

Amendments to Existing Protocols

Summary/Purpose: Provides procedures for the different types of amendment review to animal study protocols.

BACKGROUND

Protocols must meet all federal regulations. The Institutional Animal Care and Use Committee (IACUC) has the responsibility to ensure that all animal use activity meets federal law, Public Health Service policy, and accreditation standards. All animals maintained by The University of Mississippi (UM) must be covered by an active, IACUC-approved protocol. This policy addresses amendments to those protocols. Principal Investigators wanting to make any changes to an IACUC approved protocol must obtain IACUC approval in compliance with PHS Policy (IV, B, 7) and the AWAR (§2.31, c, 7).

RESEARCHER RESPONSIBILITIES

The Principal Investigator (PI) should work with the IACUC to ensure that protocols are active and current for any anticipated or ongoing animal use. Any changes must be reviewed and approved by the IACUC office before being implemented. Proposed modifications should fit with the objectives, purpose, or aims stated in the original protocol. Otherwise, the IACUC may require a new protocol.

DETERMINATION OF REVIEW TYPE

The IACUC has established the following guidelines (in compliance with PHS Guidance NOT-OD-14-126) to determine whether a requested modification is a minor or significant change to an active IACUC approved protocol. Please note that the example lists are not exhaustive, but are intended as guides to changes the IACUC might regard as minor or significant.

1. Administrative Review

- a. Some changes to active, approved protocols may be reviewed by a single IACUC member, usually the IACUC Research Compliance Specialist (RCS). These changes include the following:
 - i. Additions and deletions of personnel, other than the principal investigator.
 - ii. Addition of non-USDA animals in compliance with PHS Policy (IV, D, 1, a), provided the number of animals to be added is $\leq 20\%$ of the originally approved number (or ≤ 3 animals for projects with fewer than 20 total animals approved). Justification for the additions must be provided and approved.
 - iii. Change in funding source.
 - iv. Change in contact information.
 - v. Minor typographical or grammatical error corrections.
 - vi. Addition of supporting protocol information (e.g., updated permits).
- b. Any time the RCS is unsure whether a change may be administratively reviewed, the RCS will contact the Chair and Attending Veterinarian for guidance.
- c. Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.

2. Chair and/or Attending Veterinarian (AV) Review

- a. Other minor changes to active, approved protocols that do not have a substantial impact on the health and well-being of research animals or that may decrease the potential for pain or distress may be reviewed by the Chair and/or AV. These changes include the following:

- i. Transfer of animals to another protocol where animals (same stock/strain) are already approved on that study. This change may also be approved by the Animal Care Supervisor.
- ii. Change in stock or strain of the already-approved species.
- iii. Adding or changing location where animal procedures are conducted.
- iv. Euthanasia procedure changes to any method approved in the AVMA Guidelines.
- v. Changes in anesthesia, analgesia, sedation, or experimental substances.
- vi. Dose volume, route, and frequency increases.
- vii. Duration, frequency, type, or number of procedures performed on an animal.
- b. The Chair and/or AV may at any time decide that a change considered minor be reviewed by DR or Full Committee review.

3. DR or Full Committee Review

- a. Significant changes to active, approved protocols must go through the same process of review as new protocols. The changes will be submitted to the full IACUC for review. During the review period, members may accept the amendment as appropriate for Designated Member Review or request a Full Committee Review. These changes include, but are not limited to, the following:
 - i. Principal Investigator change.
 - ii. Use of hazardous agents in animal procedures (e.g., chemical or biological or test compounds).
 - iii. Change in study objectives (may require new protocol).
 - iv. Procedures that will result in greater pain, distress, or degree of invasiveness.
 - v. Changes in method of anesthesia, sedation, analgesia, or experimental substances not considered minor.
 - vi. Changes in feeding that are significantly different than those described in the original protocol.
 - vii. Changes in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC.
 - viii. Physical restraint of conscious animals.
 - ix. Changes in protocol where death becomes the experimental end point.
 - x. Changes in protocol that would eliminate or restrict an animal's access to veterinary care.
 - xi. Protocol change from non-surgery to surgery, from minor to major surgery, from non-survival to survival surgery, or from single to multiple survival surgery.
 - xii. Changes in euthanasia to a method not specifically approved in the AVMA Guidelines.
 - xiii. Change in species.
 - xiv. Changes that impact personnel safety.
 - xv. Addition of USDA animals.
 - xvi. Addition of non-USDA animals when the number to be added is >20% of the original number (or >3 animals for projects with fewer than 20 total animals approved).