

UH IACUC Policy on Conditions for Designated Member Review  
*Reference: PHS Policy on Humane Care and Use of Laboratory Animals: Section IV.  
Implementation by Institutions C. Review of PHS-Conducted or Supported Research Projects*

IACUC Approved: 8/16/18	Other Approvals:
Revised Dates of Approval: 6/20/19	

**Policy**

Per PHS Policy on Humane Care and Use of Laboratory Animals: Section IV. Implementation by Institutions C. Review of PHS-Conducted or Supported Research Projects, <https://olaw.nih.gov/policies-laws/phs-policy.htm> the UH IACUC has some discretion to use the Designated Member Review (DMR) review process under the following conditions.

IACUC Actions to Determine Full Committee Review (FCR) or Designated Member Review (DMR)

1. To conduct DMR, the following conditions must be met: Protocols must meet select criteria for DMR review. All members of the IACUC must be given an opportunity to call for FCR (3 business days), for each individual protocol subject to DMR review. If, and only if, no member requests FCR, the protocol may be reviewed by one or more qualified members appointed by the chair.
2. DMR committee will have 5 business days to review the protocol.
3. DMR may result in approval, return for modifications (to secure approval), or referral to the full committee for review. DMR may not result in withholding of approval.
4. If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications.
5. The specific method of review for each protocol should be documented, along with the outcome of the review in the IACUC meeting minutes.
6. Protocols that may be subject to DMR are limited to the following:
  - a. Change of Principal Investigator
  - b. Change and/or addition of species that does not change the objective of the protocol, as long as they do not require new or revised permit conditions, Institutional Biosafety Committee review, or housing that involves significant changes such as housing in a space that has not been previously IACUC approved. The PI must provide written documentation from the UH Biosafety Office that the addition of the new species does not require IBC review.
  - c. Addition of anesthesia, sedation, or analgesia that will improve animal well-being for procedures on a previously approved protocol. Examples include:
    - i. Temporary restraint for a noninvasive procedure (e.g weighing or handling) or non-survival surgery
    - ii. Methods of animal identification that may be painful
  - d. Addition of a procedure that does not result in greater pain, distress, or degree of invasiveness. Limited to pain categories C and D.

7. If the DMR process is used, 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.

The University of Hawaii will report this program change to OLAW in its next Annual Report, of its intention to conduct reviews as described in the standard procedures of this policy for DMR. An amendment to the current UH Assurance to use DMR will also occur.

#### IACUC Actions For Designated Member Review Following Full Committee Review (FCR)

Reference: NIH Notice NOT-OD-09-035 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-035.html>

When substantive information is lacking from a protocol, the committee may have questions requiring a response from the Principal Investigator (PI). In such situations, the IACUC may take the following actions:

1. If **all** members of the IACUC **are** present at a meeting, the committee will 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. The UH IACUC membership agrees that the quorum of members present at a convened meeting will 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. DMR subsequent to FCR is currently in the UH Assurance.

If the DMR process is used, 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.

#### DMR Not Required For Revisions To Previously Approved Procedures on Approved Protocols

Reference:

Per the IACUC Policy for Dealing with Specific Significant Changes to Animal Activities, administrative changes using the veterinary verification and consultation (VVC) process or through the UH Animal Welfare Compliance Office do not require FCR or DMR.