



Title: Full Committee and Designated Member Reviews

Policy Number: 015

Policy Intent: The purpose of this policy is to describe the process of reviewing and approving Animal Use Protocols and amendments through the IACUC office at TTU.

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1. General

One important function of the IACUC is to review, approve, require modification (to secure approval), or withhold approval of animal care and use activities and proposed significant changes regarding use of animals in ongoing activities.

2. Overview of Review Process

- A. The PI submits the protocol or amendment through the online Cayuse Animal Oversight system.
- B. The IACUC Coordinator completes a pre-review for general grammar and completeness of the protocol/amendment.
- C. Pre-review comments are returned to the PI to address then resubmitted to the IACUC Office.
- D. The IACUC Chair is sent the document to assign at least one member of the IACUC qualified to conduct the review.
- E. The IACUC Office sends the document out through the online system to all committee members with reviewer(s) identified. The animal use activity review process will follow Full Committee Review (FCR) or Designated Member Review (DMR) as outlined in detail below.
- F. Member comments are returned. The IACUC office will compile clarifications to ensure there is no redundancy etc. then send them to the PI to address. This process will continue until the PI has satisfied all reviewer comments to secure approval (or not).
- G. The IACUC shall notify the PI in writing of its decision to approve or withhold approval (with reasons of decision and give an opportunity to respond in person or writing) of animal use activities or of modifications required to secure approval.

3. Timing of Protocol Review

- A. Review route (full committee versus designated member review) may be determined initially by the IACUC Chair following review of the submitted Animal Use Protocol or amendment.



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- B. All protocols/amendments requiring full committee review should be submitted at least one week prior to an IACUC meeting to be reviewed and potentially approved at the upcoming meeting. If submitted less than one week prior to a regularly scheduled IACUC meeting protocols requiring full committee review it may not be reviewed until the next regularly scheduled meeting depending on the meeting agenda and review lead-time.

4. Full Committee Review

- A. Each IACUC member shall be provided with an electronic copy of all proposed research, teaching, and demonstration projects and subsequent amendments which constitute significant changes to an approved protocol. Any IACUC member may request full committee review of any University-associated project or project amendment at any time. Each IACUC member shall have three working days from dissemination to the IACUC membership to ask questions, comment, and/or call for full committee review. If any member feels that any protocol or amendment should go before the full committee, then its review must be deferred to the next full IACUC meeting.
- B. If full committee review of a protocol or amendment is requested, approval of those research projects may be granted only after review by a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- C. No member may participate in the full committee IACUC review or approval of a protocol or amendment in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
- D. The IACUC Chair will assign a primary reviewer to present the activities undergoing full committee review to the IACUC, or IACUC members can discuss collectively with direction from the Chair. Primary reviewers are encouraged to take the initiative to contact the investigator prior to the meeting for clarifications, additional information, or in anticipation of questions the IACUC may raise.
- E. The potential outcomes of full committee review of a protocol or amendment are:
 - 1) **Approve:** requires an affirmative vote by a majority of the convened quorum present.
 - 2) **Table:** In the event that substantive questions prevent final approval or moving forward with the review process, the committee can wait until the next meeting for revisions to be reviewed by the full committee.
 - 3) The committee members can also vote to **withhold approval** if they feel that the requirements of PHS Policy or other stipulations have not been satisfied.
 - 4) Alternatively, the committee can decide to handle the resubmission by **DMR subsequent to FCR** process upon a unanimous vote by convene quorum present. Committee members are given the opportunity to require that the requested modification(s) be brought before the next committee meeting.

Under no circumstances will animal work be permitted to resume or begin until final written IACUC approval is granted.

5. Designated Member Review



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- A. Each IACUC member shall be provided with an electronic copy of proposed research, teaching, or demonstration projects and subsequent amendments to approved projects that involve the care and use of vertebrate animals. All members have three days to review and make any comments or call to FCR. If no member calls to FCR then the designated member review (DMR) process continues.
The IACUC Chair will assign all protocols and amendments seeking significant change to an approved protocol to at least one IACUC member. DMRs will have five business days to approve, respond with clarifications or request full committee review. If any member feels that any protocol or amendment should go before the full committee, then its review must be deferred to the next full IACUC meeting. As stated above, any member can make the decision to send the AUP or amendment to full committee review at any time.
- B. A university veterinarian will review all protocols and amendments. In the event that more than one DMR is selected, the Chair will designate a primary DMR. No IACUC member may serve as a designated reviewer for any protocol or amendment in which the member has a conflicting interest (e.g. is personally involved in the project) except to provide information requested by the IACUC. Likewise, no veterinarian may serve as the veterinarian reviewer for any protocol or amendment in which the member has a conflicting interest (e.g. is personally involved in the project) except to provide information requested by the IACUC.
- C. The primary DMR assumes the responsibility for the full IACUC in reviewing the project and has the authority to approve, requiring modification (in order to secure approval), or request FCR. . Approval can then only be granted after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- D. Designated reviewers will be selected by the IACUC Chair from among all qualified IACUC members. Within one week of DMR assignment by the Chair and notification by the IACUC Coordinator, the designated reviewer(s) should request the IACUC Coordinator to seek clarification or pose questions to the PI if need for such clarification exists. Once questions and/or revisions have been resolved to the satisfaction of the designated reviewer(s), and a total of at least three working days have passed since the IACUC received notice of the submitted protocol, and no member of the committee has requested full review, the designated reviewer may:
- **approve**
 - **require modifications to secure approval**
 - **refer to full committee**
- E. In the event that the designated reviewer feels that approval should not be granted, the protocol or amendment will be reviewed by the full committee. Designated review may not result in withholding of approval. If a protocol or amendment is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision to grant approval. It is not acceptable to proceed with only a majority vote. They must all review identical versions of the protocol or amendment and if modifications are requested by any one of the reviewers then, the other reviewers must be aware of and agree to the modifications. If one or more of the DMRs disagrees, the DMRs may discuss amongst themselves for further clarification or refer to the full committee to review. The designated reviewer does not have the authority to withhold approval, but must, in such cases, refer the protocol or amendment for full-committee review.



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Under no circumstances will animal work be permitted to begin or resume until final written IACUC approval is granted.

6. Amendments to Approved Protocols

- A. Principal investigators (PIs) must inform the IACUC of any proposed significant changes (as described/defined below) to an approved protocol *prior to* the changes being implemented. The IACUC will only allow one amendment under DMR or FCR review for each protocol at a time. The IACUC, by full committee review (FCR) or through the designated member review (DMR) process, must review and approve these changes. In brief, significant changes include changes that have, or have the potential to have, a negative impact on animal welfare.
- B. Examples of significant changes include, but are not limited to:
- 1) from non-survival to survival surgery
 - 2) resulting in greater pain, distress, or degree of invasiveness
 - 3) In housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
 - 4) addition of a new species
 - 5) new procedure or change in a procedure being used (study objective)
 - 6) change in pain classification of the procedure
 - 7) major/critical change in post-procedural pain management
 - 8) change of Principal Investigator (PI)
- C. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant changes and may be approved administratively in consultation with a veterinarian authorized by the IACUC (Policy 18 Veterinary Administrative Approval for Significant Protocol Changes). Consultation with the veterinarian must be documented, and the veterinarian may refer any request to the IACUC for review for any reason, and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies, SOP's or drug formularies. This includes changes in:
- 1) anesthesia, analgesia, sedation, or experimental substances
 - 2) euthanasia to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#) (PDF - 1.4 MB)
 - 3) duration, frequency, type, or number of surgical procedures performed on an animal
- D. If a proposed change to a protocol is minor, it may be handled administratively. Examples of minor changes include, but are not limited to:
- 1) addition or deletion of personnel
 - 2) change in title
 - 3) change in funding source
 - 4) change of location
 - 5) correction of typographical errors
 - 6) correction of grammar
 - 7) contact information updates
 - 8) increase animal numbers by the maximum of 10% from the original protocol

7. Notification of Review Outcome



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- A. The IACUC will notify PIs in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. The IACUC procedures to notify PIs and the University of its decisions regarding protocol review are as follows:
 - Upon completion of the review process, each PI receives a written notification of review decisions (approval, clarifications required, or table) and whether any special monitoring provisions will be required.

8. Review of DMR at Full Committee Meetings

- A. At each regularly scheduled monthly IACUC meeting, members will be provided with a list of protocols and amendments to previously approved protocols that have been processed via the DMR process since the previous IACUC meeting. Full written descriptions of the protocols and amendments are accessible in the online system or will be made available to IACUC members upon request. During the IACUC meeting, the Chair will review DMR approvals, as well as protocol terminations received by the IACUC office since the last meeting. Each IACUC member will have the opportunity to review DMR actions, ask questions and express concerns regarding any approved protocols, amendments, etc.

9. References

- United States Department of Agriculture, 9 CFR Parts 1, 2, and 3.
- PHS Policy on the Care and Use of Laboratory Animals, OPRR, 1996.
- National Institutes of Health http://grants.nih.gov/grants/olaw/significant_changes.htm
- AAALAC Accreditation Guidelines: <http://www.aaalac.org>
- 8th Edition: The Guide for the Care & Use of Laboratory Animals

10. Tables

What Changes Qualify for Which Reviews?

FCR or DMR	VVC	Admin. Review
From non-survival to survival surgery	Anesthesia, analgesia, sedation or experimental substances	An increase in previously approved animal numbers
Resulting in greater pain, distress, or degree of invasiveness	Euthanasia to any method approved in the AVMA Guidelines for Euthanasia of Animals	Correction of typographical errors
In housing and or use of animals in a location that is not part of the animal	Duration, frequency, type, or number of currently approved	Correction of grammar



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program overseen by the IACUC	procedures performed on animal	
In species		Contact information updates
In study objectives		Change in personnel, other than the PI
In PI		
That impacts personnel safety		

*IACUC-reviewed and-approved policies (e.g., guidance documents, standard operating procedures, drug formularies) must be in place.