



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

**IACUC REVIEW AND APPROVAL PRACTICES
(PROTOCOL AMENDMENTS)**

PERFORMANCE STANDARD: All protocols are to be amended accurately, timely, and in compliance with federal regulations, PHS policy, and accreditation expectations. No animal numbers or procedural changes will be used / performed until approved by the IACUC and received by the PI.

BACKGROUND: According to the 9th CFR (USDA regulations), and the Public Health Service Policy, the IACUC shall “Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.” The institution is charged with developing the approval mechanisms. This policy provides the mechanism for performing reviews that are compliant and responsive to federal guidance.

ROLES:

1. The Principal Investigator will submit an amendment request (form available on the web site) with adequate justification for the change(s) to the Office of Animal Welfare Assurance (OAWA).
2. The OAWA Protocol Specialist will receive the amendment and coordinate review and approval of the request based upon the criteria within this policy.
3. The IACUC shall review, require modifications in (to secure approval), or withhold approval of proposed significant changes in an efficient, responsive, and legal manner.
4. The Designated Member Reviewer (DMR) process, as described in federal regulation and policy, will be used for these amendment procedures when so noted.
5. The IACUC’s Significant Change Subcommittee (SCSC) is a Designated Member Review (DMR) method. The Subcommittee process is described in another policy.

PROTECTION POSTURES REQUIRED: PPE not required for this activity.

OUTLINE OF POLICY:

1. The requested amendment must fit with the objectives, purpose, or aims stated in the original protocol. If this requirement is not met, then the IACUC will require submission of a new protocol.
2. Amendments are classified into four categories, according to IACUC determined welfare/well-being risk perceptions and methods of processing. Categories are processed according to IACUC approved practices as defined below.
3. Category I (Major <significant> amendments) requires Full Committee review. Examples of applicable proposals include:
 - a. Request for a new PI-Managed Housing (Housing for greater than 12 hours in a non-DLAR facility)
 - b. Exemptions to The Guide or other regulatory guidance or institutional policy.
4. Category II (Major <significant> amendments) may be reviewed by the SCSC or by Full Committee. Examples of applicable proposals include:
 - a. Addition of a new species.
 - b. Increase in animal numbers > 20% of the approved animal numbers. Note: Any increase in animal numbers requires IACUC approval.
 - c. Change of a non-survival to survival surgery.
 - d. Increased overall invasiveness of a procedure.
 - e. Increased proportion of expected animal deaths.
 - f. Increase in the duration of pain, discomfort, or distress to an animal.
 - g. Hazardous agents (as defined by OESO) administered to animals.
 - h. Principal Investigator (PI) change.
 - i. Addition of neuromuscular blocking agents.
5. Category III (minor amendments having potential welfare \ well-being impact upon animals) may be reviewed by veterinary clearance and DMR review, by SCSC, or by Full Committee. Examples of applicable proposals include:
 - a. Changes in anesthetic drug regimens.
 - b. Changes in analgesic drug regimens.
 - c. Addition of surgery or procedure that is less invasive than already on the approved protocol, or decreased proportion of expected animal deaths.
 - d. Changes in animal care and monitoring practices.
 - e. Changes in humane endpoints.
 - f. Addition of sample collection times.
 - g. Repetition of an already approved experiment.
 - h. Addition of noninvasive sampling/analysis.
 - i. Change in or addition of euthanasia procedures from an AVMA 'Acceptable Method; to an AVMA 'Conditional Method' (AVMA Guidelines).

6. Category IV (minor amendments not having direct animal welfare \ well-being impact) may be reviewed by a DMR, by veterinary clearance and DMR review, by SCSC, or by Full Committee. Examples of applicable proposals include:
 - a. Transfer of animals to another protocol where animals (same stock / strain) are already approved on that study.
 - b. Addition or deletion of personnel.
 - c. Adding or changing the site of animal procedures (less than 12 hours)
 - d. Change in or addition of euthanasia procedures to an AVMA 'Approved Method' (AVMA Guidelines).
 - e. Increase in animal numbers $\leq 20\%$ of the approved animal numbers. Note: Any increase in animal numbers requires IACUC approval.
 - f. Addition of another strain/stock of the same animal species.

7. Classification of proposed amendments that are not described herein will be determined as either significant or minor as defined by the IACUC Chairperson or designee.

8. Review processes:
 - a. Category I: Requires Full Committee review according to standing guidance.
 - b. Category II: See Policy on IACUC Review and Approval Practices – Sig Changes for the details of this segment of the policy.
 - c. Category III: This style of amendment requires a Duke veterinarian (not necessarily an IACUC member) review and clear the requested change (from a veterinary care/use perspective). This veterinary clearance is required prior to approval of the proposal by the DMR. Generally, the IACUC Chairperson, IACUC Vice Chairperson, the Assistant Director, OAWA, or the Director, OAWA will serve as the DMR (if the D, OAWA is veterinarian providing the review/clearance, then another IACUC member must be DMR). The approval of the amendment is immediate, with the signature of the DMR. A copy of the approved amendment will be returned to the Principal Investigator for maintenance in the PI's master protocol file (in addition to being maintained in the IACUC master protocol file). All approvals will be reported to the IACUC at the next scheduled meeting. Any approved activity may be called for re-consideration by the IACUC if any member determines that such a review of an approved amendment is necessary.
 - d. Category IV: This style of amendment may be approved by the IACUC Chairperson or IACUC member designee (DMR procedure). The approval of the amendment is immediate, with the signature of the DMR. A copy of the approved amendment will be returned to the Principal Investigator for maintenance in the PI's master protocol file (in addition to being maintained in the IACUC master protocol file). All approvals will be reported to the IACUC at the next scheduled meeting. Any approved activity may be called for re-consideration by the IACUC if any member determines that such a review of an approved amendment is necessary.