



Institutional Animal Care and Use Committee (IACUC)

Policy #4: Policy for the Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR)

I. Background

The Public Health Service (PHS) Policy regarding protocol review by IACUCs is reviewed here and is adopted and implemented by Villanova's IACUC. These requirements must be met when conducting FCR, DMR, or DMR subsequent to FCR. Only two methods of IACUC review are allowed by the PHS 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.

II. To conduct DMR for a protocol, the following conditions must be met

- A. 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. The Villanova University IACUC written standard procedure is described below.
- B. If, and only if, no member requests FCR, the protocol may be reviewed by one or more qualified members appointed by the IACUC Chair. ([PHS Policy IV.C.2](#)).
- C. Initial review of protocols with Pain and Distress procedures at D-level (per [Guidelines for Assigning Pain and Distress Categories](#)) will be reviewed by FCR. Subsequent amendments can be reviewed by DMR with a veterinarian assigned to review unless the PI is modifying the D-level procedures, requesting additional D-level procedures, or an increase in animal use is proposed.

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](#))

III. If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision

- A. 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. If designated reviewers are unable to reach a unanimous decision, they must notify the IACUC Chair and refer the protocol for FCR.
- B. 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 <https://grants.nih.gov/grants/olaw/faqs.htm#615> and <https://grants.nih.gov/grants/olaw/faqs.htm#616>.

IV. If a protocol receives FCR and the IACUC determines the protocol does not meet its standards for approval, then:

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

A. If all members of the IACUC are PRESENT at a meeting:

1. The IACUC 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.

B. If all members of the IACUC are NOT PRESENT at a meeting:

The IACUC may use DMR subsequent to FCR according to the following stipulations:

1. 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.
 2. 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.)
- C. If all members are not present AND the IACUC lacks written standard procedures as described above:**
1. The IACUC 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](#))

V. References

OLAW notice # <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-035.html>



Office of Research Protections
Institutional Animal Care and Use Committee

With this signature, as a member of VU IACUC, I have read the policy, received a copy, and affirm my agreement to send the protocols to DMR after an FCR has determined that the protocol is not ready for approval.

| Names of IACUC Members | Signatures | Date |
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