

SOP Title: Animal Use Protocol Submission, Review, and Determination

Responsible Committee: Institutional Animal Care and Use Committee (IACUC)

Institution: Pacific Union College

Review Method: Full Committee Review (FCR)

Last Updated: August 2026

Purpose

This Standard Operating Procedure (SOP) establishes the process by which the Pacific Union College Institutional Animal Care and Use Committee (IACUC) receives, reviews, and acts upon Animal Use Protocols (AUPs) involving live vertebrate animals.

The purpose of IACUC review is to ensure that proposed teaching, field, and research activities involving live vertebrate animals are conducted responsibly and in accordance with applicable institutional policies, federal requirements, and accepted standards for animal care and welfare.

No animal-related activity covered by PUC IACUC oversight may begin until the investigator has received final IACUC approval.

Scope

This SOP applies to new Animal Use Protocols and, as applicable, amendments or significant modifications to previously approved protocols.

An AUP is required for PUC activities involving live vertebrate animals, including teaching or demonstrations, non-invasive field observation, field research involving capture or handling, and laboratory or captive research involving animal handling or procedures.

If a project includes multiple types of animal activities, the applicant should identify the category representing the most invasive activity and describe all animal activities in the protocol.

Submission of Animal Use Protocol (AUP)

The faculty member responsible for the project submits the Animal Use Protocol through the PUC IACUC protocol submission system.

When students are conducting the proposed activity, the supervising faculty member serves as the responsible party and submits the protocol. Students may participate in preparing protocol materials but do not independently submit an AUP.

The protocol must provide sufficient information for the IACUC to evaluate the proposed use of animals. This includes, as applicable, the purpose of the activity, species and number of animals, source of animals, housing and husbandry, capture and handling procedures, experimental or teaching procedures, methods for minimizing pain or distress, anesthesia or analgesia, euthanasia, animal disposition, personnel qualifications, and required training.

Incomplete submissions may be returned to the investigator for completion before Full Committee Review.

Receipt and Preparation for Review

Upon receipt, the protocol is recorded as received by the IACUC.

The IACUC Chair or designee may conduct an administrative review to identify missing information, incomplete responses, inconsistencies, or other matters that would prevent meaningful committee review. Administrative review does not constitute IACUC approval.

When the protocol is sufficiently complete for review, the protocol and relevant supporting materials are made available to the IACUC members before the meeting at which the protocol will be considered.

Committee members are expected to review the protocol sufficiently to participate in an informed discussion and determination.

Full Committee Review

Pacific Union College uses **Full Committee Review (FCR)** for review of Animal Use Protocols.

Full Committee Review occurs at a convened meeting of the IACUC at which a quorum of voting members is present. Members discuss the proposed animal activity and may raise questions regarding animal welfare, scientific or educational justification as it relates to animal use, alternatives, animal numbers, procedures, pain and distress, housing, husbandry, personnel training, or other matters within the IACUC's responsibility.

The Committee may request clarification from the investigator when necessary to understand the proposed activity.

A member who has a conflicting interest in a protocol may provide information requested by the Committee but may not participate in the IACUC's review or approval of that protocol and may not contribute to the quorum for that review.

Following discussion, the Chair calls for a committee determination.

A majority vote of the quorum present is required for an IACUC action under Full Committee Review.

Possible IACUC Determinations

Following Full Committee Review, the IACUC will make one of three determinations:

Approval means that the IACUC has determined that the Animal Use Protocol, as submitted or as revised during the review process, satisfies the requirements for IACUC approval.

The investigator will receive written notification of approval.

Once final approval has been issued and all required personnel training or other applicable institutional requirements have been completed, the investigator may begin the animal activities described in the approved protocol.

Approval applies only to the activities described in the approved protocol.

Significant changes to the approved activity must be submitted to and approved by the IACUC before they are implemented.

Investigator action: Move forward with the approved activity.

Require Modifications to Secure Approval means that the IACUC has determined that the proposed activity may be approvable but that specific changes, clarifications, or additional information are required before approval can be granted.

This determination is **not** IACUC approval. The investigator may not begin any animal activity covered by the protocol while the protocol has this status.

The investigator will receive written notification identifying the modifications, clarifications, or additional information required by the IACUC. The investigator must address each item and submit a revised Animal Use Protocol and, when appropriate, a response explaining how the Committee's concerns have been addressed.

All substantive revisions must return to the full IACUC for Full Committee Review at a convened meeting with a quorum present. The revised protocol will be considered by the Committee, which will determine whether the required modifications have been adequately addressed. Following review, the full Committee will make one of the three permitted determinations: Approval, Require Modifications to Secure Approval, or Withhold Approval.

Administrative staff or the IACUC Chair may verify correction of purely administrative or nonsubstantive matters, such as typographical errors, missing attachments, or other information that does not affect the substance of the proposed animal activity. Such administrative verification may not be used to approve substantive changes requested by the Committee.

PUC does not use Designated Member Review to grant approval of substantive revisions requested through Full Committee Review. Substantive revisions must be considered by the full Committee.

Terms such as *conditional approval*, *provisional approval*, *approved pending revisions*, or similar language will not be used to indicate that animal activities may begin before the Committee has granted final approval.

Investigator action: Modify the existing protocol as directed and resubmit it. Do **not** begin animal activities until the revised protocol has received final approval from the full IACUC.

Withhold Approval means that the IACUC has determined that the proposed activity, as presented, cannot be approved.

This determination is distinct from a request for revisions. It indicates that the Committee has determined that the protocol does not adequately satisfy applicable

requirements or that concerns are sufficiently substantial that revision of the existing submission is not the appropriate pathway forward.

The investigator will receive written notification of the Committee's determination and the reasons approval was withheld.

No animal activities described in the protocol may begin.

If the investigator wishes to pursue the activity when approval has been withheld, the investigator must address the concerns identified by the IACUC and submit a **new Animal Use Protocol** for consideration. The new submission will enter the normal review process as a new protocol.

An institutional official may not administratively override an IACUC decision to withhold approval.

Investigator action: Do **not** proceed with the proposed animal activity. If the project is to be reconsidered, prepare and submit a new Animal Use Protocol addressing the IACUC's concerns.

Summary of IACUC Determinations

IACUC Determination	Meaning	May Animal Work Begin?	Investigator's Next Step
Approval	The protocol satisfies IACUC requirements and final approval has been granted.	Yes	Proceed according to the approved protocol after completing applicable training requirements.
Require Modifications to Secure Approval	The protocol may be approvable but specified changes or additional information are required. This is not approval.	No	Modify the existing protocol, respond to the Committee's requirements, and resubmit.
Withhold Approval	The Committee has determined that the proposed activity cannot be approved as submitted.	No	Do not proceed. If the activity is to be reconsidered, address the Committee's concerns and submit a new Animal Use Protocol.

Communication of the IACUC Determination

Following review, the investigator will be notified in writing of the IACUC's determination.

For an approved protocol, the notification will identify the protocol as approved and provide the applicable approval information.

When modifications are required to secure approval, the notification will identify the changes, clarifications, or additional information required by the Committee. The investigator must respond to these requirements and resubmit the revised protocol.

When approval is withheld, the notification will explain the basis for the Committee's decision and provide the investigator with an opportunity to respond to the Committee's concerns.

Committee decisions and communications regarding the protocol will be maintained as part of the IACUC's records.

Changes to an Approved Protocol

IACUC approval authorizes only the animal activities described in the approved protocol.

Investigators must submit proposed amendments or significant modifications to an approved protocol before implementing those changes. Changes that may require IACUC review include changes to animal procedures, species, animal numbers, methods of restraint, anesthesia or analgesia, euthanasia, study objectives, or other aspects of the activity that may affect animal welfare.

Animal activities affected by a proposed modification must continue under the currently approved protocol until the modification has received IACUC approval.

If the proposed change is sufficiently extensive so that it substantially changes the nature or scope of the approved activity, the IACUC may require submission of a new Animal Use Protocol rather than an amendment.

Protocol Expiration and Renewal

IACUC approval does not authorize animal activities indefinitely. Protocols must be reviewed and renewed in accordance with applicable federal requirements and PUC policy. A protocol will be approved for a maximum of three years. Animal activities may not continue under an expired protocol.

When continued animal activity will extend beyond the approval period, the investigator must submit the required renewal or new Animal Use Protocol in advance to allow IACUC review.

Investigator Responsibility

Approval of an Animal Use Protocol carries an ongoing responsibility to conduct the activity as approved.

The primary investigator must ensure that personnel understand and follow the approved protocol, complete required training, use only approved animal procedures, maintain appropriate animal care and welfare, and obtain IACUC approval before implementing significant changes.

Questions about whether an activity requires IACUC review or whether a proposed change requires an amendment should be referred to the PUC IACUC before the activity or change occurs.

The Review Process Summarized

Animal Use Protocol submitted → Administrative completeness review → Distribution to IACUC → Full Committee Review → Committee determination

The determination results in one of three pathways:

APPROVAL → Proceed with approved animal activities

REQUIRE MODIFICATIONS TO SECURE APPROVAL → Revise existing AUP → Resubmit → IACUC review → Final determination

WITHHOLD APPROVAL → **STOP** → Address IACUC concerns → Submit a new AUP if the investigator wishes to pursue the project

At no point may animal activities begin solely because a protocol has been submitted, reviewed, discussed, or returned for modification. **Final IACUC approval is required before the animal activity begins.**