

University of Colorado at Boulder; Office of Research Integrity; Institutional Animal Care and Use Committee

SOP # 4 | **Title: Designated Member Review**

Date: 1/18/2012

Revision: second

Effective Date: 2/28/2009

Pages: 4

1. PURPOSE

To describe the circumstances under which Designated Member Review (DMR) may be used for review of applications.

2. DEFINITIONS

- 2.1. Designated Member Review (DMR): a procedure in which at least one member of the IACUC, designated by the Chair and qualified to conduct the review, reviews the protocol or addendum if a full committee review is not requested by members of the IACUC¹.
- 2.2. Designated Member Review (DMR) subsequent to a full Committee Review: a procedure in which named members of the IACUC are assigned responsibility for reviewing information provided in response to a Full Committee Review of an application.
- 2.3. Qualified member who can conduct reviews: a voting member of the IACUC who does not have a conflict of interest².

3. PROCEDURES FOR DMR:

- 3.1. In most cases, the FCR method is used for new protocols and renewals. However, should a situation warrant it, the IACUC may want to use the designated-member review (DMR) method for review of new protocols, renewals, and addenda. In such instances, the protocol will be distributed to all IACUC members to allow all members the opportunity to call for a full committee review (FCR)³; records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after two working days (48 hours), are maintained and recorded in the minutes of the next convened IACUC meeting.
- 3.2. In accordance with the PHS Policy IV, C, 2, if full committee review is not requested, a DMR will be conducted and the outcome included in the minutes of the next convened IACUC meeting. For a DMR, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, will be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request

¹ PHS Policy IV, C, 2: "If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present."

² PHS Policy IV, C, 2: "No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC..."

³ PHS Policy IV, C, 2: "Prior to the review, each IACUC member shall be provided with a list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects."

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full committee review of those protocols. Designated reviewers cannot withhold approval of a protocol. Other IACUC members may provide the designated reviewer with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the designated-member review (DMR) method may not be conditioned. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. The designated member review will be recorded in the minutes of the next convened IACUC meeting.

3.2.1. For DMR review of a new protocol or renewal at least three designated members will review the protocol if any of the following procedures are included:

- Major survival surgery
- Death as an endpoint
- Unrelieved pain and distress

3.2.2. For DMR review of an addendum, at least three designated members will review the addendum if any of the following elements are part of new procedures requested in the addendum:

- Major survival surgery
- Death as an endpoint
- Unrelieved pain and distress

3.3. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

3.4. If full committee review is requested, the protocol or addendum must be reviewed at a convened meeting and approved by a majority of a quorum present.

4. PROCEDURES FOR DMR SUBSEQUENT TO A FULL COMMITTEE REVIEW:

4.1. A quorum of members present at a convened IACUC meeting may decide by unanimous vote of those present to use a designated member review subsequent to the IACUC meeting (i.e. after the full committee review is completed) when modification is needed to secure approval. This procedure was adopted by the IACUC on February 18, 2009 and reported to OLAW in the annual report for 2009.

4.2. Any member of the IACUC may, at any time, request to see the revised protocol and/or request full committee review of the protocol.

4.3. Required modifications Subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows

4.3.1. FCR or DMR following the procedures delineated above.

4.3.2. DMR if approved unanimously by all members at the meeting at which the required modifications are developed, delineated AND if the entire current Committee has

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previously approved, in advance and 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 protocol⁴.

4.3.3. Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

4.4. Time limit for addressing modifications.

4.4.1. For FCR and DMR, investigators have 60 days to respond to modifications requested by the IACUC for a protocol. After 60 days, the investigator will be notified that the unapproved protocol will be administratively closed. If there is still no response, the unapproved protocol will be closed after 90 days. After the protocol is closed, resubmission of the protocol will be

⁴ OLAW Frequently Asked Questions 19: “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:

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, or returned for FCR at a convened meeting.

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:

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.)

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](#))

In response to questions from the community regarding this guidance, OLAW offers the following clarifications:

To avoid temporal delays associated with the PHS Policy requirement that all members of the IACUC must be provided the opportunity to call for FCR for a proposal requiring modifications to proceed to DMR ([PHS Policy IV.C.2.](#)), OLAW formally recognized an alternative practice in [NOT-OD-09-035](#) (*Guidance to IACUCs Regarding the Use of DMR for Animal Study Proposal Review Subsequent to FCR*) issued on January 8, 2009. USDA concurred with this practice.

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accepted as a new submission after the modifications are addressed in the protocol and a new protocol number is assigned.

4.4.2. Review of addenda will be handled in the same manner. If after 90 days the modifications for an addendum have not been addressed, the addendum will be removed from review.