

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
Policy #7
DESIGNATED REVIEWS

In concurrence with
TTUHSC El Paso Assurance #D19-01056
and Federal Regulations and Guidelines

Purpose

Multiple protocol review methods fulfill USDA and PHS requirements depending on the circumstances, these include:

- Full Committee Review (FCR),
- Designated Member Review (DMR),
- Veterinary Verification and Consultation (VVC) and
- Administrative Approvals of Amendments.

This policy describes the process for DMR. The other processes for protocol approval (FCR, VVC and administrative approval) are described in separate policies, referenced below.

Overview

Ordinarily, for FCR the IACUC members (during a convened meeting) review and vote on the acceptability of animal use protocols submitted by a principal investigator (PI). For DMR, at least one member of the IACUC shall review those protocols and have the authority to approve, require modifications (to secure approval) or request FCR. DMR may be used to secure approval for (1) new or renewing full protocols and amendments that require immediate evaluation, (2) Annual Status Reports (ASR), (3) simple strain changes that do not affect the intent of the protocol or animal welfare, or (4) protocols that have first undergone FCR.

Requesting DMR to Expedite Review

This section will describe the DMR process as applied to submissions of either full protocols or amendments that require immediate evaluation. The use of this process must be justified.

- a. The PI shall submit an appropriately completed IACUC protocol form and a request for DMR to the IACUC staff. The request must contain a justification for conducting a DMR.
- b. The IACUC staff will notify the IACUC Chair (or designee) of the request. The Chair will determine whether or not to approve DMR. The IACUC Chair (or designee) will advise the PI at this step only if the DMR request will not be forwarded to IACUC members.
- c. If the DMR request is approved by the chair, the Chair (or designee) will notify the IACUC staff to poll the IACUC members. Each IACUC member will have access to the item submitted for IACUC consideration, the request for DMR, and any other necessary information concerning the proposed research project for their consideration about a DMR. Each IACUC member will have an opportunity to call for FCR of the protocol rather than the DMR.

IACUC members must respond to the request within 72h of initiation of the poll. If an IACUC member has not responded within that time, the lack of a response will indicate their approval of the request for DMR.

Records of the polling will be maintained within the IACUC office. The IACUC staff will notify the investigator of the IACUC's decision only if a DMR will **not** occur.

- d. If the results of the poll support the DMR, the Chair (or designee) will initiate the DMR process. At least one member of the IACUC will be assigned by the Chair (or designee) to review the protocol and have the authority to approve, require modification to secure approval or request FCR prior to the previous approval's anniversary date. If there are multiple designated reviewers, there must be unanimous approval. If agreement is not unanimous, the protocol will automatically go to FCR.
- e. Once the DMR process is complete, the designated reviewer will notify the IACUC staff of the review decision and any recommendations. The IACUC staff will notify the IACUC Chair and investigator of the designated member's decision and of any recommendations made.
- f. The IACUC members will be notified of the results of the DMR at the next convened IACUC meeting. All deliberations and results will be documented in the IACUC minutes.

DMR for Annual Status Reports

This section will describe the DMR process as applied to the review of Annual Status Reports.

The Annual Status Report (ASR) is a crucial element of the Institutional Animal Care and Use Committee's (IACUC) assessment of the handling of animals. The ASR provides the Committee with a status report on animal usage within the previous twelve-month period, and a plan for animal research during the next twelve-month period. In order to remain compliant with USDA rules, those protocols using USDA-regulated species must have the ASR submitted and approved by the one-year anniversary date of the last approval.

The TTUHSC El Paso IACUC goes one step further and requires all protocols to submit an ASR whether they have USDA-regulated species or not, as a method of Post Approval Monitoring (PAM). As calendar dates for IACUC meetings are based on the second Friday of a given month, it is theoretically possible that the deadline for receipt of an ASR might pass prior to a meeting of the full committee. Therefore, the deadline for submission might be a full month prior to the usual deadline to avoid a lapse of approval.

In order to facilitate this process, the IACUC will routinely review ASRs without amendments by DMR. One member of the IACUC will be assigned by the Chair (or designee) to review the ASR and have the authority to approve, recommend FCR, or require modification to secure approval prior to the previous approval's anniversary date. All ASRs will be posted to an IACUC agenda and documented in the IACUC minutes. Additionally, all study documents will be available (in iRIS) for every IACUC member to review. ASRs with amendments will be assigned for FCR.

DMR for Simple Animal Strain Changes

In certain circumstances, the PI may wish to change the animal strain used in an IACUC protocol in a manner that does not change the purpose of the study, or impact animal welfare. Examples include changes between "wild-type" mouse or rat strains with a different genetic background (such as changing C57BL/6 to BALB/c), or the use of a different strain with the same gene knocked out.

In order to expedite this process, the IACUC will routinely assign such strain change amendments for DMR. One member of the IACUC will be assigned by the Chair (or designee) to review the strain change amendment and have the authority to approve, recommend FCR, or require modification to secure approval.

All strain change amendments will be posted to an IACUC agenda and documented in the IACUC minutes. Additionally, all study documents will be available (in iRIS) for every IACUC member to review.

DMR following Full-Committee Reviews

This section will describe the DMR process as applied to protocols that have first undergone FCR (post-committee review process).

Following the presentation and associated discussion of a protocol, amendment or ASR at FCR, the IACUC members who are present will vote to either a) approve, b) require modifications to secure approval, or c) withhold approval. Modifications of these items may be designated as either minor (modifications that do not involve animal health or welfare) or major (modifications that do involve animal health or welfare). Minor modifications will be confirmed by DMR or processed administratively, as decided in the FCR meeting (see Policy #13). For major modifications, the protocol will be discussed at the next FCR meeting.

Specifically, the DMR will occur subsequent to FCR, if approved unanimously by members at the meeting in which the matter is discussed. At least one member of the IACUC will be assigned by the Chair (or designee) to review the amendment (typically the same reviewers assigned for this initial review) and will have the authority to approve, require modification to secure approval or request FCR. If any member calls for a second FCR to consider the modifications further, then the DMR process will not be followed. Such modifications will only be reviewed and approved by FCR.

DMR in Special Circumstances

While the TTUHSC El Paso IACUC prefers that protocol reviews be conducted at a full committee meeting, the IACUC office may, during times of extended shut downs of the university under special situations, including pandemic, war and inclement weather, when the committee cannot make quorum, or other circumstances when FCR is impractical, switch to full DMR review of all protocols, at the discretion of the IACUC chair. This review would occur according to the procedure specified for expedited review (above). Full committee review would commence on the normal schedule when the special circumstance has passed.

Related policies

Investigators must comply with all other institutional policies at TTUHSC El Paso and Federal Guidelines. This list includes, but is not limited to, the following:

- IACUC policy #13: Protocol approval, implementation, review and amendment processes
- IACUC policy #20: Administrative Approval of Amendments
- IACUC policy #27: Veterinary Administrative Approval for Significant Protocol Changes (VVC)
- IACUC policy #28: Standard Extension During Emergencies