



IACUC Policy 15: Full Committee and Designated Member Reviews

Policy Purpose: 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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| Revision No: 03 | Replaces: 02 | Date in effect: 3/5/2020 |
| Authors: Paul Stonum Phil Smith Karin Fritz | | Responsible faculty: (Signature/Date)  Phil Smith 3/5/2020 |

1. Timing of Protocol Review

- a. All protocols/amendments must 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 will not be reviewed until the next regularly scheduled meeting.
- b. Review route (full committee versus designated member review) will be determined initially by the IACUC Chair following review of the submitted Animal Use Protocol (AUP) or amendment

2. 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. Each IACUC member shall have three working days from the time the electronic AUP or amendment is disseminated to the IACUC membership to ask questions, comment, and/or call for full committee review. If any member feels that any AUP or amendment should go before the full committee, then its review must be deferred to the next full IACUC meeting. Any member can determine that any AUP or amendment be called to full-committee review at any time.
- b. If full committee review of an AUP 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 an AUP 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 AUP or amendment 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. There are three potential outcomes of full committee review of a protocol or amendment:
 - **Approval:** requires an affirmative vote by a majority of the convened quorum present.



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- **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. 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.
- Alternatively, the committee can decide to handle the resubmission by the **DMR process**. 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.

3. Designated Member Review

- a. Each IACUC member shall be provided with an electronic copy of proposed research, teaching, and demonstration projects and subsequent amendments to approved projects that involve the care and use of vertebrate animals. As stated above, any IACUC member may request full committee review of any University-associated project or project amendment utilizing vertebrate animals. The IACUC Chair will assign all AUPs and amendments seeking significant change to an approved protocol to a designated member reviewer (DMR) or reviewers. DMRs will have four business days to respond with clarifications to the IACUC Coordinator, and the lead DMR will have five business days to respond with clarifications. If any member feels that any AUP or amendment should go before the full committee, then its review must be deferred to the next full IACUC meeting. 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 AUPs and amendments. In the event that more than one DMR is selected, the Chair will designate a lead DMR. No IACUC member may serve as a designated reviewer for any AUP 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 AUP 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 DMR(s) assume the responsibility for the full IACUC in granting approval, requiring modification, or sending the AUP or amendment for full review. However, at any point during the review process, any IACUC member (including DMR(s)) may request a full committee review of any AUP or amendment at which point the DMR process immediately ceases and the AUP or amendment is placed on the next full committee meeting agenda.
- d. Designated reviewers will be selected by the IACUC Chair from among all IACUC members, but consideration should be given to expertise and current workloads. 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**
 - **approve with modifications**
 - **refer to full committee**
- e. In the event that the designated reviewer feels that approval should not be granted, the AUP or amendment will be reviewed by the full committee. Designated review may not result in withholding of approval. If an AUP or amendment is assigned 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 AUP or amendment and if modifications are requested by any one of the reviewers



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then, the other reviewers must be aware of and agree to the modifications. If one or more of the DMRs disagrees, then the AUP or amendment must be referred to the full committee to review. The designated reviewer does not have the authority to withhold approval, but must, in such cases, refer the AUP or amendment for full-committee review.

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

4. **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:
 - from non-survival to survival surgery
 - resulting in greater pain, distress, or degree of invasiveness
 - In housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
 - addition of a new species
 - new procedure or change in a procedure being used (study objective)
 - change in pain classification of the procedure
 - major/critical change in post-procedural pain management
 - 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:
 - anesthesia, analgesia, sedation, or experimental substances
 - euthanasia to any method approved in the [AVMA Guidelines for the Euthanasia of Animals](#) (PDF - 1.4 MB)
 - 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:
 - addition or deletion of personnel
 - change in title
 - change in funding source
 - change of location
 - correction of typographical errors
 - correction of grammar
 - contact information updates
 - increase animal numbers by the maximum of 10% from the original protocol



5. Notification of Review Outcome

- 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. Records of communication are maintained within the IACUC protocol files.
 - Upon completion of the review process, a copy of the meeting minutes is provided to the IO. This informs the IO of all actions taken by the IACUC.

6. Review of Designated Reviews at Full Committee Meetings

- a. At each regularly scheduled monthly IACUC meeting, members will be provided with a list of AUPs and amendments to previously approved protocols that have been processed via the designated review process since the previous IACUC meeting. Full written descriptions of the AUPs and amendments will be made available to IACUC members upon request. During the IACUC meeting, the Chair will review DMR approvals of AUPs and amendments, as well as annual review and progress reports and 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 AUPs, amendments, annual review and progress reports, etc.

7. References

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

What Changes Qualify for Which Reviews?@

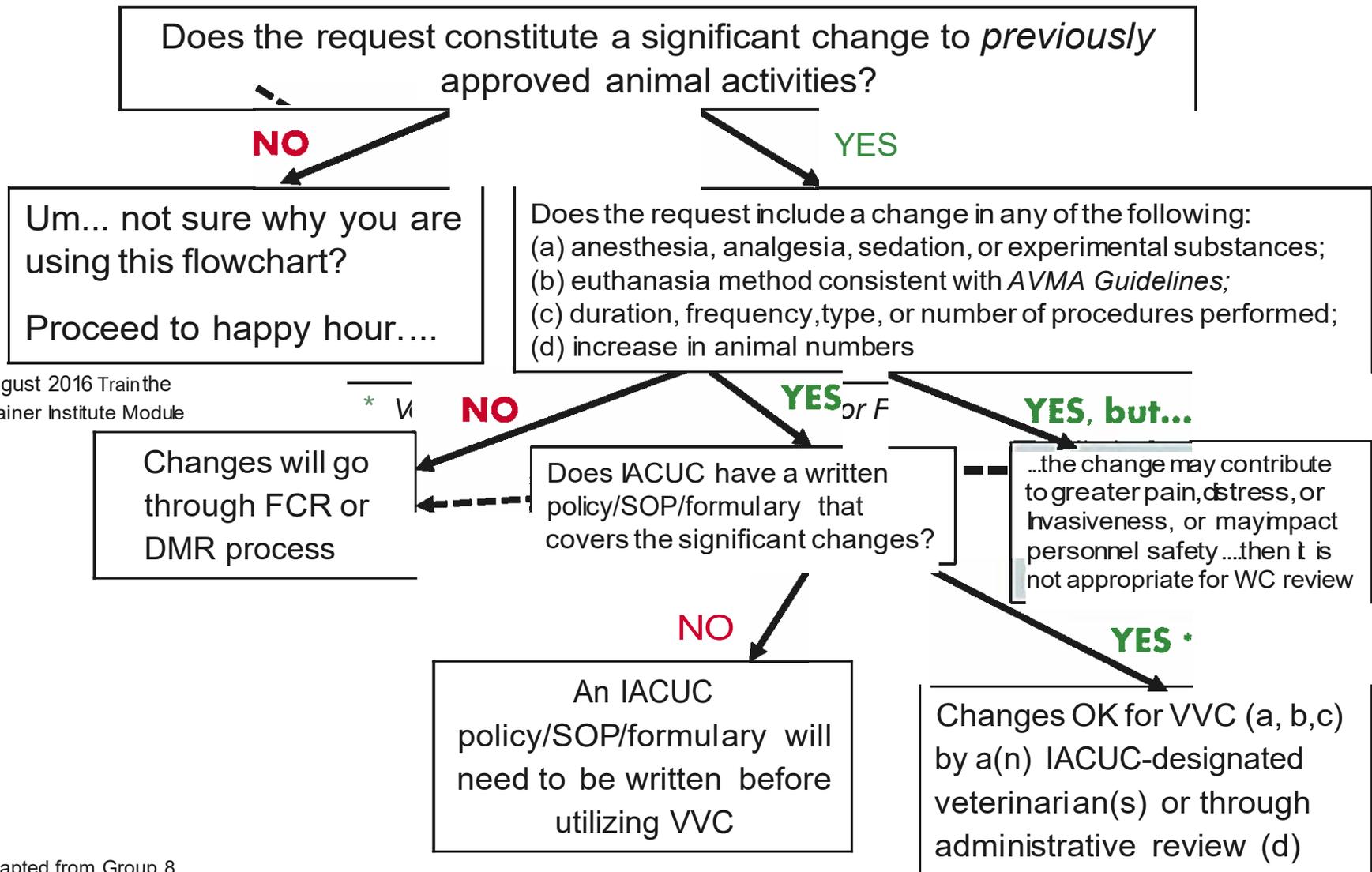
| FCR or DMR | WE | Admin. Review |
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| From nonsurvival to survival surgery | Anesthesia, analgesia, sedation or experimental substances | An increase in previously approved animal numbers* |
| Resulting in greater pain, distress, or degree of invasiveness | Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals | Correction of typographical errors |
| In housing and or use of animals in a location that is not part of the program overseen by the IACUC | Duration, frequency, type, or number of procedures performed on an animal | Correction of grammar |
| Species | | Contact Information updates |
| Study objectives | | Change in personnel, other than the Principal Investigator |
| In Principal Investigator | | |
| That impact personnel safety | | |

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

Significant Changes

@Adapted from Group 5, Train the Trainer Institute, October 2016

Significant Changes Process Flow



August 2016 Train the Trainer Institute Module

Adapted from Group 8,