.

Possible IACUC recommendations after FCR include:

1. **Approval**

2. **Require Modifications to Secure Approval**: If revisions are needed, and the committee agrees unanimously, the protocol may proceed to DMR following FCR.

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3. **Withhold Approval**: Requires a majority vote. Investigators are notified in writing and invited to address concerns for future resubmission. Re-review must occur via FCR.

Designated Member Review (DMR)

Outcomes following DMR may include:

1. **Approval**

2. **Modifications Required to Secure Approval:** Investigators will be notified in writing of the IACUC committee's edits and clarification requests.

3. **Referral to 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.

Designated reviewers must be unanimous in approving a protocol. Reviewers cannot withhold approval — withhold must occur via FCR.

Commented [CW1]: Change to the decision to withhold approval must occur via FCR

Continuing Review:

Triennial Review

Per PHS Policy and the Guide, all IACUC-approved protocols must undergo de novo review at least once every three years.

1. For protocols that do not involve Pain Category E procedures approval is granted for a maximum of three years.
2. Any changes made via amendment during the approval period must be incorporated into the renewed protocol.

Annual Review

1. Protocols involving Category E procedures require annual continuing review.
2. The IACUC must confirm annually that the activities remain consistent with the approved protocol.
3. During annual review, Investigators should provide the following information:
    - In response to Question #1 ("Progress made over the last year"), summarize the protocol's progress over the past year. Include the total number of animals used including how many of those animals underwent a Category E procedure.
    - Respond to Question #2 ("Describe any unanticipated results involving animal health and well being during the previous year"). Ideally, these have already been communicated to the IACUC via submission of a UAE (Unanticipated Adverse

Event) Form, but a summary should still be given. For more information, refer to the "Policy on Adverse Event Assessment and Reporting for Animal Research."

- Submit any outstanding monitoring charts to the IACUC by emailing them to iacuc@research.buffalo.edu. When required for a protocol, monitoring charts should be submitted at the completion of each cohort of animals. If charts haven't been submitted throughout the year, they need to be submitted at the time of annual review.

Protocol Review Procedures

The standard method for reviewing new protocols, triennial renewals, and annual reviews is Full Committee Review (FCR). Investigators are given adequate notice to allow timely submission and prevent lapses in approval.

All approvals are reported at the next convened IACUC meeting. Any protocol may be re-evaluated at any time if warranted by concerns or IACUC member request.

Inactive Submissions:

Protocols or amendments lacking a response or requested edits for 6 months after initial submission will be administratively withdrawn. Re-submission is required for further consideration.

Review of Amendments:

Administrative Amendments

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

- Typographical or grammatical corrections
- Contact information updates
- Non-PI personnel changes
- Animal number increases (<10%) for non-USDA species
- Addition of another strain (same species, no welfare concerns)
- Changes in the sex of animal used
- Reduction/removal of water or food restriction
- Addition or removal of housing locations already under IACUC oversight

Significant Changes

Significant changes require DMR or, if requested, FCR. These include:

- New species or PI
- Change to scientific aims
- USDA-regulated species number increase

- Animal number increase (>10%)
- New or altered surgical procedures
- New or altered painful or distressful procedures
- The addition of neuromuscular blockers
- Any changes increasing pain, distress, or invasiveness
- Modifications to euthanasia procedures
- New or altered anesthetic, analgesic or dosages
- Use of hazardous agents, BSL-2 or BSL-3 containment
- Addition of PI-managed or satellite housing (>24 hrs)
- USDA species housed >12 hrs outside vivarium
- Exemptions from the Guide or regulatory requirements
- Unanticipated adverse events or mortality changes

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