Policy # BP-02-2012

Policy Title: Use of Designated Member Review (DMR)

Policy: Designated Member Review (DMR) allows an appointed IACUC Member to review a protocol on behalf of the IACUC, and return a vote on the protocol. A DMR sub-committee may return a vote of “Approve”, “Requires Modifications to Secure Approval”, or “Requires Full Committee Review (FCR)”.

DMR may be used appropriately for protocol review as follows:
1. At the Chair’s discretion, DMR may be used to review and approve any new or 3-year renewal of protocols with a USDA Pain and Distress Categorization of B, C or D.
2. At the Chair’s discretion, DMR may be used for annual review of USDA protocols
3. At the Chair’s discretion, DMR may be used in emergency or extenuating situations to review any protocol (including USDA Category E).
4. DMR is used to review and approve all modifications.
   a. For minor modifications, the Chair and/or the Attending Veterinarian will review and approve the modification.
   b. For major modifications, at least one of the DMRs will be a veterinarian-typically the Attending Veterinarian or her designee, unless there is a conflict of interest.
5. DMR is used to complete the review and approval process when a majority of a quorum at a convened meeting vote to: “Require Modifications to Secure Approval” of a protocol.

When using DMR, the following conditions must be met:
1. All members of the IACUC must have access to all protocol materials
2. All members have at least 48 business hours to review materials and raise concerns, or to require FCR of a protocol
3. Designated Reviewers are assigned by the Chair or his/her designee, and must be trained and qualified to perform a review
4. DMR decisions are equivalent to Full Committee decisions
5. An assigned designated reviewer may refuse appointment
6. The chair or his or her designee has the authority to assign a new designated reviewer if an assigned reviewer will be unavailable during the review period or if the assigned reviewer cannot or does not provide a review and recommendation within 1 week of protocol submission.
Guidelines for the use of DMR after FCR:
It is in the interest of both the IACUC and the PI that this process be handled efficiently in order to provide the PI with a start date within a reasonable period of time. After reviewing the PI response and modified documents for thoroughness and accuracy, the DMRs may:

- **Vote to approve the protocol**
- **Request minor changes, with PI approval, to be made administratively by the IACUC Chair or her designee** (Examples of minor changes are volume, dose, needle gauge, word choice, etc.)
- **Require (the PI to make) additional changes to the protocol to address the original revisions requested by the IACUC in its letter**
- **In unusual circumstances, require (the PI to make) additional modifications to the protocol (beyond those originally requested in the letter) to secure approval.** Such additional modifications are strongly discouraged unless both DMRs agree that the modifications were overlooked initially, but are absolutely needed because they are substantive in nature and failure to address them will negatively impact human or animal well-being, or will make the protocol non-compliant with applicable regulations and policies.
- **Send the protocol back for Full Committee Review (FCR).** For example the reviewers do not agree on a course of action or there is an issue that would best be handled by member discussion at a convened IACUC meeting; in either case, the Chair should be notified.