

Institutional Animal Care and Use Committee

THE UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

POLICY STATEMENT

Management of Suspected Protocol Noncompliance

The Animal Activity Protocol form is recognized as a binding agreement between the Principal Investigator and the institution (via the IACUC). This document is designed to address the unique information relative to the animal study, as required by the USDA's Animal Welfare Act and the NIH/OLAW's Public Health Service Policy on Humane Care and Use of Laboratory Animals.

The IACUC recognizes that over the life of an Animal Activity Protocol, the experimental studies with animals may "drift" or take seemingly minor paths from their original, documented plan. These deviations from the original, IACUC-approved protocol are considered issues on noncompliance if they have not been covered by an amendment to the original protocol.

Situations of potential/noncompliance may include: conducting unapproved animal procedures (surgery, treatments, behavioral testing, etc.), obtaining animals without IACUC knowledge, inappropriate anesthesia, and failure to provide appropriate analgesia.

Suspected or known situations of noncompliance will be managed accordingly by the IACUC. Institutional policy dictates the following course of action:

1. Upon receipt/report of suspected problem, a subcommittee appointed by the Chair will evaluate the report in relation to the IACUC-approved protocol in a timely, systematic manner. If deviations are in fact found, the full IACUC (or an IACUC compliance subcommittee) will further evaluate the specific severity of the situation (major deviations=suspension, minor deviations=remediation) to determine the course of action. The IACUC will draft a memo counseling the Principal Investigator of the noncompliance problem, specifically noting the possibility of suspension of all activities, halting funding, and reporting to the respective funding agency. In addition to the written memo, a one-on-one meeting involving the PI and all lab personnel assigned to this project may be warranted. A meeting will allow the PI to acknowledge receipt of the communication, and assure the IACUC that all parties understand the nature of the protocol noncompliance. Relative to the situation, the departmental chair may be copied and included in all correspondence.

A detailed plan for remediation will be developed by the full IACUC (or an IACUC compliance subcommittee), with input from the investigator. This plan will take the form of a written document communicated to the appropriate lab personnel. Remediation options may include: 1) Specific training courses (<http://www.citiprogram.org>) or hands-on lab sessions, 2) placing a hold on all future animal orders, and/or 3) random, unannounced laboratory visits by the IACUC. **More severe deficiencies may result in IACUC suspension of activities at a convened meeting of a quorum of IACUC members and euthanasia of any existing animals on that particular protocol.** [Reference: PHS Policy IV.C.6&7 and IV.F3&4; USDA 9 CFR Part 2, Subpart C 2.31 (d) (7)]

2. If the problem persists, the Principal Investigator will again be contacted via written memo. The departmental chair and Institutional Official will also be included in this correspondence. As in #1, the relative severity of the situation will be considered in conjunction with the continuing nature of the noncompliance. Action plans may include suspension of the activity or other forms of remediation.
3. As per PHS Policy, suspension can only occur after review of the matter by the convened meeting of a quorum of the IACUC and with a suspension vote of a majority of the quorum present.
4. If the IACUC suspends an activity involving animals, the IO in consultation with the IACUC shall review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

IACUC Approved 8/21/01
Updated 5/18/04; 6/17/08; 9/15/09

Animal Research Related Issues of Noncompliance

Examples of major animal research issues which could result in action (investigation, protocol suspension, etc). Examples are for reference only and may include, but are not limited to:

- Animal mistreatment: includes physical or psychological wrongful or abusive treatment of an animal.
- Conducting animal experimentation or manipulations that are not approved in the IACUC reviewed protocol
 - Unauthorized surgical procedures
 - Participation of unauthorized personnel in a research project
 - Injection of drugs/compounds that the IACUC has not approved
 - Unauthorized restraint of an animal
 - Acquiring animals from unauthorized sources
 - Conducting "Pilot" studies that have not received IACUC approval

This listing is not all inclusive, yet serves as a reminder that all experimental procedures involving animals **must** secure IACUC approval prior to the start of the work. Instances of noncompliance or mistreatment will be evaluated by the IACUC on a case-by-case basis.