



## Resolving Issues of Noncompliance

### 359.1 Background

Under the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), and the Animal Welfare Act Regulations, the IACUC has the responsibility to review concerns regarding the care and use of animals involved in research.<sup>1</sup> In addition, reporting requirements exist that describe those instances that must be reported to regulators by the IACUC through the university's Institutional Official. For example, the PHS policy requires the reporting of "a. any serious or continuing noncompliance with [the PHS] Policy; b. any serious deviation from the provisions of [the Guide for the Care and Use of Laboratory Animals]; or c. any suspension of an activity by the IACUC."<sup>2</sup> The National Institutes of Health's Office of Laboratory Animal Welfare additionally provides guidance on reportable matters, which includes a non-exhaustive list of what it deems are reportable events.<sup>3</sup> The Animal Welfare Act Regulations further require the IACUC to report the failure to correct, during the time frame allotted, any significant deficiency discovered during an IACUC semiannual facility inspection or program review.<sup>4</sup> Note that a significant deficiency is defined as one that "in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals" (§2.31c3)<sup>4</sup>

### 359.2 Introduction

**359.2.1** The Emory University Institutional Animal Care and Use Committee (IACUC) has developed a system for evaluating issues of noncompliance per regulatory guidelines. Note that this policy applies to both protocol noncompliance (failure to follow specific elements of the approved protocol) as well as the failure to follow Emory Policy or other regulations and guidelines. In order to identify and track conditions of greatest need and to enable optimal application of IACUC resources to assist needy parties, the IACUC uses a point system to evaluate and track noncompliance. Points are tracked on a rolling 12 month basis and are assigned to the Principal Investigator rather than to the individual protocol. The PI is held responsible for the action of those who work under their supervision.

**359.2.2** This system was designed to determine the level of action to be taken based on the seriousness of an occurrence or its repetition. Remedial actions will be taken to ensure correction of issues of noncompliance; the nature and intensity of which will be determined by the number of points accumulated (see below). Actions that result in direct, observable animal welfare concerns garner high point values and reach subsequent action levels quickly. Findings that do not meet this criterion garner lower point values, and trigger instructive interactions. Sporadic and/or low-level accumulation of points should not be a source of alarm, but are designed to identify and offer an opportunity to improve research operations. However, failure to address minor items resulting in repeat offenses leads to both the accumulation of point totals over time and the escalation of points for a given finding, possibly leading to higher level of IACUC action.

<sup>1</sup> See PHS Policy IV.B.4 (stating the IACUC must "review concerns involving the care and use of animals at the institution"; and 9 CFR § 2.31(c)(4) (stating the IACUC shall "[r]eview, and, if warranted, investigate concerns involving the care and use of animals at the research facility...").

<sup>2</sup> PHS Policy IV.F.3.

<sup>3</sup> See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>

<sup>4</sup> See 9 CFR § 2.31(c)(3). Note also the PHS Policy, in section IV.B.3. states "[a] significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals."

**359.2.3** Mediating factors the IACUC will consider when evaluating an incident involving noncompliance include, but are not limited to, the extent to which the findings are continuing or repeated, the length of time involved in continuing noncompliance (if applicable), and the degree of harm to animals resulting from the event or condition. When evaluating any noncompliance or considering points, the IACUC also will consider whether the incident was self-reported by the PI and if any proactive corrective actions were taken. It is important that the IACUC office be informed of all details so that remedial actions can be documented and the university can meet its reporting obligations per regulatory requirements.<sup>5</sup>

### **359.3 Definition of Types of Findings**

#### **359.3.1 Direct Animal Welfare Issues: 4 pts.**

Improper or unapproved activities directly resulting in animal distress or suffering are considered serious issues of noncompliance. In these cases, the IACUC Chair and/or veterinary staff may request that all animal work be immediately halted pending a review. Examples of these types of deviations are found in Appendix A. Four points will generally be applied per type of finding, thus prompting the first level of intervention described below. Repeated acts may result in higher point totals and direct escalation to second or third level action.

#### **359.3.2 Protocol nonadherence with no direct adverse effect on Animal Welfare: 1-3 pts.**

For issues that do not directly result in animal pain or distress, the PIs will be assigned one to three points for each occurrence, depending upon severity. Repeat findings or widespread noncompliance may result in greater point totals and more rapid escalation of subsequent action. Examples are found in Appendix A.

#### **359.3.3 Exception**

Impeding or obstructing the IACUC's procedures for conducting the Semiannual Site Inspection, Semiannual Program Review or Post Approval Monitoring will result in 6 points. These are required regulatory activities and the failure to comply puts both the University and its Institutional Official at significant risk for penalties from funding organizations and regulatory entities. Note that facilities MUST be inspected as detailed by federal mandates. Thus, failure of the lab to facilitate the timely rescheduling of a site inspection during the required reporting period will result in a protocol suspension, and possibly revocation of the use of space outside the animal facility.

### **359.4 Levels of corrective action**

**359.4.1 First level:** accumulation of 4 points. Only those activities related to the point accumulation will be affected. Potential corrective actions may include but are not limited to the following:

- Request for voluntary suspension of the activity during investigation and/or completion of corrective actions
- Retraining of staff in procedures (Hands-on training)
- Retraining of staff via online training modules

---

<sup>5</sup> Reporting of incidents by the IACUC via the Emory University Institutional Official to regulators will follow regulatory requirements, irrespective of points levied by the IACUC.

- Letter from PI to the IACUC detailing other corrective actions to prevent future occurrences
- Reporting to appropriate internal and external authorities

**359.4.2 Second level:** accumulation of 8 points. Future animal orders *and on-hand animal use* may not be allowed until the PI provides a written response addressing the specific issues to the satisfaction of the IACUC. Potential corrective actions may include not only those listed above, but also the following:

- Protocol test administered by the IACUC office
- Face-to-face meeting with the PI and the IACUC office Director or representative
- Suspension of protocol
- Loss of animal use privileges of relevant lab personnel
- Notification to the PI's Department Chair or Division Director

**359.4.3 Third level:** accumulation of 12 points. Relevant animal activities will be halted immediately until such time as the IACUC, at a convened meeting with quorum, can investigate the matter and develop a plan to assist the PI in meeting research obligations.. The Public Health Service, USDA (if applicable), AAALAC International, and funding agencies will be notified where suspension of the protocol(s) is invoked and the resolution, if an activity is suspended. Potential corrective actions may include not only those listed above, but also the following:

- Requiring that animal resources personnel conduct or supervise specified research procedures on a fee-for-service basis
- Permanent suspension of some or all activities using animals
- Permanent suspension of animal use privileges of specific personnel

**359.4.4** Repeated occurrences will be handled on a case-by-case basis. Once the IACUC has notified the PI of the requirement(s) for correction, repeated incidents of the same type will result in additional, escalating point values, thereby jeopardizing ongoing activities (e.g., animal use privileges, protocol approval).

## **359.5 Appeal Process**

**359.5.1** PIs may appeal the application of points or levels of disciplinary actions taken. To do so, written correspondence must be submitted in a timely manner. The correspondence must be addressed to the IACUC Chair and mailed to the IACUC office. Further, it must identify the action under appeal and clearly explain why it should be removed from the record. Appeals will be held and discussed at the next scheduled IACUC meeting after the appeal submission. Any decision by the IACUC in response to an appeal may only be overturned by the IACUC; there is no appeal body beyond the IACUC.

[Acknowledgement is given to the IACUCs of the University of Cincinnati and the University of Indiana/Purdue University at Indiana University School of Medicine for permission to use content from portions of their corresponding documents in the creation of this "Guideline."]

### **359.6 Document Properties**

Authored by: IACUC

Administering Division/Department: IACUC Office

Original Approval Date: 09/07/2014

Review/Revision Date: 12/07/16

Version: v. 20161207

## APPENDIX A: Common Findings and Suggested Point values

NOTE: Point values given below are based on common points given since the introduction of this policy. Note that points may be adjusted as explained under sections 359.2.1 and 359.3.2

Category	Description of Finding	Points
Animal Welfare	Performing a procedure in such a manner that animals endure distress, pain, or suffering that is not addressed in the approved protocol.	4
Animal Welfare	Not performing, or inadequately applying a physical means, to assure death when euthanizing animals.	4
Animal Welfare	Not following aseptic technique as described in the protocol when performing survival surgery.	4
Animal Welfare	Failure to monitor animals adequately following an invasive procedure	4
Animal Welfare	Extreme cage overcrowding associated with morbidity or mortality	4
Animal Welfare	Severe stress/distress or morbidity/mortality of animals caused by improper handling or failure to follow approved protocol or IACUC policy	4
Animal Welfare	Failure to provide food or water to animals post-weaning, or experimental manipulation resulting in animal morbidity/mortality	4
Animal Welfare	Not administering analgesics as required in the approved IACUC protocol	4
Animal Welfare	Interfering with the veterinary staff and/or failing to adhere with veterinary-mandated instructions	4
MISCONDUCT	Falsification of animal Care records	4
Personnel safety	Not following safety procedures such that personnel are unknowingly exposed to hazards (e.g. dangerous chemicals, radioactivity, biohazards)	4
Procedures	Animal Care: Lack of Post-procedural Heat Source	4
Procedures	Body Weight or Health Status Logs: Evidence of weight loss beyond that approved in the protocol	4
Procedures	Post-procedure Records: Failure to maintain as per approved protocol with potential to adversely affect animal welfare	4
Procedures	Surgical or Surgery Monitoring Records: Failure to maintain as per approved protocol with potential to adversely affect animal welfare	4
Protocol Violation	Acquiring animals for research without IACUC approval and/or knowledge of the animal resources program.	4
Protocol Violation	Conducting animal-related activities beyond the expiration date established by the IACUC (note that a complete review, as mandated by PHS Policy IV.C, is required at least once every three years)	4
Substances	Controlled Substances: Expired and with EVIDENCE OF USE IN ANIMALS	4
Substances	Drugs, Substances, or Supplies (for Animal Use): Expired and with EVIDENCE OF USE IN ANIMALS	4
Substances	Drugs, Substances, or Supplies (for Animal Use): Not Sterile and with EVIDENCE OF NON-TERMINAL USE IN ANIMALS	4
Equipment	Equipment: Direct Animal Contact - Inadequate Level of Sanitation or Improper Sterilization	2
Physical Environment	Work surfaces for Animal Use: Inadequate Level of Sanitation or Improper Sterilization	2
Policy/Regulatory	Failure to respond to the IACUC by designated deadlines	2
Policy/Regulatory	Failure to participate in the semi-annual inspection and/or review process	2

Policy/Regulatory	Not participating in the Occupational Health and Safety Program where it is mandatory	2
Policy/Regulatory	Failure to follow proper weaning procedures	2
Procedures	Body Weight or Health Status Logs: Inadequately Maintained	2
Protocol Violation	Housing animals in a laboratory without approval (with no other associated transgression, such as insufficient food, water, or other actions required for animal welfare)	2
Protocol Violation	Allowing new personnel to work with animals before completing IACUC requirements	2
Protocol Violation	Performing unapproved procedure with no adverse animal welfare concern.	2
Protocol Violation	Relocating a laboratory without properly notifying the IACUC; research conducted in unapproved areas	2
Sanitation	Inadequate Sanitation SOP's	2
Substances	Drugs, Substances, or Supplies (for Animal Use): Not Sterile	2
Substances	Drugs, Substances, or Supplies (for Animal Use): Inadequate Storage to ensure sterility/integrity of the substance	2
Substances	Drugs, Substances, or Supplies (For Direct animal use): Lack of a Physical Barrier between animals and inhalant anesthesia	2
Equipment	Equipment: Direct Animal Contact - In disrepair, in need of repair	1
Equipment	Equipment: Direct Animal Contact - Isoflurane Vaporizer - Calibration Out-of-date	1
Equipment	Equipment: Direct Animal Contact - Isoflurane Vaporizer - F-Cannister improper usage or record-keeping	1
Equipment	Equipment: Direct Animal Contact - Unsealed or Unsanitizable Surfaces	1
Equipment	Equipment: No Direct Animal Contact - Inadequate Level of Sanitation or Improper Sterilization	1
Equipment	Equipment: No Direct Animal Contact - In disrepair, in need of repair	1
Equipment	Equipment: No Direct Animal Contact - Unsealed or Unsanitizable Surfaces	1
Physical Environment	Work surfaces for Animal Use: Unsealed or Unsanitizable Surfaces	1
Physical Environment	Lab Space: Human Food and/or Drink Found	1
Policy/Regulatory	Failure to adhere to IACUC expired drug policy without specific exemption	1
Policy/Regulatory	Controlled substances not secured properly or dispensing logs not kept	1
Policy/Regulatory	Improperly labeled bottles or secondary containers	1
Policy/Regulatory	Improper waste disposal practices	1
Policy/Regulatory	Overcrowded animal enclosure(s) as per IACUC policy and/or or the Guide with no associated adverse affect on animal welfare	1
Policy/Regulatory	Improper laboratory or animal facility attire	1

Policy/Regulatory	Cage cards not containing required information (e.g. date of surgery, chemical administration, tumor inoculation, etc.)	1
Policy/Regulatory	Failure to maintain cleanliness, hygiene, and upkeep of lab space where animal work is done	1
Policy/Regulatory	Failure to follow established IACUC policy, except as specified above	1
Procedures	Post-procedure Records: Inadequately Maintained	1
Procedures	Surgical or Surgery Monitoring Records: Inadequately Maintained CAGE CARD LEVEL	1
Procedures	Surgical or Surgery Monitoring Records: Inadequately Maintained LOG BOOK LEVEL	1
Protocol Violation	Insufficient records of monitoring animals (disease condition, PI care, survival surgery, post-procedure care)	1
Protocol Violation	Personnel ignorant of protocol content	1
Protocol Violation	Exceeding the number of animals approved on the study (e.g., breeding colonies)	1
Sanitation	Cage(s): Empty, soiled cages left in Lab	1
Sanitation	Lab Space: Cluttered	1
Sanitation	Sanitation Solutions: expired or inappropriate use	1
Substances	Drugs, Substances, or Supplies (for Animal Use): Expired	1
Substances	Drugs, Substances, or Supplies (for Animal Use) - Drug usage records inadequately maintained	1
Substances	Drugs, Substances, or Supplies (for Animal Use): Improperly Labeled or unlabelled	1
Substances	Substances (For Animal Use/No Direct Animal Contact): Improperly Labeled	1
Substances	Substances (For Animal Use/No Direct Animal Contact): Expired with no evidence for use in animals	1