

University of Notre Dame Institutional Animal Care and Use Committee (IACUC) Policy Title: Designated Member Review Effective Date: 3/13/2024 Last Revised Date: 3/13/2024

I. Purpose

Animal care and use regulations permit review by several methods, including Full Committee Review as well as review by specifically designated members of the IACUC.

II. Definitions

Full Committee Review (FCR): Review of animal protocols that involves a convened quorum of the IACUC.

Designated Member Review (DMR): Review of animal protocols that involves specific IACUC members, in place of review by the entire IACUC.

III. Policy

1. DMR subsequent to FCR

- a. When substantive information is lacking from a protocol under FCR at a convened IACUC meeting, they may vote to send the protocol to DMR following the meeting.
 - i. If all IACUC members are present at the meeting, the protocol can be sent to DMR.
 - ii. If not all IACUC members are present at the meeting, written agreement of all IACUC members is recorded to allow for protocols to be sent to DMR following FCR.
- b. DMR reviewers are appointed by the IACUC Chair at the meeting.
- c. A DMR reviewer may take the following actions after review:
 - i. Approve the submission as submitted
 - ii. Request modifications to secure approval
 - iii. Request FCR of the protocol

2. DMR prior to FCR

- a. All new protocols submitted to the IACUC are reviewed either by Full Committee Review (FCR) or Designated Member Review (DMR).
- b. All new protocols will be reviewed by the Attending Veterinarian or their designee, whether they go through DMR or FCR.
- c. When any new protocol or three year renewal protocol submission is received, IACUC staff will determine whether it is eligible to be considered for DMR in initial review. Any protocol submission not eligible for initial DMR will be sent to FCR.
- d. Protocols may be eligible for DMR in initial review if they meet the following criteria:
 - i. Pain/Distress Category is B/C only
 - ii. Species are not USDA regulated
 - iii. Minimally invasive:
 - 1. Breeding/holding protocols
 - 2. Injections
 - 3. Routine blood collections
 - 4. Non-survival surgery

iv. Amendments

- e. If a protocol is determined to be eligible for initial DMR review, all IACUC members are sent a notification asking them to review the description of the protocol and an option to call for FCR or DMR.
- f. IACUC members will have five working days from receiving the notification to select FCR or DMR.
- g. If any member calls for the submission to be reviewed by FCR the protocol will be assigned to the next IACUC meeting (within submission deadlines).
- h. If no member calls for the submission to be reviewed by FCR the protocol will be assigned to the DMR reviewer or reviewers appointed by the IACUC Chair.
- Any member who does not respond to the invitation to select FCR or DMR within five working days will be considered concurrence with a decision to send to DMR.
- j. If an IACUC member calls for FCR at any point prior to full approval, the protocol will be sent to the next IACUC meeting.
- k. The IACUC Chair will appoint a DMR reviewer or reviewers through designated IACUC staff.
- If an appointed DMR reviewer identifies a potential conflict, or declines to review, the IACUC Chair will appoint a new DMR review through designated IACUC staff.
- m. A DMR reviewer may take the following actions after review:
 - i. Approve the submission as submitted
 - ii. Request modifications to secure approval
 - iii. Request FCR of the protocol
- n. If more than one DMR reviewer is appointed, the reviewers must be unanimous in their decision. All modifications requested by one of the DMR reviewers will be available for all other reviewers to see.

IV. References

- 1. Public Health Service (PHS) Policy IV.C.2
- 2. "Correct Conduct of Full-Committee and Designated-Member Protocol Reviews", Lab Animal 31(9):28-31, 2002
- 3. National Institutes of Health NOT-OD-09-035, issued January 8, 2009