

<b>Policy Number:</b>	115	<b>Version Number:</b>	1.0
<b>Approval Date:</b>	June 20, 2024		
<b>Title:</b>	IACUC Review of Proposed Activities		

## Purpose

The purpose of this policy is twofold:

- (1) To establish the criteria by which the Princeton IACUC has determined to require Full Committee Review (FCR)
- (2) To define the different types of proposed changes to approved activities and establish criteria for determining the allowable mechanism for review and approval of the proposed changes.

## Scope

This policy is applicable to all animal activities conducted under the auspices of Princeton University and applies to all locations.

## Regulatory Background

In accordance with Federal Mandates (i.e., the PHS Policy on Humane Care and Use of Laboratory Animals (Policy), the United States Department of Agriculture (USDA) Animal Welfare Regulations (AWAR), and related guidance documents), the IACUC shall “Review and approve, require modifications to (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.” Furthermore, the PHS Policy defines the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution’s PHS Assurance and must be consistent with the Guide unless an acceptable justification for a departure is presented, see NOT-OD-14-126: Guidance on Significant Changes to Animal Activities. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy IV.C.1.a.-g.

## Responsibility

Research Integrity & Assurance (RIA) – For the purposes of this policy, oversees the review process; appropriately routes proposed changes to approved activities in accordance with Princeton University IACUC Policy (noted herein) and assigning Designated Member Reviewers as delegated by the Chair.

IACUC – For the purposes of this policy, responsible for the review of all submissions requiring Designated Member Review (DMR) and/or Full Committee Review (FCR).

IACUC Chair – For the purposes of this policy, (1) designates at least one member of the IACUC, qualified to conduct a DMR review, and (2) when requested, make the determination that any submission can be reviewed by DMR unless a member of the IACUC calls for FCR.

Principal Investigator – For the purposes of this policy, responsible for submitting an IACUC application (new, triennial renewal, changes to approved activities) before initiating any animal activities.

LAR or PRR Veterinarian - Responsible for approving amendments that can be reviewed by Veterinary Verification and Consultation (VVC); Primate Research Resources (PRR) when non-human primates are involved and Laboratory Animal Resources (LAR) for all other species.

## Definitions

Proposal / Submission / Application: Synonymous terms referring to the eRIA IACUC form for a new or triennial renewal protocol, or an amendment to IACUC approved activities involving applications for (1) Vertebrate Animal Use, (2) Field Research, and (3) Invertebrate Animal Use, when required.

Designated Member Review (DMR): The review of proposals by at least one IACUC member, designated by the IACUC Chair and qualified to conduct the review on behalf of the IACUC. DMR may be utilized only after all IACUC members have been provided the opportunity to call for Full Committee Review (FCR). The outcome of DMR may result in approval, a requirement for modifications (to secure approval), or referral to FCR. If a proposal is assigned more than one designated reviewer, the reviewers must be unanimous in any decision, must all review identical versions of the protocol, and, if modifications are requested by any one of the reviewers, then the other reviewers must be aware of and agree to the modifications.

Full Committee Review (FCR): The review of proposals during a convened meeting of a quorum of IACUC members. FCR is to take place in real time with interaction of the members and may occur live or virtually. The outcome of FCR may result in approval, a requirement for modifications (to secure approval), or withholding approval of the protocol or amendment.

Veterinary Verification and Consultation (VVC): The review of proposed changes to IACUC approved activities (i.e., amendments) by at least one LAR or PRR veterinarian that are designated by the IACUC to verify the changes are in accordance with Princeton University IACUC Policy (noted herein).

## Policy

**(1) IACUC review and approval of proposed animal activities (i.e., new or triennial/de novo applications) is conducted via full committee review (FCR) or designated member review (DMR), as follows:**

- a. Protocol Applications may be considered for DMR except when:
  - i. The application involves a USDA-regulated species that is new to Princeton or to the PI's lab (i.e., the PI does not have a current IACUC approval for that species), and/or
  - ii. The application contains the addition of:
    1. Animal activities designated as pain/distress Category E (i.e., no Category E activities are included on the specific IACUC approved

application under review, including the expiring protocol under triennial/de novo renewal);

2. New pilot studies;
3. Animal activities adding a new category of exceptions/exemptions (refer to the Princeton University IACUC Application in eRIA) which include:
  - a. The use of prolonged physical restraint;
  - b. The application of food and/or water restriction;
  - c. Exceptions to social housing;
  - d. Housing outside of LAR holding rooms > 12 hours; and/or
  - e. Exceptions to the established acclimation, enrichment, and/or standard husbandry practices.
- b. The IACUC Chair may determine that any submission can be reviewed by DMR, at their discretion, unless a member of the IACUC calls for FCR.
- c. Any member of the IACUC may call for FCR of any application at any time.

**(2) Changes to approved activities (i.e., amendments) are reviewed according to the following criteria:**

- a. **Significant changes are reviewed by FCR or DMR when they include:**
  - i. A change from non-survival to survival surgery;
  - ii. Any change that results in greater pain, distress, or degree of invasiveness;
  - iii. A change to, or addition of, a housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC;
  - iv. A change in, or addition of, species;
  - v. A change in the study objective(s);
  - vi. A change of Principal Investigator (PI); and/or
  - vii. A change that impacts personnel safety.
- b. **Significant changes that meet the criteria listed in Section (1)a, above, also required FCR (or DMR as described in Section (1)b)**
- c. **Veterinary Verification and Consultation (VVC) are modifications made to protocols using the VVC process according to the following policy:**
  - i. OLAW notice NOT-OD-14-126: "Guidance on Significant Changes to Animal Activities" defines an administrative process that can be used to make certain significant changes to IACUC approved protocols. The IACUC has approved specific changes (according to established criteria and resources defined in the VVC Policy) that can be incorporated into IACUC approved protocols by specifically designated LAR/PRR

veterinarians using the VVC process. VVC changes are verified by a designated veterinarian and documented by RIA. The Princeton IACUC applies the word “enhancement” to indicate changes that improve outcomes based on veterinary professional judgment after evaluating the procedure and outcome. The following procedural changes can be made to animal activities that have already been IACUC approved if the proposed change does not result in an increase in pain, distress, or degree of invasiveness:

1. Increase in previously approved regulated animal numbers;
  2. Changes in the duration, frequency, type, or number of procedures performed on an animal;
  3. Changes in the methods of euthanasia providing the changes are consistent with the acceptable methods described in the American Veterinary Medical Association (AVMA) panel publication on acceptable methods for euthanizing animals;
  4. Changes in pain management drugs (i.e., anesthesia and/or analgesia) to ensure the approved plan continues to meet the clinical and humane requirements as well as the needs of the research protocol, and meets the acceptable veterinary standards;
  5. Change in method of animal acquisition, quarantine, or conditioning;
  6. Revising the sex, weight or age of animal to be used, or adding an additional strain of the same species;
  7. Enhancements to surgical procedures, including pre- or post-operative procedures, that reduce the invasiveness or discomfort of the process;
  8. Modifications to the process of collecting tissue samples (e.g., blood sampling, genotyping, identification);
  9. Addition or deletion of standard dosing, route, volume, or bleeding technique providing the techniques are less or equally invasive and appropriate for the species as determined by the veterinarian; and/or
  10. Minor changes in animal enrichment or husbandry requirements.
- ii. LAR/PRR veterinarians may defer the amendment to FCR at any time and for any reason.
  - iii. Any member may call for FCR of any amendment application and any time during the review process or post-approval period.

**d. Administrative Amendments:**

- i. Certain protocol changes have no impact on animal activities and are considered administrative amendments. Administrative changes can be made to IACUC approved protocols by any member of RIA.
- ii. The following protocol amendments may be made by administrative staff:

1. Changes in funding sources;
  2. Changes in IACUC approved housing and/or procedure room locations;
  3. Changes in personnel information and personnel, other than the PI;
  4. Changes due to typographical or grammatical errors; and
  5. Increase in previously approved non-regulated animal numbers.
- iii. The IACUC Chair may determine that any modifications required to secure approval identified during FCR can be reviewed and approved administratively, if they fall within the criteria noted above.

### References

Public Health Service. (2015). *PHS Policy on Humane Care and Use of Laboratory Animals*.

Retrieved from U.S. Department of Health & Human Services:

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Office of Laboratory Animal Welfare (OLAW). (2021, Apr 20). *Guidance on Significant Changes to Animal Activities*. Retrieved from Office of Laboratory Animal Welfare:

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United States Department of Agriculture Animal and Plant Health Inspection Service. (2020, July). *Animal Welfare Regulations: Code of Federal Regulations - Title 9 - Animals and Animal Products, Part 2, Subpart C, Section 2.31 and 2.32*. United States. Retrieved from

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### Version History

Version Number	Revision Date	Revision Description
1.0	June 20, 2024	New; a consolidation of these two documents, which will be retired after approval of Policy #115: (1) IACUC Policy #112 “Minor and Significant Amendments” and (2) IACUC Policy #113 “Designated Member Review”