

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

PURPOSE

To describe the circumstances under which the committee conducts Designated Member Review (DMR) and Full Committee Review (FCR) that may be used by the Institutional Animal Care and Use Committee (IACUC) to review applications.

DEFINITIONS

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 IACUCⁱⁱ.
2. Addendum: A form used for submitting protocol changes to the IACUC.
3. Significant changes: include but are not limited to the addition of new procedures; changes in the species; in approximate number of animals used; in Principal Investigator; in addition or deletion of a drug in anesthetic agent(s) or the use or withholding of analgesics; in the method of euthanasia; and in the duration, frequency, or number of procedures performed on an animal;.
4. Administrative changes include changes in the funding source, in personnel (other than the PI), in the use of a different UCB building location for animal housing, and in protocol title (changes in procedures due to a new grant requires an addendum).
5. Full Committee Review (FCR): a review at a convened meeting of a quorum present.
6. 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.
7. Qualified member who can conduct reviews: a voting member of the IACUC who does not have a conflict of interestⁱⁱⁱ¹.
8. Quorum: a majority of the IACUC voting members at a convened meeting.
9. Recuse: a member steps out of the room during discussion and vote of a motion at a convened meeting due to a conflict of interest.
10. Majority vote: majority of a quorum present at a convened meeting.
 - a. A quorum must be present at the time of the discussion and vote (recusals do not count towards quorum).
 - b. There must be a majority of the voting members in the room voting for a motion in order for that motion to pass.
 - c. Example: IACUC membership is 15 (quorum is 8), there are 10 members voting with a vote of 5 for, 2 against, 3 abstain; motion does not pass because 6 members or greater are needed to vote for the motion in order to pass the motion.

PROCEDURES FOR FCR:

1. In most cases, the FCR method is used for new protocols and renewals. If FCR is requested, approval of those protocols may be granted only after review and vote by a majority of the quorum present at a convened meeting.

2. At any time during a designated member review a full committee review is requested or a unanimous decision by the designated members cannot be obtained, 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.
3. The protocol or addendum will be distributed to all IACUC members before the IACUC meeting to allow for comments before the IACUC reviews the documents at an IACUC meeting.
4. The IACUC will review the protocol and all modifications requested.
5. The committee conducting reviews of proposals and significant changes have the authority to
 - a. Approve
 - b. Require modifications in (to secure approval). In this case the IACUC may use DMR subsequent to FCR (see below for details on this procedure). For substantial modifications required to be seen by the IACUC again, the term “Defer” is often used. Defer is not an official vote recognized by the PHS or Animal Welfare Regulations.
 - c. Withhold approval

If the committee did not review the protocol, the committee can send the protocol to DMR as described below unless a member specifically requested FCR (DMR subsequent to FCR is not appropriate in this case); all IACUC members, including those absent, must be notified that DMR will be used. Otherwise the protocol or addendum will be sent to another IACUC meeting (often called “Tabled” - no vote necessary); “Tabled” protocols may have modifications that will be sent to the principal investigator.

PROCEDURES FOR DMR:

1. Most protocols and renewals go to full committee review except in certain situations initially deemed appropriate for DMR.
2. For a DMR, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review. However, three designated member reviewers are required in the following cases.
 - DMR will be assigned to at least one member of the IACUC who is qualified to conduct the review.
 - 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
 - b. 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. The designated-member review (DMR) method can be used for review of new protocols, renewals, and an addendum. 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)^{iv}; records of polling of members to obtain concurrence to use the DMR method; or concurrence by silent assent after two full working days (48 hours), are maintained and recorded in the minutes of the next convened IACUC meeting [example: IACUC notified Monday afternoon, and the protocol or addendum cannot be approved until Thursday morning]. FCR can be called by any IACUC member at any time during the review.
4. The designated member will be assigned to review those protocols and have the authority to
 - Approve
 - Require modifications in (to secure approval)
 - Request 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.

5. 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.
6. 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.
7. All designated members must approve the final version of an addendum or protocol after modifications are addressed, sometimes multiple times, by the investigator regardless of whether the IACUC member approved previous versions.

PROCEDURES FOR DMR SUBSEQUENT TO A FULL COMMITTEE REVIEW:

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.
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.
3. Required modifications Subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows
 - a. FCR or DMR following the procedures delineated above.
 - b. 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 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 protocol^v.
 - c. Minor modifications 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 addendum 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:
 - An investigator will be sent modifications in writing.
 - Upon receipt of the revised protocol or addendum, the designated member(s) will review the responses and either verify that it is adequate and approve, or require further modifications.
 - For FCR and DMR, investigators have 60 days to respond to modifications requested by the IACUC for a protocol or addendum. 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

When a protocol is drafted by the principal investigator in an electronic database and not submitted to the IACUC, the protocol will be removed from the database after 1 year or after the investigator's name is removed from PeopleSoft, whichever is first. The investigator will be notified at least once before the protocol is removed after 1 year.

Overview of changes:

	Major Significant changes	Other Significant Changes	Administrative Change
Review Type	Full Committee or Designated Member Review; may require a new protocol	Designated member review	IACUC Administrator, and other as necessary
Average Turn-around Time	Next IACUC meeting For deadlines see: http://www.colorado.edu/vcr/iacuc/protocols/submit For DMR: Average 14-21 days	Average 14 days	2 business days

ⁱ This SOP became effective on 2/28/2009 (V.2)

This is version 3. Version 3 reviewed and approved by the IACUC on June 18, 2014

ⁱⁱ 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.”

ⁱⁱⁱ 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...”

^{iv} 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.”

^v 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.