

PROCEDURE FOR PROTOCOL REVIEW	The IACUC is responsible for the review and approval of all proposed activities related to the care and use of animals. [2.31]
Procedure	<p>A written protocol, i.e., a proposal for animal use activities, must be submitted to and approved by the IACUC prior to the start of any animal use activity.</p> <p>The IACUC must review all submitted protocols and decide to: [2.31(c)(6)]</p> <ul style="list-style-type: none">• approve the protocol, OR• require modifications in the protocol to secure approval, OR• withhold approval of the protocol <p>The IACUC review must be conducted by: [2.31(d)(2)]</p> <ul style="list-style-type: none">• the full IACUC, or• a subcommittee of at least one member of the IACUC designated by the IACUC chair who:<ul style="list-style-type: none">▶ is qualified to conduct the review, and▶ has the authority to:<ul style="list-style-type: none">□ approve□ require modifications in the protocol to secure approval, or□ request a full IACUC review of the protocol <p>Note: This person or subcommittee might be referred to as the Designated Reviewer(s) or Designated Member(s).</p> <p>Prior to IACUC review, each member of the IACUC must be provided: [2.31(d)(2)]</p> <ul style="list-style-type: none">• a list by the IACUC chair or his/her designee of the protocols to be reviewed• upon request, a copy of any protocol <p>NOTE: Any member of the IACUC may request</p>

and must be granted a full IACUC review of a protocol.

NO member of the IACUC or subcommittee may grant approval of a protocol UNTIL the entire IACUC has been informed that the protocol is to be reviewed and members are given the opportunity to read the protocol.

If an IACUC member has a conflicting interest with a protocol being reviewed, e.g., is personally involved, that member may **NOT**: [2.31(d)(2)]

- contribute to the constitution of a quorum
 - participate in the review or approval of the protocol
- NOTE: The member may provide information about the activity proposed in the protocol.

Full Committee Review

If a protocol is reviewed by the full IACUC: [2.31(d)(2)]

- the review must be conducted at a convened meeting with a quorum of the IACUC, AND
- approval must be by a majority vote of the quorum present

Subcommittee Review (Designated Reviewer)

The Designated Reviewer(s) has the authority to:

- approve a protocol
- approve a significant change(s) to a protocol
- require modifications to a protocol/significant changes
- request a full IACUC review

A protocol or significant change approved by the Designated Reviewer does **not** need to be reviewed and approved by the full IACUC.

NOTE: Only after all members of the IACUC have decided that a full committee review of a protocol is not necessary, can the protocol be reviewed by the Designated Reviewer.

Consultants	<p>The IACUC may confer with a consultant(s) or the principal investigator(s) to aid in understanding complex areas of a protocol. [2.31(d)(3)]</p>
	<p>Unless the consultant is a member of the IACUC, he/she must NOT: [2.31(d)(3)]</p> <ul style="list-style-type: none">• approve or withhold approval of a protocol• vote with the IACUC
Notification	<p>The IACUC must notify in writing the principal investigator(s) and the appropriate person(s) at the research facility (usually the Institutional Official or his/her designee) of its decision regarding the approval of the protocol. [2.31(d)(4)]</p>
	<p>If the IACUC decides to withhold approval or require modifications in the protocol, it must: [2.31(d)(4)]</p> <ul style="list-style-type: none">• include in its written notification the reason for the decision• give the principal investigator(s) an opportunity to respond in person or in writing
	<p>The IACUC may reconsider its decision to withhold approval if the principal investigator corrects the deficiencies in the protocol to the IACUC's satisfaction. Any change in the IACUC's decision must be documented in the minutes. [2.31(d)(4)]</p>
Annual Review	<p>The IACUC must review all active protocols at least once a year or more often, at the discretion of the IACUC. [2.31(d)(5)]</p>
	<p>The annual reviews should be documented in writing.</p>
Changes in Protocols	<p>The principal investigator(s) must inform the IACUC of any proposed significant changes to an approved protocol prior to the changes being implemented.</p>
	<p>The IACUC or a designated subcommittee must review and approve these changes. [2.31(c)(7)]</p>

Non-IACUC Review

Examples of significant changes include, but are not limited to:

- increase or decrease in the number of animals
- addition of a new species
- new procedure or change in a procedure being used
- change in pain classification of the procedure
- major/critical change in post-procedural pain management
- change from terminal to survival surgery
- change in personnel conducting the procedures

NOTE: If a proposed change to a protocol is minor, it may be handled administratively or at the annual review.

IACUC-approved protocols and IACUC-approved significant changes may be further reviewed and approved by officials of the research facility, such as: [2.31(d)(8)]

- the Institutional Official
- the Department Head
- Grants and Funding Committee
- Safety Committee
- Radiation Safety Committee

HOWEVER, these officials may NOT approve a protocol or significant change that has not been approved by the IACUC. [2.31(d)(8)]

NOTE: The research facility may have an internal policy requiring further approval of a protocol or significant change by a non-IACUC official for the protocol or significant change to be implemented BUT this is an internal issue, not an AWA/Animal Care issue.