DESIGNATED REVIEWS

Background: Only two protocol review methods fulfill USDA and PHS requirements—full committee review (FCR) and designated member review (DMR). 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 (I) new or renewing full protocols and amendments that require immediate evaluation, (II) Annual Status Reports (ASR), or (III) protocols that have first undergone FCR.

I. 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 grant the request for a 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 granted, 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.

D. IACUC members must reply to the IACUC staff within 96 hours 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.

E. If the results of the poll support the DMR, the Chair (or designee) will initiate the DMR process by appointing a subcommittee consisting of not less than one designated reviewer and the Institutional Veterinarian or another veterinarian. The subcommittee is authorized to review and approve, require modifications, or...
request FCR of the submitted item.

F. 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.

G. The IACUC will be notified of the results of the DMR at the next convened IACUC meeting.

II. 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 addition, 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 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 by DMR. All ASRs will be posted to an IACUC agenda. Additionally, all study documents will be available (within iRIS) to every IACUC member for review. Any IACUC member may call for FCR prior to finalization of the agenda. At least one member of the IACUC will be assigned by the Chair (or designee) to review the ASR 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. All deliberations and results will be documented in the IACUC minutes.

III. 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). While minor modifications will be confirmed by DMR and processed administratively (see Policy #13), approval of required major modifications will be delayed until appropriate changes are approved via DMR.

Specifically, the DMR will occur subsequent to FCR, if approved unanimously by members at the meeting at which the matter is discussed. 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.