

Institutional Animal Care and Use Committee

Policy: Animal Use Application Review

General

- All animal use at Brown University, including for research, instruction or testing, must be approved by the Brown University Institutional Animal Care and Use Committee (IACUC).
- The IACUC review will be conducted in accordance with the Animal Welfare Regulations (AWR) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The proposed animal use must also be consistent with the guidelines found in the *Guide for the Care and use of Laboratory Animals* unless acceptable justification for departure has been justified and approved.

Types of application

The Principle Investigator (PI) is responsible for preparing an application for animal use and obtaining IACUC approval prior to using animals. The first step in preparing an application is to determine which type of application is appropriate. A *New Application* covers newly proposed projects, whether they are to be funded externally (e.g., NIH or NSF) or internally (e.g., start-up funds or GIP accounts). Applications are approved for a maximum of 3 years. A brief *Annual Protocol Review Application*, which includes a progress report, is required at the end of each project year on the Anniversary date of the signed approval of the project for the continuation of approved projects. For projects continuing more than 3 years after the original approval (e.g., for 4- or 5-year grants), the project must be reviewed *de novo*, using the same process as for *New* applications. Finally, *Significant Changes* in ongoing projects must be submitted by memo for approval by the IACUC as soon as the need for such changes arises. Examples of significant changes in animal use include:

- altered objective of a study
- addition of survival surgery
- increased invasiveness or potential discomfort to animals caused by a procedure
- change in species or in the number of animals to be used
- addition of new personnel participating in animal procedures
- modified choice of anesthetic or analgesics agents(s), or in the route of administration or dosage of these agents
- altered method of euthanasia
- duration, frequency or number of procedures performed on an animal

These application types are summarized in the following table:

Project Proposed

New
Renewal of project within 3 years of original approval
Continuation of approved project beyond 3rd year
Significant Change to existing project

Required Forms

Application with required Appendices
Annual Protocol Review

Application with required Appendices

Memo with a complete description of change

Preparation of Application

- Current forms for new and continuation (post-3rd -year) applications, including all required appendices, can be obtained from on the Brown University IACUC webpage (<http://bms.brown.edu/iacuc>) or by contacting the Animal Care office (401.863.3223). To request approvals for significant changes to an ongoing project, no form is needed. Instead, a memo should be sent to the IACUC detailing the changes requested and the rationale for them.
- Consultation with a campus veterinarian is required for all research projects that have the potential for producing pain or distress. The likelihood of successful review of an application can be enhanced by sending it in draft form for “pre-review” to the Animal Care facility (Animal_Care@Brown.edu) prior to formal submission.
- The PI must allow a minimum of 4 weeks for application review. The process can take longer if problems or concerns are identified during review. For projects proposed to the NIH, the newly implemented “just in time” process now requires IACUC approval only after peer review is complete and only if a proposal is likely to be funded. To avoid delays in funding, be sure to submit your application as soon as you are notified of a potentially fundable score.

Submission of Application

- Submit the completed application or memo to the IACUC Coordinator in the Animal Care Office (BioMed Center, Room 287; Animal_Care@Brown.edu). For externally funded projects, be sure to include that part of the grant covering the research plan, including any section describing vertebrate animal use (Section F for NIH grants).

Review of Application

- The formal review process is initiated with the acceptance of the application by the IACUC Coordinator. Before accepting the application, the IACUC Coordinator may request that the PI correct simple technical errors or omissions to expedite the review process. The Coordinator assigns the protocol a Receipt Date and forwards the application to the appropriate reviewers, according to the application type. Annual progress reports are reviewed by a campus veterinarian. Memos describing protocol changes are screened by a University veterinarian and those involving significant changes are forwarded to the Protocol Review

Subcommittee, which is described below. New applications and *de novo* applications for continuation of ongoing projects are distributed to the Protocol Review Subcommittee.

- Concurrent with distribution of the application, the Coordinator notifies the IACUC members and alternates that an application has been received and is available for review in the Animal Care office. This notification, typically sent by email, includes the Receipt date, application number, title, principal investigator, and species and number of animals to be used, listed by pain/stress category (B, C, D or E). In addition, for Category E protocols, each IACUC member receives a copy of the protocol itself. In addition, the members are encouraged to review the applications and to make comments to the Protocol Review Subcommittee. IACUC members are requested to promptly notify the coordinator if they wish to request a full IACUC review (“Full review”), rather than by the Protocol Review Subcommittee (a “Subcommittee review”). Committee members are encouraged to scrutinize Category E protocols especially closely and to consider whether a Full review may be necessary. A request by a single member of the IACUC is sufficient to trigger a Full review. If no such request is received within 14 calendar days of the initial email notification, the IACUC will be considered to have authorized a Subcommittee review.
- Full Review - A meeting of the full IACUC is convened and the application is reviewed and discussed. At the discretion of the Chair, the PI may be invited to address questions the committee may have, but will be excused from the room before the vote. Approval of the application requires a majority affirmative vote of a quorum of the IACUC. IACUC members participating in the proposed work or who have a real or potential conflict of interest must recuse themselves from the deliberations and the vote.
- The *Protocol Review Subcommittee* consists of three regular members: the IACUC Chair, the Assistant Director of Animal Care, and a faculty member appointed by the Chair of the IACUC. Alternate members of the Protocol Review Subcommittee are the Director of Animal Care and two additional faculty members appointed by the Chair of the IACUC. Subcommittee reviews are normally conducted by the three regular members of the Protocol Review Subcommittee. Alternate members, at the direction of the IACUC Chair, review protocols when regular subcommittee members are unavailable or have a real or potential conflict of interest. Non-voting consultants may be recruited to review aspects of protocols requiring expertise not adequately represented on the Subcommittee. Protocol reviewers may request that the PI revise the application or provide additional information before approving the protocol. Such requests are relayed anonymously to the PI by the IACUC Coordinator or University veterinarians. Copies of these requests and the PI’s responses are attached to the application. Approval of an application by the Subcommittee requires the concurrence for acceptance of the three members or alternates reviewing the application. Lacking this concurrence, the application is referred to the IACUC for a Full review. The subcommittee’s action does not take effect until 21 calendar days after the application’s Receipt Date to permit the IACUC members to request a Full review.

Approval or Disapproval of Application

- For applications approved by the IACUC, the Director of Animal Care will sign and date the Vertebrate Animal Use Certification of Research Protocol form and send it to the PI. Notification of approval is also sent to Research Administration. Approval for New or *de novo* applications is granted for a maximum of 3 years. The date of the Director of Animal Care's signature constitutes the Approval Date. The anniversary Approval Date typically does not coincide with the start date of an external grant funding the approved animal work.
- For applications rejected by the IACUC, the reasons for rejection are detailed in writing and sent to the PI. The PI is given an opportunity to respond in person or in writing to address the concerns of the committee. The PI is encouraged to resubmit a revised protocol that substantively addresses the shortcomings of the original protocol and is urged to consult with the IACUC chair and University Veterinarians in preparation for such a resubmission. Animal use for the proposed project is not permitted until the application receives final approval, nor can a date of approval by the IACUC be submitted to the NIH or other external agencies that may require such approval before funding the project.

References

- Institute of Laboratory Animal Resources, National Research Council. *Guide for the Care and Use of Laboratory Animals* 8 (National Academy Press, Washington, DC, 1996).
- Public Health Service Policy on Humane Care and Use of Laboratory Animals
- Animal Welfare Act Regulations, CFR, Title 9, Chapter 1, Subchapter A, Parts 1 - 3.
- ARENA/OLAW. *Institutional Animal Care and Use Committee Guidebook*, 2nd edn (2002).