



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.¹ In addition, reporting requirements exist that describe those instances that must be reported to regulators by the Institutional Animal Care and Use Committee (IACUC) through the university's Institutional Official (IO). 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."² 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.³ 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.⁴ 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)⁴

359.2 Introduction

359.2.1 The Emory 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 (PI) 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.

¹ 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 "review, and, if warranted, investigate concerns involving the care and use of animals at the research facility...").

² PHS Policy IV.F.3.

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

⁴ 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 that 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.⁵

359.3 Definition of Types of Findings

359.3.1 Direct Animal Welfare Issues:

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. Note that the IACUC reserves the right to issue fewer or greater points for a specific incidence based on mitigating factors as discussed above.

359.3.2 Protocol non adherence with no direct adverse effect on Animal Welfare:

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 serious penalty which may range from 6 points up to protocol suspension, and possibly revocation of animal use privileges. 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.

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

⁵ 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 may 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. 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 available 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.

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359.6 Document Properties

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APPENDIX A: Violation/Deficiency (By category)	recommended points
PROTOCOL VIOLATIONS	
Acquiring animals for research without IACUC approval and/or knowledge of the Animal Resources Program	4
Conduct of animal-related activities on an expired/lapsed protocol	4
Performance of experiments or housing of animals in unapproved locations (without other animal welfare concerns)	2
PROCEDURAL VIOLATIONS	
Improper Euthanasia (failure to assure death)	4
Failure to follow proper aseptic technique	4
Failure to properly monitor animals or to provide adequate supportive care post-procedure (Direct Animal Welfare)	4
Failure to document monitoring of animals as per protocol or IACUC policy (no direct animal welfare concern)	2
Failure to follow humane endpoint guidelines as per policy or the approved protocol	4
Improper housing conditions (overcrowding/failure to provide food or water) resulting in an animal welfare concern	4
Failure to provide analgesia/anesthesia as per approved protocol	4
Performance of unapproved procedures	4
Individuals performing procedures without proper training	4
CONDUCT/MISCONDUCT	
Interference with vet staff or failure to follow veterinary-mandated instructions	4
Falsification of animal care records (example: post-operative monitoring records)	4
Failure to follow safety protocols resulting in potential exposure to others (chemical, biological, radiation)	4
Failure to respond to IACUC-mandated deadlines, or participate in the semi-annual review process in a timely manner	2
SUBSTANCES/REAGENTS/SUPPLIES	
Use of expired materials in animals in violation with policy or the approved protocol	4
Use of improperly stored or sterilized materials or substances in animals	4
Presence of expired materials not properly labeled (Example: "EXPIRED: NOT FOR USE IN ANIMALS")	1
Improper storage/sterilization of substances or materials (but, no evidence of animal usage)	2
Inhalant anesthesia: Improper use (lack of physical barrier between animals and the agent)	2
Failure to properly store or monitor controlled substances	refer to RC
Improper or incomplete labelling on bottles or secondary containers	1
REPORTING/DOCUMENTATION	
Failure to provide adequate documentation as required by IACUC protocol or IACUC/DAR policy	2
PHYSICAL ENVIRONMENT	
Inadequate sanitation as evidenced by physical examination (workspace and/or equipment)	2
Equipment: broken, in need of repair, or out of date for required calibration	1
Presence of human food and/or drink	refer to EHSO
Facilities or housing: In disrepair or in need of repair	2
Facilities or housing: In disrepair or in need of repair: Immediate and direct animal welfare concern	4