

Institutional Animal Care and Use Committee (IACUC)

TITLE: IACUC Protocol Review Processes	Effective Date: 28-February-2022
IACUC POLICY: 003 REVISION: 0	Last Revised: 10-November-2023
SCOPE: This process applies to submission of all IACUC protocols	Review Date:
PURPOSE: To define an accepted process for intake and processing of IACUC submissions.	
KEYWORDS: IACUC, Protocol review path	
Policy Owner: Research Compliance Office Radford University	
Policy Contact: Anna Marie Lee, Research Compliance Manager, alee16@radford.edu or irb-iacuc@radford.edu	

1. BACKGROUND

PHS Policy on Humane Care and Use of Laboratory Animals (Policy) ([PHS Policy at IV.C.1-2](#)) and Animal Welfare Regulations ([9 CFR 2.31 \(d\) \(1\) \(i\)-\(iv\)](#)) define the only two protocol review methods that fulfill USDA and PHS requirements for the conduct of animal activities, full committee review (FCR) or designated member review (DMR).

[OLAW FAQ](#) state in the review of an IACUC protocol, the committee must confirm that:

- The protocol is consistent with [the Guide](#), unless a scientific justification for a departure is presented and acceptable to the IACUC
- The protocol conforms to the institution’s Assurance
- The protocol will be conducted in accordance with the USDA’s Animal Welfare Regulations, if applicable, and
- The protocol meets the requirements of [PHS Policy](#) IV.C.1.a.-g.

The intent of this policy is to outline the IACUC Protocol Submission and review process.

2. POLICY

In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-conducted or supported activities related to the care and use of animals. The IACUC procedures for protocol review are detailed in the following policy. Investigators are not permitted to begin any in vivo animal related research, order animals for research, or make changes to any research already approved unless they have received an approval letter from the IACUC office.

Radford University’s Institutional Animal Care and Use Committee review process for applications for the use of vertebrate animals in research, teaching, or testing is described here.

Institutional Animal Care and Use Committee (IACUC)

Protocol Preliminary Review

All protocols undergo both an administrative and veterinary pre-review of essential components. Upon receipt of a new IACUC application, the Research Compliance Office (RCO) will review the application ensuring all necessary information has been addressed including identification of any typographical errors, and confirmation that all animal users have completed the required IACUC training.

Any preliminary review comments will be noted, and the application returned to the PI for revisions. The PI may choose to accept and include these suggestions or not. The initial intake/preliminary review process has a general turn-around time of three business days after submission.

[PHS Policy](#) and NIH Grants Policy statement ([NIH GPS, chapter 4.1.1.2](#)) require the institution to verify, before the award, that the IACUC has reviewed and approved those components of the grant applications and contract proposals related to the care and use of animals. While this is not an explicit requirement for the IACUC to conduct a side-by-side comparison of an application/proposal and the IACUC protocol, institutions are responsible for ensuring the information that the IACUC reviews and approves is congruent with what is in the application/proposal. (Some institutions have delegated this responsibility to a particular office or position (e.g., sponsored programs or the compliance office).

The process is referred to as “Congruency Review” and is performed by the Radford University Research Compliance Office, which serves as the administrative office for the IACUC.

Protocol Veterinary Review

Following RCO preliminary review, the revised IACUC application is forwarded to the Attending Veterinarian (AV) and Environmental Health and Safety (EHS) for review. EHS review comments on the application that are not directly related to the humane care and use of laboratory animals will be handled directly between EHS and the PI, outside of the IACUC review process. Veterinary review is on average, received by the RCO within seven (7) business days, after which the protocol is returned to the PI for revisions.

The preliminary veterinary review includes, but is not limited to, a review of the following components within the protocol:

- Contact Information
- Verification of Personnel Training and Qualifications
- Appropriate number of personnel (three-deep) for animal care
- Animal Use Location
- Assurance Signature from PI
- Rationale for the following:
 - Animal Use
 - Numbers of animals used
 - Assurance of nonduplication of research
 - Species and strain
 - Search for alternative methods

Institutional Animal Care and Use Committee (IACUC)

- Description of Animal Use
- Description of Surgeries, including (if needed):
 - Pre-operative planning
 - Minimization of contamination
 - Intra-operative monitoring
 - Post-operative procedures
 - Scientific justification for multiple survival surgeries on a single animal
- Type of exogenous substance administered, including:
 - Dosage
 - Route
 - Frequency
 - Scientific justification for the use of nonpharmaceutical grade substances, including consideration of grade, purity, sterility, acid-base balance, pyrogenicity, osmolality, stability, compatibility of components, expected adverse reactions, storage, and pharmacokinetics
- Hazardous Substance Approvals
- Euthanasia according to the most current AVMA Guidelines
- Details regarding:
 - Unrelieved pain and distress
 - Tumors
 - Physical Restraint
 - Surgery
 - Breeding
 - Adjuvant/Antigen Administration
 - Exemption from standards (departures from the Guide or AWA) Field Studies

Veterinary review comments are forwarded to the PI. The revised protocol is routed back to the veterinarian upon receipt for confirmation all concerns have been addressed prior to the application moving forward with IACUC review. The veterinarian will notify the RCO whether all concerns have been addressed and review of the protocol continue.

IACUC Preference Check/Designated Member Review (DMR)

Following confirmation that veterinary review concerns have been addressed, the pending IACUC protocol is forwarded to committee members for DMR preference check.

IACUC members are requested to review the application, responding directly to the RCO (NOT reply all) with their vote for Designated Member Review (DMR) or Full Committee Review (FCR) as well as any comments.

Institutional Animal Care and Use Committee (IACUC)

Except in unusual circumstances, members are allowed approximately three (3) business days to complete their review of the proposed protocol and indicate whether the application will proceed to DMR or be reviewed under FCR. As per Federal guidelines, only one member's requirement of FCR is sufficient to require a protocol to be reviewed via FCR.

When a period of less than three (3) business days is requested, electronic routing of protocols to determine review preference will require 100% response by the IACUC to proceed to confirm that all members had the opportunity to view and comment on the submission unless the shorter DMR preference routing was previously unanimously approved by the full IACUC at a convened meeting of the entire IACUC. If after the allotted time limit has been reached and a quorum has not been reached, the IACUC administrator will reach out to the committee members to reach a quorum.

If the protocol proceeds via DMR, the RCO and the IACUC Chair will collaborate to determine a reviewer appropriate for the protocol. Upon assignment, the protocol will be sent to the DMR for review of the protocol. DMR review is requested to be conducted in a reasonable period, typically within seven (7) business days.

Should any ONE member or more of the IACUC request protocol review by the Full Committee, or the application contains the use of USDA Pain Category E animals; the protocol will be placed on the agenda for committee discussion at the next convened IACUC meeting that does not correspond with a semi-annual program review or facility inspection. The PI is invited to the meeting to answer any questions and address any concerns the IACUC may have regarding their protocol.

Following DMR or FCR, any committee concerns are forwarded to the PI and the protocol returned for revisions. Once all IACUC concerns have been adequately addressed, an IACUC approval letter is generated using the IACUC online software system with a three-year approval period.

Members with a conflict of interest or who are to be listed as an active participant in the project are expected to recuse themselves and are requested to leave the room during final deliberations or should it be otherwise deemed prudent.

The quorum is then re-calculated to address the loss of any recused voting members at this time. Final deliberations and voting may then take place, if a quorum remains available to allow for voting.

Resources

- [PHS Policy on Humane Care and Use of Laboratory Animals](#)
- [Code of Federal Regulations. Title 9, Chapter 1, Subchapter A-Animal Welfare, Parts 1-3](#)

Institutional Animal Care and Use Committee (IACUC)

REVISION HISTORY:

Revision	Summary of Revisions	Revision Date
#1	Statement regarding the need for three-deep personnel for animal care.	27-March-2023
#2	Statement regarding congruency review for funded projects.	10-November-2023