

University of Colorado Boulder
Office of Research Integrity
Institutional Animal Care and Use Committee
SOP #4
IACUC Reviews (previously Designated Member Review)

PURPOSE

The IACUC must review and approve all proposed components of a protocol involving the care and use of vertebrate animals or significant changes to previously approved protocols either through Full Committee Review (FCR) or Designated Member Review (DMR). This SOP describes these procedures. The IACUC must also review annual reviews of protocols.

Most protocols and renewals go through FCR and most amendments to protocols go through DMR. The IACUC can send any protocol to DMR unless a member specifically requests FCR. All IACUC members, including those absent, must be notified that DMR will be used. Otherwise the protocol or amendment will be sent to another IACUC meeting. Administrative changes do not need to be reviewed by the IACUC and can be verified as complete by the IACUC Office or designee but significant changes must be reviewed and approved by the IACUC. For a definition of significant changes please see SOP 32 Significant and Administrative Changes.

PROCEDURES FOR FCR

1. The FCR method is a review at a convened meeting of a quorum present (i.e., a majority of the IACUC voting members at a convened meeting) and is generally used for new protocols and renewals. Approval of those protocols may be granted only after review and vote by a majority of the quorum present at a convened meeting.
2. If a FCR is requested during a DMR, the protocol or amendment must be reviewed at a convened meeting and approved by a majority of a quorum present.
3. The protocol or amendment will be distributed to all IACUC members before the meeting to allow for careful consideration of the project.
4. The IACUC has the authority to:
 - Approve
 - Require modifications to secure approval. The IACUC may also use DMR subsequent to FCR (see for procedure below).
 - The IACUC may "Defer" or "Table" a protocol if substantial modifications are required but these motions are not officially recognized by the PHS or Animal Welfare Regulations.
 - Withhold approval

PROCEDURES FOR DMR

1. DMR is a procedure in which the IACUC chair designates at least one qualified member of the IACUC to review a protocol or amendment and make a recommendation regarding approval to the full committee. A "qualified member" of the IACUC is one who does not have a conflict of interest with the particular protocol.ⁱ
2. The DMR method can be used for review of new protocols, renewals, and amendments. In such instances, the protocol will be distributed to all IACUC members to give them the opportunity to call for a FCR.ⁱⁱ FCR can be called by any IACUC member at any time during the review. The IACUC will maintain records and record in the minutes the polling of members to obtain concurrence to use the DMR method or a record of concurrence by silent assent after two full working days (48 hours).
3. Three DMR members are required in cases where a protocol or amendment includes any of the following:
 - Major survival surgery
 - Death as an endpoint
 - Unrelieved pain and distress

4. The DMR has the authority to:
 - Approve
 - Require modifications in (to secure approval)
 - Request FCR of those protocols.
 DMRs cannot withhold approval of a protocol.
5. Other IACUC members may provide comments to the DMR.
6. DMR decisions must be unanimous; if not, the protocol will be referred for FCR.

PROCEDURES FOR DMR SUBSEQUENT TO A FCR

1. DMR subsequent to a FCR is a procedure in which the IACUC designates one or more members to review information provided by PIs in response to a FCR of a protocol application. This procedure may proceed if approved unanimously by all members at the meeting at which the required modifications are developed, delineated AND if the entire current Committee has 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.
2. A quorum of members present at a convened IACUC meeting may decide by unanimous vote of those present to use a DMR subsequent to FCR when modifications are needed to secure approval.
3. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.ⁱⁱⁱ
4. Minor changes of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

OUTCOMES OF IACUC ACTIONS

1. If the protocol is approved, the approval letter and approved amendment will be sent to the investigator indicating that animals may be ordered and research covered by the protocol may begin. A protocol is approved for a maximum of 3 years.
2. If the protocol is approved pending modification:
 - The IACUC will notify the investigator in writing.
 - Upon receipt of the revised protocol or amendment, the DMR will review the response and either determines that it is adequate and approve, or require further modifications.
 - Investigators have 60 days to respond to modifications requested by the IACUC for a protocol or amendment. 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 accepted as a new submission after the modifications are addressed in the protocol and a new protocol number is assigned.

PROCEDURE FOR UNSUBMITTED DRAFT PROTOCOLS

Protocols drafted by the principal investigator in an electronic database but not submitted to the IACUC will be removed from the database after 1 year or when the investigator’s name is removed from PeopleSoft, whichever is first. The IACUC will notify the investigator at least once before the protocol is removed.

ⁱ 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...”

ⁱⁱ 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, FCR of those research projects.”

ⁱⁱⁱ OLAW Frequently Asked Questions 19; [PHS Policy IV.C.2](#); [PHS Policy IV.F.3](#); [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.