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| <b>PROCEDURE<br/>FOR PROTOCOL<br/>REVIEW</b> | The IACUC is responsible for the review and approval of all proposed activities related to the care and use of animals. [2.31]  |
| <b>Procedure</b>                             | <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:<br/>[2.31(c)(6)]</p> <ul style="list-style-type: none"><li>• approve the protocol, OR</li><li>• require modifications in the protocol to secure approval, OR</li><li>• withhold approval of the protocol</li></ul> <p>The IACUC review must be by: [2.31(d)(2)]</p> <ul style="list-style-type: none"><li>• the full IACUC, or</li><li>• a sub-committee of at least one member of the IACUC designated by the IACUC chair who:<ul style="list-style-type: none"><li>▸ is qualified to conduct the review, and</li><li>▸ has the authority to:<ul style="list-style-type: none"><li>R approve</li><li>R require modifications in the protocol to secure approval, or</li><li>R request a full IACUC review of the protocol</li></ul></li></ul></li></ul> |

Prior to the review whether by the full committee or the subcommittee, **each** member of the IACUC must be provided:  
[2.31(d)(2)]

- a list by the IACUC chair or his/her designee of the protocols to be reviewed
- a copy of each protocol, if a full IACUC review is to be conducted
- a copy of any protocol requested, if the protocol is to be reviewed by the subcommittee

**NOTE:** Any member of the IACUC may request 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.

NOTE: Any IACUC member may request to be on the subcommittee reviewing a protocol and must be appointed to the subcommittee.

**NO** protocol-related animal activity may be started until the protocol has been properly approved.

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

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.

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| <b>Consultants</b>   | <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"><li>• approve or withhold approval of a protocol</li><li>• vote with the IACUC</li></ul>  |
| <b>Notification</b>  | <p>The IACUC must notify in writing the principal investigator(s) and the appropriate people at the research facility 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"><li>• include in its written notification the reason for the decision</li><li>• give the principal investigator(s) an opportunity to respond in person or in writing</li></ul> <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> |
| <b>Annual Review</b> | <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>  |

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| <b>Changes in Protocols</b> | <p>The principal investigator(s) must inform the IACUC of any proposed significant changes to an approved protocol <b>prior to</b> the changes being implemented.</p> <p>Examples of significant changes include, but are not limited to:</p> <ul style="list-style-type: none"><li>• increase or decrease in the number of animals</li><li>• addition of a new species</li><li>• new procedure or change in a procedure being used</li><li>• change in pain classification of the procedure</li><li>• change in post-procedural pain management</li><li>• change from terminal to survival surgery</li><li>• change in personnel</li></ul> <p>The IACUC or a designated sub-committee must review and approve these changes. [2.31(c)(7)]</p> |
| <b>Non-IACUC Review</b>     | <p>IACUC-approved protocols and IACUC-approved significant changes may be reviewed by officials of the research facility, such as: [2.31(d)(8)]</p> <ul style="list-style-type: none"><li>• the Institutional Official</li><li>• the Department Head</li><li>• Grants and Funding Committee</li><li>• Safety Committee</li><li>• Radiation Safety Committee</li></ul> <p>HOWEVER, these officials may <b>not</b> approve a protocol or significant change that has not been approved by the IACUC. [2.31(d)(8)]</p>  |