



TITLE: Protocol Review

Purpose: In compliance with PHS Policy and the Guide for the Care and Use for Laboratory Animals, 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 policy describes these procedures. The IACUC must also review annual reviews of protocols.

PROCEDURE: 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 Animal Welfare Program Manager or designee but significant changes must be reviewed and approved by the IACUC.

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 by an IACUC member before approval of 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. Protocol submissions to the IACUC (including new protocols, renewals, and proposed significant changes to approved protocols) are initially routed by the IACUC Chair (or designee) to the full IACUC. These protocols are available to all IACUC members for review and comment over the course of two business days. If any committee member requests full committee review of the protocol, the protocol will be scheduled for review by a quorum of the IACUC. If no member requests full committee review, then the Designated Member Review (DMR) process will be used.

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2. In the DMR process, the IACUC Chair delegates (or designee; i.e., Animal Welfare Program Manager or Reporter) primary review authority to a member of the IACUC. If the designated member is not a veterinarian, s/he may request veterinary review as part of the designated member review process.
3. The designated reviewer may
 - Approve a protocol as submitted,
 - Require modification to the protocol in order to secure approval, or
 - Recommend the protocol for full committee review. A designated reviewer may not unilaterally disapprove a protocol.
4. Complex protocols may be exchanged between the designated reviewer and the investigator multiple times for changes and clarifications prior to approval.

If a protocol is assigned to multiple designated reviewers, approval must be a consensus decision. If designated reviewers cannot reach a consensus decision on a given protocol, then that protocol is sent for full committee review.

Approved by the IACUC 19 May 2015

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