

**University of Texas at Austin
 Institutional Animal Care and Use Committee**

IACUC Procedure # 4.0

Title	Protocol Review and Notification Procedures		
Date of Approval	11-12-18		
Date of Last Revision	07-13-2020	Version	2.0

In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with PHS Policy, AWRs, and the applicable US Government Principles. Since the PHS Policy further requires that the provisions of the Guide apply, there are many other aspects of research that an IACUC should review, such as food and water deprivation, use of noxious stimuli, and physical restraint. The Guide provides useful guidance on these and other practices.

The procedural review requirements of the PHS Policy or the AWRs take precedence even though they may differ from some commonly used parliamentary procedures. The Institution may develop its own meeting procedures as long as the procedures do not contradict or are not inconsistent with the requirements of the PHS Policy or the AWRs.

If a proposed activity may cause more than momentary or slight pain or distress to animals, the AWRs specifically require investigators to consult with the Attending Veterinarian (AV) or his or her designee during protocol development. Investigators are encouraged to receive a veterinary consultation for procedures with pain/distress categories D and E prior to protocol submission.

The PHS Policy and AWRs recognize two methods of protocol review: Full Committee Review (FCR) and Designated Member Review (DMR). These review methods pertain to review of initial protocols as well as to review of proposed significant changes in previously approved protocols.

The investigator must actively participate in the review process in order to prevent unfair use of reviewer time. Investigators will be reminded when they have not responded to Committee comments. Failure to respond may lead to administrative action including withdrawal or non-approval of the submission.

The methods of IACUC review are as follows.

1. **Full Committee Review (FCR)** - Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that proposals reviewed by the full committee must receive the approval vote of a majority of the quorum present in order to receive approval.

At least three (3) business days prior to a meeting, the Office of Research Support and Compliance distributes copies of the protocols being presented or any other items of discussion to each IACUC member, including alternate and non-voting member(s). Protocols are assigned a primary reviewer, who at the meeting orally presents the protocol to the rest of the committee for review

and discussion. In addition, each protocol is assigned to a veterinarian to conduct an in-depth review of the protocol. The Committee then votes on protocol approval. A simple majority vote of the members present is required for approval.

The Committee has the authority to approve, require modifications in (to secure approval), disapprove, or table (defer until future meeting) any proposed activity. In many cases, the Committee finds the protocols approvable on certain conditions and votes to allow the protocol to be reviewed, and approved, using the Designated Member Review (DMR) process, as described in #2 of this procedure. Approval of the change from FCR to DMR must be unanimous (of a quorum of members) and is recorded in the minutes. 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 approval is granted.

Primary reviewers can also take the initiative to contact the investigator prior to the meeting for clarifications, additional information, or in anticipation of questions the IACUC may raise. Primary review differs from designated member review, which delegates authority to approve a proposal to one or more members.

2. **Designated Member Review (DMR)** - To utilize designated member review (DMR), each IACUC member must be provided with, at a minimum, a list of the proposed research protocols or proposed significant changes to previously approved protocols prior to the review. Written descriptions of the research proposals must be made available to IACUC members upon request. Each IACUC member is provided a copy of the protocol document from the Office of Research Support and Compliance. Committee members are given a five (5)-business day member consideration period to review the protocol document and respond either allowing the DMR to review the protocol or to hold the protocol for the next FCR. Members are reminded that failure to respond within the member consideration period is considered as approval to use DMR for review. At the end of the member consideration period if no member calls for full committee review, ORSC staff sends the protocol to DMR for review. If any one member votes to hold the protocol until the next IACUC meeting, then the protocol is placed on the agenda for the next available IACUC meeting. If all members vote to allow the DMR to review the protocol before the end of the member consideration period, then ORSC staff may send the protocol to DMR for review.

The IACUC Chair (and in his/her absence, the Vice-Chair) designates one or more qualified members to review the proposal (or proposed amendment or annual renewal). These designated member(s) have authority to approve, require modifications in (to secure approval), or request full committee review. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

3. **Administrative Review (AR)** - While Federal regulations allow for two types of review of animal use protocols (FCR and DMR), guidance from the Office of Laboratory Animal Welfare (OLAW) grants authority for a small number of items to be administratively approved, i.e., Administrative Review (AR).

AR will be utilized to review non-significant changes (see Policy 4.3) and continuing review applications that do not contain significant changes or USDA-covered species.

4. **Veterinary Verification and Consultation (VVC)** - The IACUC has pre-approved methods, materials, and reference resources to support the expedited approval of certain significant changes in protocols. Conditions are described in IACUC Policy # 4.4 (Veterinary Verification & Consultation and Protocol Changes).

4.0.1 Use of Outside Expert Consultants- If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal, it may bring in outside expert consultants to provide information. Such consultants will not have a conflict of interest with the research activity and may not vote on any matters pertaining to the protocol. In all cases, the onus should be on the investigator to justify and explain his or her proposed experiments to the satisfaction of the IACUC.

4.0.2 Notification of Review Outcome- The IACUC will notify investigators and the University 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 as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the University of its decisions regarding protocol review are as follows:

- Upon completion of the review process, each Principal Investigator receives a written notification of review decisions (approved, modifications required in (to secure approval), approval withheld, or tabled) 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.

Approval Date	Major Change(s) Approved
07/13/2020	<ul style="list-style-type: none"> • Clarification statement added that investigators are encouraged to receive a vet consultation for category D/E procedures prior to protocol submission. • Statement that a quorum of IACUC members is needed for DMR voting was removed. • VVC review method and reference to VVC policy added.