

## Institutional Animal Care and Use Committee (IACUC)

<b>TITLE:</b> Designated Member Review	<b>Effective Date:</b> 28-February-2022
<b>IACUC POLICY:</b> 002 <b>REVISION:</b> 0	<b>Last Revised:</b>
<b>SCOPE:</b> This policy applies to all IACUC protocol submissions	<b>Review Date:</b>
<b>PURPOSE:</b> To define an accepted method of protocol review of animal activities.	
<b>KEYWORDS:</b> Protocol review, Full Committee Review (FCR), or Designated Member Review (DMR).	
<b>Policy Owner:</b> Research Compliance Office Radford University	
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### 1. BACKGROUND

PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (PHS Policy at IV.C.2) and Animal Welfare Regulations ([9 CFR 2.31 \(d\) \(1\) \(i\)- \(iv\)](#)) define the only two protocol review methods that fulfill USDA and PHS requirements for the conduct of animal activities.

PHS Policy '[NOT-OD-09-035](#),' states: If full committee review (FCR) 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." Using this method, all IACUC members receive a list of proposed research projects and access to the necessary information on the protocol to be reviewed. If any member feels that this protocol should go before a full committee, then its review must be deferred to the next full IACUC meeting. Any member can make the decision to send the protocol to FCR at any time during the time period designated for providing this opportunity. It is useful for IACUCs to allow a predetermined time period during which members may indicate which method of review is preferred. If no member calls for a full-committee review, then the Chair shall refer the protocol in question to a designated reviewer. The Chair may select one or more members, qualified to review this specific protocol, who will act on behalf of the entire IACUC to approve the protocol, request additional information from the PI to approval, or refer it for full committee review. The designated reviewer does not have the power to withhold approval, however, but must in such cases refer the protocol for FCR.

The designated-reviewer approval has equal validity to full-committee review approval and does not require subsequent reapproval or notification by a convened IACUC meeting. It is always possible for the IACUC to discuss protocols approved by either method in future meetings as a form of continuing review or in response to animal welfare concerns.

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:

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1. 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 (DMR) or returned for FCR at a convened meeting.
2. 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:
  - a. 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.
  - b. 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.)
3. 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).

The institution is charged with developing approval mechanisms, within the context of USDA and PHS boundaries. These policies must be reviewed by the IACUC at appropriate intervals of no less than once every five years to ensure they are appropriate and accurate.

## **2. POLICY**

Radford University's IACUC establishes, by virtue of the signatures attached to this policy, the use of DMR as an acceptable method of IACUC protocol review. All members of the committee shall have the opportunity to examine the proposed protocol and after an agreed period of time to be determined by the IACUC, shall decide to forgo a full review in favor of the designated-member review (DMR). Once members have chosen DMR, the reviewer(s) assumes the responsibility for the full committee in granting unanimous approval, requiring modification, or sending the protocol for full committee review. The designated member reviewer may approve the protocol, request additional information in order to secure approval, or refer the submission for full committee review.

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The IACUC Chair should use discretion in assigning a DMR submission to the Attending Veterinarian unless absolutely necessary to avoid a conflict of interest.

This policy also acknowledges the ability for the quorum of members present at a convened meeting to decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. It should be noted that at any time, any member of the IACUC may request the revised IACUC application be returned for FCR.

### Resources

- [PHS Policy on Humane Care and Use of Laboratory Animals](#)
- [Code of Federal Regulations. Title 9, Chapter 1, Subchapter A-Animal Welfare, Parts 1-3](#)

### REVISION HISTORY:

Revision	Summary of Revisions	Revision Date

# RADFORD UNIVERSITY

Research Compliance Office

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### IACUC Member Signature Page

<b>Member Name</b>	<b>Signature</b>	<b>Date</b>