



**Duke University & Duke University Medical Center
Animal Care & Use Program
Policy**

**IACUC REVIEW AND APPROVAL PRACTICES
(REVIEW OF SIGNIFICANT CHANGES)**

PERFORMANCE STANDARD: Proposed activities involving animals are reviewed as efficiently as possible, to facilitate the research effort and funding agency needs. Investigators are provided the maximum amount of support with funding agency needs, while restricting actual animal activities until approval and required clearances are completed.

BACKGROUND: In part due to the success of the Compliance Liaison Program, the numbers of Significant Changes (also called significant amendments or SCs) reviewed by the IACUC each month has grown significantly. By mid 2005, the numbers of SC reviews were extending the length of the Full Committee by over 90 minutes. This SC review could be performed in an alternate manner, with improved response time for the investigators, improved robustness of the review process, and less time investment by all of the members of the IACUC. The method described below meets / exceeds the minimum requirements of the USDA, the PHS, and the AAALAC. Any defined process will require notification of both the PHS and AAALAC at the next Annual Report.

METHODOLOGY:

1. **Meeting:** The Significant Change Designated Member Review Sub-Committee (DMSC) shall meet twice a month – on the 1st and 3rd Thursday of the month (except November and December). Generally, the meeting will begin at 3:30 PM and is forecast not to exceed one hour in duration.
2. **Meeting Membership:** While any IACUC member can attend, the DMSC shall consist of:
 - a. Sub-Committee Chair: One of the Duke IACUC Vice Chairpersons.
 - b. Veterinarian: A Duke veterinarian
 - c. Member: One of the Primary (or alternate) Members
 - d. Member: One of the Primary (or alternate) Members
 - e. Compliance Liaison (OAWA): One of the Compliance Liaisons will attend each meeting as a matter of information sharing and assistance. This is a non-voting and non-member position.
 - f. Protocol Specialist (OAWA): This individual provides general meeting support, minutes capture, and document processing. This is a non-voting and non-member position.
3. **Member Selection / Designation:** Membership on this Designated Member Sub-Committee shall be by appointment by the IACUC Chairman. Volunteers encouraged. Members may request specific dates for participation to facilitate their schedules.

4. Member Participation Benefits:

- a. The assigned Designated Members will serve for a one month period (two SC meetings). Generally this will require an individual IACUC member participate in the SC meeting for only one month each year (approximate).
- b. The member participating in the DMSC WILL NOT be assigned any New Protocols to review at the Full Committee meeting during the month they are assigned SC duty.
- c. Alternate members can be appointed as DMSC participants by the primary member if the Primary Member is not available.

5. SC Submission Process: Investigators will download a current version of the Amendment Request from the animal program web site. The Amendment Request may be submitted by Fax, hard copy (hand carry, U.S. mail, or campus mail), or as a PDF or Word file attached to an Email. The sequencing of the meeting will be as follows:

- a. 1st week meeting: Deadline for all Amendment Requests is the 4th Monday
- b. 3rd week meeting: Deadline for all Amendment Requests is the 2nd Monday

6. Review Process Background:

- a. The OAWA protocol specialist will provide an Email of the requested amendment requests received by the deadline and assigned for review by the SC Sub-Committee, to all IACUC members approximately 5-7 business days prior to the scheduled DMSC meeting.
- b. Any Committee member can call for Full Committee review of any SC request. The member who calls for Full Committee review will present the amendment request to the Full Committee.
- c. After 5 business days, any SC not identified by the IACUC as requiring Full Committee review, will be assigned to the Designated Member Sub-Committee (DMCS) agenda.
- d. The SC Chair shall review all of the SCs.
- e. All members are encouraged to review all proposals, but are obligated to review the SCs that they have been assigned prior to the DMSC.
- f. A Duke veterinarian will review all SCs involving altered animal care or animal use. Usually this is by the SC member veterinarian but could include the OAWA veterinarian if an additional opinion is needed. A veterinary review is not required for non-altered animal care or animal use (ex: numbers change).

7. Approval Mechanism: As a Designated Member Review Sub-Committee, the decision options are:

- a. Unanimous for acceptance of the protocol amendment; or
- b. Unanimous for required modifications prior to approval. In this case all members of the sub-committee are provided PI responses to the DMSC required modifications via Email. No poll (or vote) is taken. If the DMSC member does not accept the PIs response, they may call for full Committee review.
- c. If a unanimous agreement cannot be reached, the document is automatically placed on the agenda for the next regularly scheduled Full IACUC meeting.
- d. NOTE: The DMSC cannot disapprove proposals - such decisions can only be made by the full committee. Any proposals not receiving unanimous approval are forwarded to the full IACUC for consideration.

8. **Reporting Mechanism:** The DMSC's decision is final. A report of DMSC action shall be provided to the Full Committee as a matter of information at the next regularly scheduled IACUC meeting. This report becomes part of the IACUC minutes for that month. Any action performed by the DMSC can be re-visited by the IACUC if any member of the IACUC determines that such review is necessary.

9. **OAWA Support Activities:**
 - a. Responsible Personnel:
 - i. Jenny Baker is designated as the Admin Support for the 1st Week SC activity.
 - ii. Sandra Pierce is designated as the Admin Support for the 3rd Week SC activity.
 - b. Activity:
 - i. The assigned OAWA person will gather the amendment requests submitted by the deadline, log the amendments requests in the master database, prepare and Email the proposed agenda to the Full Committee. The OAWA staff person will also distribute the materials electronically to the members of the Sub-Committee, take meeting minutes, and process actions post meeting.
 - ii. The Assistant Director & Director (OAWA) will oversee and assist as required to assure completion of the tasks in a timely manner.

10. **OESO / EOHW clearance** is required for any IACUC approval. All amendment requests will be submitted to the OESO / EOHW office by the OAWA. Clearance from both offices is required prior to release of the approval of the Amendment (This is an administrative action managed by the OAWA and not part of the approval process).