

Institutional Animal Care and Use Committee		UNTHSC
Title: Expedited (DMR) Protocol Procedures		
Document #: 019	Version #: 05	
Approved by IACUC Date: December 17, 2019		

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 and Designated Member Review.

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 Designated Member Review process.
- b. It is the IACUC Chair's responsibility for reviewing the request for consideration for the Designated Member Review Process.
- c. It is the responsibility of the IACUC Office to communicate the Chair's decision, and process the designated member review 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 Designated Member Review (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 Administrator 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 and the protocol, together with a summary including animal numbers and procedures will be made available to the full IACUC.
- d. IACUC members have 5 business days to review the protocol in which, any member may reply to the IACUC Administrator to 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 application 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.

- e. If there has been no call for full committee review after the five business days, the Chair will designate members of a subcommittee consisting of a primary reviewer, the IACUC Chair (or designee) and the Veterinarian or designee. This subcommittee will be authorized to review, approve, require modifications, or request full committee review of the application. All communications between members are copied to the IACUC Administrators.
- f. Any requests for revisions will be sent to the IACUC Administrator and then forwarded to the PI. The PI will send any revisions to the IACUC Administrator who then forwards them to the reviewers. Once the reviewers find the protocol acceptable for approval, the IACUC Administrators will process the approval, and will notify the PI of the approval, by providing an approved version of the protocol with the approval letter.
- g. 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. *Guide for the Care and Use of Laboratory Animals, Eighth Edition*. National Academy Press, Washington, D.C. 2011.
- e. 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