

Institutional Animal Care and Use Committee		UNTHSC
Title: Designated Member Review Protocol Procedures		
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Approved by IACUC Date: September 24, 2024		

A. BACKGROUND INFORMATION

The UNTHSC IACUC has the responsibility to assure that all animal use activity meets federal law mandates, Public Health Service policy, the National Research Council Guide recommendations and all accreditation expectations. The PHS Policy and Animal Welfare Regulations (AWRs) recognize two methods of Review: Full Committee Review (FCR) and Designated Member Review (DMR).

B. RESPONSIBILITY

- a. It is the Principal Investigator’s (PI) responsibility to notify the IACUC Office should they wish for their protocol to be considered for the DMR process.
- b. It is the IACUC Chair’s responsibility for reviewing the request for consideration for the DMR Process.
- c. It is the responsibility of the IACUC Office to communicate the Chair’s decision, and process the DMR request.

C. PROCEDURES

- a. There may be circumstances that require a protocol to be reviewed and approved before the next IACUC meeting. Should the PI wish to submit a protocol for DMR, the PI shall submit a protocol and send a request for DMR to the IACUC Office. The request must include justification for the DMR request.
- b. The IACUC Office will forward the request to the IACUC Chair (or designee) and Veterinarian who will determine the appropriateness of the request for DMR. Appropriateness for DMR will depend upon: (i) invasiveness of procedures, (ii) level of pain or distress, (iii) species and number requested, and (iv) peer review status for the research activity and (v) previous IACUC review. For example, a protocol involving invasive procedures may be rejected if the same or similar procedures have not previously been reviewed by the IACUC, are deemed controversial, or involve a request for exception to regulations.
- c. If the DMR is determined to be appropriate, the Chair will notify the IACUC Administrator.
- d. The protocol will be submitted electronically to the IACUC Office, who will initiate the Designated Review process.
- e. IACUC members will be notified of the DMR request and receive a copy of the submission. Members are given 5 business days to review the protocol, in which any member may call for full committee review. If any member calls for full committee review, the DMR

process will not be exercised, the PI will be notified, and the protocol will be placed on the Agenda for the next IACUC meeting. If any member does not respond within that time, the lack of response will be considered as that member's agreement to exercise the DMR process.

- f. If there has been no call for full committee review after the five business days, at least one member will be assigned as the Designated Reviewer, and will be authorized to review, approve, require modifications, or request full committee review of the application.
- g. Any requests for revisions will be communicated to the PI electronically from the IACUC Office. The PI will make any revisions to the protocol, and will submit the revised protocol, electronically to the IACUC Office. The response will then be sent to the Designated Reviewers for review. Once the reviewers find the protocol acceptable for approval, the IACUC Office will process the protocol approval. The review will then be considered complete, and the protocol will enter into an approved state.
- h. The IACUC will be notified of the results of the designated review at the next IACUC meeting.

D. REFERENCES

- a. [Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.](#)
- b. [USDA Animal Welfare Act Regulations and Standards, 9 CFR Parts 1, 2, 3 and 4.](#)
- c. [PHS Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised 2015.](#)
- d. [Health Research Extension Act of 1985, Public Law 99-158, November 20, 1985, "Animals in Research." Available from OLAW, National Institutes of Health, RKL1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982](#)
- e. [Guide for the Care and Use of Laboratory Animals, Eighth Edition. National Academy Press, Washington, D.C. 2011.](#)