IACUC REVIEW AND APPROVAL PRACTICES
(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. The goal of this policy is to establish a clear, appropriate review process that is responsive to the needs of the research community and serves to efficiently utilize institutional resources and skills.

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 and/or 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 Sub-Committee (SCSC) functions as a Designated Member Review process. The SCSC shall meet twice a month – typically on the 1st and 3rd Thursday of the month, except November and December when there shall be a single meeting each month, typically on the 1st Thursday of that month (due to holiday conflicts).

2. Meeting Membership: While any IACUC member can attend, the SCSC shall generally consist of IACUC members, satisfying the following roles:
   a. Sub-Committee Chair: IACUC Chair or designee, generally or 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

NOTE: A minimum of 3 IACUC members is required to conduct business.
OAWA Staff: These individuals provide general meeting support, minutes capture, and document processing. Compliance Liaisons may attend as a mechanism for informational sharing and assistance. These are non-voting and non-member positions.

e. **Member Selection / Designation:** Members are encouraged to volunteer for service on this Designated Member Sub-Committee on dates compatible with their schedules, with final approval of appointment by the IACUC chair. A primary and their alternate may not function as separate voting members of the SCSC. Alternate members can be appointed as SCSC participants. NOTE: If you participate as a primary reviewer in both SCSC in a given month, OAWA will make every effort not to assign you as primary reviewer of a new protocol that month.

3. **Significant Change Submission Process:**
a. Investigators will download a current version of the Amendment Request from the animal program web site.
b. The completed Amendment Request should be submitted electronically as a PDF file attached to an Email.
c. Hard copy or FAXed submissions are generally not accepted. This may be waived in extraordinary circumstances with agreement of Chair or Director, OAWA or their designee.
d. The deadlines for receiving amendment to be assigned to specific SCSC meetings will be as follows:
   i. 1st week meeting: Deadline for all Amendment Requests is typically the Monday of the previous week.
   ii. 3rd week meeting: Deadline for all Amendment Requests is typically the 2nd Monday.

4. **Review Process Background:**
a. The OAWA protocol specialist will provide an Email of the agenda for the upcoming SCSC meeting to all IACUC members approximately 5 business days prior to the SCSC meeting.
b. Any Committee member can call for Full Committee review of any Significant Change request. The member who calls for Full Committee review will present the amendment request to the Full Committee.
c. Significant Change amendments be assigned to a member of the SCSC and be reviewed at the SCSC meeting.
d. The SCSC Chair shall serve as an additional reviewer for each of the SCs assigned to their meeting.
e. All members are encouraged to review all proposals, but are obligated to review the SCs that they have been assigned prior to the SCSC meeting.
f. A Duke DLAR veterinarian and OAWA veterinarian will review all SCs involving altered animal care or animal use. A veterinary review is not required if animal care use is not altered (example: numbers change, change in PI, etc.).
5. **Approval Mechanism:** As a Designated Member Review Sub-Committee, the decision options are:
   a. Acceptance of the protocol amendment: This vote must be unanimous; or
   b. Modification(s) Required to Secure Approval: The vote for deferral for clarifications must be unanimous. In this case, all members of the SCSC are provided subsequent PI responses describing the modifications via email. SCSC members then individually indicate their acceptance of the PI's response via return email.
      i. If all members of the SCSC accept the response, the amendment is approved.
      ii. If any SCSC member fails to accept the PI's response, then the Significant Change is referred to the Full Committee for review and disposition.
   c. Unanimity cannot be reached as described in ‘a’ or ‘b’ above: If a unanimous agreement cannot be reached, the document is automatically placed on the agenda for the next regularly scheduled Full IACUC meeting. **NOTE:** The SCSC cannot disapprove proposals - such decisions can only be made by the Full Committee. Any proposals not receiving ultimate unanimous acceptance are forwarded to the full IACUC for consideration.

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

7. **OAWA Support Activities:**
   a. OAWA Protocol Specialists are designated as the Administrative Support for the SCSC meetings.
      i. The OAWA Protocol Specialist will gather the amendment requests submitted by the deadline, log the amendments requests in the master database, and prepare and Email the proposed agenda to the Full Committee. They will also distribute the materials electronically to the members of the SCSC and process actions post meeting.
      ii. The Assistant/Associate Director & Director (OAWA) will oversee and assist as required to assure completion of the tasks in a timely manner.
   b. OAWA Administrative Support will be provided to assist the Chair of the SCSC meeting in generation of the meeting minutes and modification letters sent to PIs to detail the request for additional information from the SCSC.
8. **OESO clearance** is required for all SCSCs. All SCs will be submitted to the OESO office by the OAWA. Clearance 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).

9. **EOHW clearance** is NOT required for all SCSCs. Significant Changes involving the addition of new personnel must have those personnel cleared, but absent any new personnel additions, EOHW clearance is not required.