



Standing Committee on Animals Guidance for ARCM on Mandatory Reporting of Non-Compliance Issues to the IACUC

(Adopted March 25, 2004; Revised **October 26th**, 2006)

Introduction

This guidance is to comply with a resolution passed by the HMA Standing Committee on Animals (hereinafter, IACUC) on 18 September 2003 regarding Mandatory Communications from the ARCM Veterinary Staff to the IACUC.

1. Immediate Reporting Required

The ARCM veterinary and animal care staff (ARCM staff) is hereby instructed to notify the IACUC immediately in the following circumstances:

- **Animal Abuse** - Any reports or findings of animal abuse should be reported by the ARCM staff to the IACUC immediately.
- **Endangerment of Animals or Humans** - Any situation that represents an immediate endangerment to animals or humans should be reported by the ARCM staff to the IACUC immediately. This includes, but is not limited to inadequate designation of Biosafety level of Facility, use of outdated pharmaceuticals, and infractions involving hazardous and biohazardous substances.
- **Non-Compliance with Posted Animal Experimentation Protocols** - Any of the following should be reported to the IACUC by the ARCM staff:
 - a. Research activity at significant variance from activities described or not described at all in the approved animal experimentation protocol.
 - b. Use of Species (whether USDA covered or non-covered rats, mice and birds) not assigned to an approved protocol.
 - c. Falsification or fabrication, such as pre-dating, of clinical or study records or documents.
 - d. Health records which are insufficiently maintained by the investigative staff, such that it is difficult to discern the adequacy of supportive care of research animals (e.g. EAE, inflammatory arthritis induction, etc.).

- **Animal Use Area Infractions:**

- a. Unapproved animal housing satellites.
- b. Use areas not listed on an IACUC approved Animal Experimentation Protocol

IACUC Notification

- ARCM staff notifies IACUC office by phone or email after consultation with ARCM Supervisors about incident.
- The IACUC staff evaluates information and emails the investigator asking for a response to allegations.
- This response and the allegations are forwarded to the next IACUC meeting for review.
- In circumstances whereby animals are deemed to be in immediate danger, the IACUC and the ARCM will work in concert to remove animals from such danger, notify the investigators, and place the protocol on hold with appropriate notifications to departments and funding agencies made by the IACUC staff.

2. Reporting after Repeated or Chronic Non-compliance

A. Repeated Non-Compliance with IACUC/ARCM Approved Research Policies

A second (or subsequent) infraction involving non-compliance with an IACUC/ARCM policy is to be reported to the IACUC by the ARCM staff following an initial resolved infraction by the PI.

Such infractions include:

- 1) Non-compliance with IACUC/ARCM policy on post-operative analgesic drug administration.
- 2) Inadequate animal care required for ameliorating the effects of research procedures
- 3) Improper pre-operative sterile preparation including hair clipping and instrument and surgical site sterilization.
- 4) Improper post-operative suture removal.

- 5) Inadequate supportive care required because of an induced illness (EAE).
- 6) Inadequate care during recovery from anesthesia.

B. Chronic Non-Compliance with ARCM Facility Procedures or Instructions

Non-compliance with ARCM procedures or instructions is initially addressed through the ARCM administration which documents the communication between ARCM personnel and the involved individuals. If the ARCM administration is not able to resolve such non-compliance issues and the issues become chronic; they should be reported to the IACUC by the ARCM veterinary staff/administration

Such non-compliance includes:

- 1) Repeated failure to wear approved and proper personal protective equipment (PPE) in accordance with the standard operating procedures of the animal facility.
- 2) Repeated failure to conform to animal ordering procedures,
- 3) Repeated lack of appropriate maintenance of rodent barrier integrity.
- 4) Repeated failure of principal investigator to supervise animal colonies held for his/her benefit.
- 5) Repeated failure to provide a program of animal enrichment.
- 6) Repeated failure to adhere to institutional instructions for animal cage housing density.
- 7) Outdated pharmaceuticals found on the shelf but not in use.
- 8) Infractions involving controlled substances.

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3. Forms of Communication:

Communications with Investigators - When ARCM staff communicate with investigators concerning infractions or deficiencies in accordance with this Guidance, the notice will be made to the Principal Investigator by telephone (to be followed by written notice), by written notice, or by email and will detail the specifics of the infraction. Laboratory managers and Post-doctoral fellows and any other involved personnel may be carbon-copied in the correspondence, but the primary contact must be the Principal Investigator.

Communications with the IACUC - The ARCM staff will direct communications regarding infractions or deficiencies to the IACUC administrative staff in accordance with this Guidance. Such communications will be made by written notice or email that details the specifics of the non-compliance. These communications will include the following:

- 1) The Animal Experimentation Protocol, if known, and the name of Principal Investigator.
- 2) Pertinent times, dates, and location.
- 3) Persons involved, if known.
- 4) Species and number of animals involved.
- 5) A description of the incident, action or failure to act as is applicable.
- 6) Photographs, if practical and pertinent.
- 7) Documentation of relevant communication with investigators.

Summary:

This Guidance remains in effect as voted on by the Harvard Medical Area Standing Committee on Animals on **October 26th**, 2006 until further notice.