



University of Maryland College Park Animal Care and Use Standard

Use of Designated Member Review (DMR)

Purpose: This standard describes the Designated Member Review process for animal use protocols and amendments.

Background: Proposed activities involving animals are reviewed as efficiently as possible to support the research or teaching effort and funding agency needs. Animal activities may not begin until approved by the Institutional Animal Care and Use Committee (IACUC); however, the IACUC staff provides extensive support to facilitate the review and approval process. Most Animal Study Protocols (ASP) undergo full committee review (FCR) at a convened meeting of the IACUC. An alternate method of review and approval for ASPs and proposed significant changes to ASPs may be used at the discretion of the IACUC Chairman. Designated member review (DMR) provides shorter review timelines for investigators because the review occurs outside a convened meeting. This also decreases the time investment by all members of the IACUC while still providing a robust review.

Standards: Designated Member Review is conducted by a subset of the IACUC members and occurs outside a convened meeting. The DMR process is generally used to review and approve proposed significant changes to ASPs. A DMR subsequent to FCR may be used, with unanimous vote of the quorum present at a meeting, to review and approve ASPs that require modifications to secure approval. An ASP may undergo DMR at the IACUC Chair's discretion. The use of DMR to review full ASPs may occur when the ASP involves only extramural work approved by the other institution's IACUC; under extenuating circumstances that may warrant review and approval prior to the next convened meeting; or under other circumstances deemed appropriate by the IACUC Chairman. The IACUC Chairman will appoint one or more qualified reviewer(s) for DMR. Any IACUC member may, at any time, request a FCR of ASPs or proposed significant changes to ASPs that have been sent to DMR. The use of DMR subsequent to FCR to review proposed animal use activities is acknowledged and approved by ALL IACUC members. This process will be explained to new committee members during IACUC member orientation.

Methodology:

1. Use of DMR for ASPs and proposed significant changes to ASPs:

a. IACUC staff will send a list of all proposed animal use activities identified for DMR and the corresponding reviewer(s) to the entire IACUC (full written descriptions are available through IRB.net). The message will include a reasonable date by which IACUC members should request FCR if desired.

b. IACUC members generally have three (3) calendar days in which to respond with a request for FCR.

1) If a member requests FCR, the ASP or proposed significant change will be reviewed at the next convened IACUC meeting.

2) If there are no requests for FCR, review and approval proceeds by DMR.

c. All designated reviewers must review the same version of the document.

d. Possible outcomes of DMR include unanimous approval by all designated reviewers;

request for modifications to secure approval (all reviewers must agree on the requested modifications); or request for FCR.

1) If modifications are requested to secure approval, the original designated reviewers will review the modified document.

2) If FCR is requested for any ASP or proposed significant changes to an ASP, that ASP may only be approved after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

d. Once an ASP or proposed significant change is approved, animal use may begin consistent with the approved activity.

2. Use of DMR subsequent to FCR for ASPs or proposed changes to ASPs requiring modifications to secure approval:

a. Following discussion of an ASP or proposed significant change to an ASP at a convened meeting of quorum of the IACUC, the committee may vote to review the modified ASP or proposed change by DMR if modifications are required to secure approval.

1) If the IACUC determines that modifications are required to secure approval, the committee may, by **unanimous vote of the quorum present**, agree to send the revised protocol to DMR for final review and approval.

2) The DMR subsequent to FCR will be conducted as described for DMRs above; however, any member may request to see the revised document and/or request FCR.

b. Once an ASP or proposed significant change is approved, animal use may begin consistent with the approved activity.