

<b>IACUC SOP:</b>	<b>Statement on Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee (FCR)</b>	
<b>SOP#107.00</b>	<b>IACUC Approval: 12/16/2021</b>	<b>IO Approval: 6/3/2022</b>

## Background

The PHS Policy regarding protocol review by IACUCs provides these requirements must be met when conducting FCR, DMR, or DMR subsequent to FCR. Only two methods of IACUC review are allowed by the Policy ([PHS Policy IV.C.2](#)): FCR by a convened quorum of the members of the IACUC, or DMR by one or more members. Regardless of the review method used, animal activities can only be initiated after a proposed research protocol has been approved. PHS Policy does not allow for “approved pending modification” and does not recognize this approval designation.

To conduct DMR, the following conditions must be met: all members of the IACUC must be given an opportunity to call for FCR, either for each individual protocol or by previously established written standard procedure, as described above. If, and only if, no member requests FCR, the protocol may be reviewed by one or more qualified members appointed by the Chair. ([PHS Policy IV.C.2](#))

DMR may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. DMR may not result in withholding of approval. ([PHS Policy IV.C.2](#))

If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications.

The specific method of review for each protocol should be documented, along with the outcome of the review in the IACUC meeting minutes. ([PHS Policy IV.E.1b-c](#))

Several OLAW FAQs also address these issues. See [http://grants1.nih.gov/grants/olaw/faqs.htm - proto\\_3](http://grants1.nih.gov/grants/olaw/faqs.htm - proto_3) and [http://grants1.nih.gov/grants/olaw/faqs.htm - proto\\_4](http://grants1.nih.gov/grants/olaw/faqs.htm - proto_4).

## IACUC Actions Following Full Committee Review (FCR)

The research community has raised questions regarding the action an IACUC may take when the committee reviews a proposed animal study at a convened IACUC meeting and determines that the study protocol does not meet its standards for approval.

When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

1. If **all** members of the IACUC **are** present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review (DMR) or returned for FCR at a convened meeting.
2. If **all** members of the IACUC **are not** present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:
  - a. All IACUC members agree **in advance in writing** that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
  - b. In order to conduct reviews by DMR subsequent to FCR, the institution should specify its intention to conduct reviews in this manner in its Assurance with OLAW. (IACUCs that newly elect to utilize a standard operating procedure for DMR subsequent to FCR should provide information about this program change to OLAW in the next Annual Report.)
3. If all members are not present **and** the IACUC lacks written standard procedures as described above, the committee has the option to vote to return the protocol for FCR at a convened meeting or to employ DMR. If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted **only** if all members of the committee have had the opportunity to request FCR and none have done so. ([PHS Policy IV.C.2](#))

If an IACUC uses DMR, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date must be reported to OLAW as a serious noncompliance with the PHS Policy. ([PHS Policy IV.F.3](#))

Members concur with the adoption of the SOP by signing their name below:

Name	Signature & Date

**History:**

Version 01 - Initial Approval: 12/16/21; IO Approved 6/3/2022