

**MONMOUTH UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
POLICIES AND PROCEDURES**

Policy Name: Designated Member Review

Revision Date:

Original Issue Date: June 23, 2022

Issued by: IACUC

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Approved by: IACUC/Office of Research Compliance

Effective Date: June 23, 2022

Reviewed by: Institutional Official

I. Purpose:

The purpose of these policies and procedures is to provide guidelines for the use and implementation of a designated member review process for IACUC submissions. It also serves as a written, advanced understanding that the quorum of members present at a convened meeting may decide by unanimous vote to use Designated Member Review (DMR) subsequent to Full Committee Review (FCR) when the decision of the Institutional Animal Care and Use Committee (IACUC) is to “require modification to secure approval.”

II. Scope:

This policy applies to the Monmouth University IACUC which operates within the guidelines established by the *Guide for the Care and Use of Laboratory Animals* (“Guide”), the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, and the applicable provisions of the Animal Welfare Act and Regulations.

III. Regulatory Background:

The Office of Laboratory Animal Welfare (OLAW) outlines the method for review of IACUC submissions, based on requirements of the PHS Policy – Full Committee Review (“FCR”) and Designated Member Review (“DMR”). DMR approval has equal validity to FCR approval and does not require subsequent review or re-approval at a convened meeting.

IV. Responsibility:

- A. IACUC - The IACUC must ensure that all such research and teaching is conducted in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Animals, the 8th Edition of the Guide for the Care and Use of Laboratory Animals, and Monmouth University’s IACUC policies and procedures.
- B. Chair- The Chair is responsible for assigning designated member reviewers. This may be delegated in writing to the Office of Research Compliance.

- C. Office of Research Compliance – The Office of Research Compliance (ORC) is responsible for implementing this policy and for assigning designated member reviewers as delegated by the Chair.

V. Definitions:

- A. Submission – This includes all applications for using live, vertebrate animals for research, teaching, or testing, and annual reviews, de novo reviews, and amendments of these applications.
- B. Full Committee Review – A quorum of IACUC members review and vote on the acceptability of research proposals (protocols) involving the use of live, vertebrate animals submitted by a principal investigator (PI) during a convened meeting. FCR is to take place in real time with interaction of the members and may occur live or virtually.
- C. Designated Member Review - There are two types of DMR: DMR subsequent to FCR and DMR in lieu of FCR. The processes for using each of these methods are outlined below.
- D. Designated Member Reviewer – A voting member of the IACUC who has the authority to approve, require modifications (to secure approval), or request full committee review. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using FCR.
- E. Quorum – One person more than one half of the total number of voting members of the IACUC.

VI. Policy:

- A. All submissions may be considered for designated member review with the following exceptions:
- New submissions
 - Amendments with animals designated as pain/distress categories 3 and 4
 - Amendments which include pilot studies
 - Amendments which include exceptions/exemptions to *The Guide*
 - Prolonged physical restraint
 - Food or water deprivation, restriction, or regulation
 - Social housing
 - Housing outside of facility holding rooms > 12 hours
 - Acclimation, enrichment, or standard husbandry practices
- B. The IACUC Chair may determine that any submission can be reviewed by DMR, at their discretion, unless a member of the IACUC calls for FCR.

VII. Process:

- A. DMR Subsequent to FCR: Voting members of the IACUC will sign a DMR subsequent to FCR letter which will be kept on file by the ORC. (Attachment A).
- B. FCR Decision Process: Following FCR of a submission, where the decision of the committee is to “require modification to secure approval”, the IACUC Chair will call for a vote as to whether the review of the revised submission should be by FCR or by DMR. If any IACUC member present votes for FCR, then the revised submission will be returned for FCR at a convened meeting. If the vote is unanimous for DMR, then the revised submission will be sent to DMR. However, any voting member who wishes to see the revised protocol can request to be assigned as a designated reviewer. (All members are provided with a copy of the submission prior to the meeting, and if a member cannot attend the meeting, they can, at any time request to see the revised protocol and/or request FCR of the protocol.) The DMR reviewer(s) will be agreed upon during the meeting after the vote. Decisions will be captured in the meeting minutes.
- C. Subsequent DMR Review Process: Following the IACUC meeting, the committee’s comments specifying the modifications needed to secure approval, are communicated to the PI in writing. Once the PI has incorporated the changes required by the committee and has submitted the revised document, at least one member of the IACUC, who was previously identified by the IACUC during FCR, will review the revisions. The designated reviewer(s) will include any member who requested a desire to see the revision. If the designated reviewer(s) do not find the revisions satisfactory, then the IACUC Chair and/or ORC will contact and work with the PI to revise the submission until all concerns are addressed to the satisfaction of the designated reviewer(s). The Attending Veterinarian or their designee may also be enlisted to resolve any questions. The designated reviewer(s) may request FCR and the submission will be placed on the agenda for the next convened FCR meeting. Once the designated reviewer(s) is/are satisfied that the concerns of the FCR have been addressed, the reviewer(s) will notify IRB/IACUC Coordinator that the submission can be approved.

DMR in lieu of FCR: As set forth in Section VI.A., ORC will determine the initial review method (FCR or DMR) based on the content of the submission. Submissions which may be reviewed by DMR will follow this process. Voting members of the IACUC will be notified and provided access to the submission for review. As long as no member requests a full committee review of the submission by the end of five (5) business days, the submission becomes eligible for review and approval by the DMR process. Alternatively, prior to the end of five (5) business days, IACUC members can vote to approve via email that the submission meets established criteria for DMR. Submissions eligible for DMR will be assigned by the Chair to the AV or the AV’s designee and at least one IACUC member, designated by the

IACUC Chair (or the Vice Chair in their absence). Other expert consultants may be assigned when applicable, but only an IACUC designated reviewer is authorized to take action on the submission. DMR may result in approval, a request for modifications (to secure approval) or referral to the full committee for review. DMR may not result in withholding of approval. The IACUC designated member reviewers review the submission electronically via email. IACUC designated member reviewers collaboratively submit their comments and requests for modifications to the IAB/IACUC Coordinator. Both designated member reviewers are aware of each designated member reviews and agree to the requested modifications before sending to the IAB/IACUC Coordinator. The Coordinator then sends the request for modifications to the PI via email. Upon the IRB/IACUC Coordinator's electronic receipt of the PI's response to the comments and requests for modifications to the submission, the IRB/IACUC Coordinator reviews the responses and modifications and then forwards (as applicable) to the IACUC Designated Member reviewer(s). If additional questions are raised or further modifications need to be made as determined by the designated member reviewers, a second request for modifications is send to the PI by the IRB/IACUC Coordinator via email. The designated member reviewers must unanimously agree on the disposition of the submission. If the submission requires modifications, the designated member reviews must agree that the PI's modification adequately address the concerns and that the submission can be approved. If the designated member reviewers disagree, the submission must receive a full committee review. At any time during the DMR process, any voting member of the IACUC may request FCR. After the designated member reviewers notify that the protocol is approved, the IRB/IACUC Coordinator sends the official approval notice to the PI.

References

Public Health Service. Policy on Humane Care and Use of Laboratory Animals (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2000).

ARENA/OLAW. Institutional Animal Care and Use Committee Guidebook, 2nd ed. (2002).<https://grants.nih.gov/grants/olaw/GuideBook.pdf>.

Attachment A

To: File

From: The Office of Research Compliance, IACUC Office

Subject: Designated Member Review Following Full Committee Review Procedure

All protocols brought before the IACUC for Full Committee Review at a convened meeting may be sent to Designated Member Review only after the quorum of members present at the convened meeting have decided by unanimous vote to use Designated Member Review when Modifications are Required to Secure Approval. However, any voting member of the IACUC may, at any time, request to see the revised protocol and/or request Full Committee Review of the protocol.

Signed:

Date:

Name