



**Animal Facility SOP 48.1
IACUC Procedures for Protocol Review**

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Reviewed by	

Protocol Review Procedures

Protocols may either be reviewed by the full committee or by the designated member review process. Morgan uses full committee review at a convened meeting for initial review of protocols. The designated review process is often used subsequent to the initial review to ensure that changes requested by the IACUC are made appropriately.

Protocols are received by the IACUC coordinator or IACUC Chair and forwarded to the IACUC veterinarian for pre-review. The veterinarian provides comments and suggestions to the principal investigator. Once revised protocols are received, the Coordinator or IACUC chair distributes them to committee members by email and schedules a meeting of the IACUC. Committee members with conflicts of interest (e.g., if they are on the protocol) leave the room during discussion and do not take part in the vote, a quorum (simple majority of all the voting members) must be met without that committee member. The PI may answer questions from the committee about their protocol. Committee review is primarily to assure the health and welfare of the animals and does not include scientific review unless it directly impacts the health and welfare of animals. During the meeting, members discuss submitted protocols and a majority of the quorum present can vote to determine the outcome of the review. For voting, the Chair calls for recommendations from a member and a second, and the outcome is determined by a show of hands. The IACUC may approve, require modifications to secure approval, or disapprove reviewed protocols. Any minority views are recorded in the minutes. The IACUC decides at the time of review whether to use the DMR process (and then the resubmitted protocol will be sent to all members to determine if anyone requests FCR) or to determine to use the FCR process as the modifications are sufficiently complex.

Designated Review Process

The IACUC Chair assigns a designated reviewer who has the authority to recommend approval of the modified protocol to the Chair. The designated reviewer may request additional changes of the investigator to fulfill the changes originally requested by the IACUC. If the investigator is not able to make requested changes, the reviewer will refer the protocol back to the IACUC for full committee review. The investigator may be asked to answer questions at that meeting. In all cases of designated review, the IACUC coordinator provides copies of the modified protocol to all committee members by email. Any committee member may call for review at a convened meeting within 48 hours of receiving the protocol. If there are no requests for full committee review at a convened meeting and the designated reviewer determines that the modified proposal contains the changes requested by the IACUC, the protocol is approved by the Chair. There are three outcomes of designated member review: 1) approve, 2) require modification to secure approval; or 3) revert back to full committee for review of the protocol. The IACUC Chair or coordinator records the outcome of the review and notifies the investigator. There are no additional special procedures for expedited review. All protocols are reviewed at a convened meeting or by designated review.

- 7) Review and approve, require modifications to secure approval, or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C.
- Proposed changes are assigned as minor or significant. Minor changes may be approved by the Chair or his or her designate and reported at the next IACUC meeting. Significant changes must be reviewed by full committee review at a convened meeting conducted as described in part III.D.6. Significant changes include: a change from non-survivable to survival surgery; an increase in pain, distress, or degree of invasiveness; housing outside locations overseen by the IACUC; change in species; change in study objectives; change in PI; or any change that impacts personnel safety.

Corrections to spelling and grammar and format plus changes to personnel other than the PI may be approved administratively and do not require committee review.

- 8) The IACUC notifies investigators and the Institutional Official in writing of the IACUC decision within one week of the review decision.
- If modification is required, the modified protocol is resubmitted by the investigator to the IACUC coordinator for designated review or full committee review as described above.
 - If a protocol is disapproved, the investigator is notified of the reasons for disapproval in writing. The investigator may request to appear at a convened meeting of the full committee to answer questions and clarify the reasons for disapproval. If the committee determines during discussion that a new protocol would fulfill the requirements for approval, that protocol must be reviewed at a convened meeting of the full committee and not by designated review. Any further modifications subsequent to that may be by FCR or DMR as determined by the committee.
 - Approval is sent in writing to the Investigator and IO within one week of the decision.
- 9). Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

- Annual Review of Protocols occurs yearly. The IACUC administrator distributes a form to the investigator prior to the anniversary of the approval date. The form requests:
- The number of animals used for a given protocol to date.
- Any unexpected adverse events (not foreseen/described in protocol)
- In addition, any IACUC member may request observation and review of procedures by the veterinarian or committee member (s).

Prior to the three-year expiration date, protocols must be resubmitted for complete full committee review. The IACUC coordinator or Chair sends a reminder to the investigator three months prior to expiration of the original protocol indicating that a new protocol must be submitted if work is to continue. If the same protocol is being continued, any prior amendments must be incorporated into the new protocol. The protocol must be reviewed by the full committee and approved prior to the expiration date to allow uninterrupted work to continue. If a new protocol is not approved prior to the expiration date, all work must cease, and any animals on the existing protocol must be transferred to a holding protocol under the control of the veterinarian until the new protocol is approved.

