Guidelines to Resolve Issues of Non-compliance

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. 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.” 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. 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.

Introduction

The Emory University Institutional Animal Care and Use Committee (IACUC) has developed a system for evaluating issues of non-compliance per regulatory guidelines. The IACUC will evaluate issues of non-compliance using a point system.

This system was designed to determine the level of action to be taken based on the seriousness of an occurrence or its repetition. Disciplinary and remedial actions will be taken to ensure correction of issues of non-compliance; the severity of the action taken will be determined by the number of points accumulated (see below). The points for each Principal Investigator (PI) will be tallied on a rolling 12 month basis. PIs are responsible for actions of those who work under their supervision.

Mediating factors the IACUC will consider when evaluating an incident involving noncompliance include, but are not limited to, the extent to which the findings represent continuing or repeated violations, 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 demerits, the IACUC also will consider whether the incident was self-reported by the PI to the IACUC and any proactive corrective actions taken by the PI. However, it is important that the IACUC office be informed of all issues so that remedial actions can be documented and the university can meet its reporting obligations per regulatory requirements. Some examples of point assignment are listed below.


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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 “[r]eview, and, if warranted, investigate concerns involving the care and use of animals at the research facility…”).
2 PHS Policy IV.F.3.
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.”
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.
Deficiencies or infractions directly resulting in animal distress or suffering are considered serious issues of non-compliance and four points will be applied, thus prompting the first level of disciplinary action described below. If an occurrence of non-compliance directly results in animal distress, the IACUC Chair and/or veterinary staff may interrupt all animal work immediately pending a review.

Examples of serious animal welfare and/or human safety issues:

- Performing a procedure in such a manner that animals endure distress, pain, or suffering that is not addressed in the approved protocol
- Acquiring animals for research without IACUC approval and/or knowledge of the animal resources program.
- Not performing, or inadequately applying a physical means, to assure death when euthanizing animals.
- Not following aseptic technique as described in the protocol when performing survival surgery
- Failure to monitor animals adequately following an invasive procedure.
- Extreme cage overcrowding (as defined in IACUC policy)
- Not administering analgesics as required in the approved IACUC protocol
- Not following safety procedures such that personnel are unknowingly exposed to hazards (e.g. dangerous chemicals, radioactivity, biohazards)
- Interfering with the veterinary staff and/or failing to adhere with veterinary-mandated instructions
- 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)

Corrective Actions for Animal Welfare Issues and/or Animal Welfare and/or Human Safety Issues

First Offense (any or all of the following):

- Noncompliant Procedures stopped immediately by authorized veterinary staff or IACUC official
- A letter to the PI from the IO or IACUC Chairperson outlining the problem and requesting a detailed plan of corrective action
- PI required to appear before the IACUC or subcommittee to present plans for corrective action
- Notification to the PI’s department chair or division director
- Retraining of personnel
- Suspension of protocol and/or loss of animal use privileges
- Reporting to appropriate internal and external authorities

Additional Animal Welfare and/or Human Safety Issue Offenses (in addition to the above, corrective actions will require):

- Retraining of personnel
- Protocol knowledge assessment (e.g. test) of applicable personnel
- IACUC vote regarding loss of animal use privileges
- IACUC vote regarding suspension of protocol

II. Regulatory guideline issues and minor animal welfare issues: 1-4 pts.

With respect to non-compliance issues that do not directly result in animal pain or distress, the PIs will be assigned one to four points for each occurrence, depending whether the IACUC
considers it to be a minor animal welfare issue and/or a minor or major regulatory issue. Repeated or widespread findings may be accorded greater weight beyond 1-4 points.

Examples of minor animal welfare, IACUC policy, and regulatory guidelines issues:

- Housing animals in a laboratory without approval
- Allowing new personnel to work with animals before completing IACUC requirements
- Insufficient records of monitoring animals (disease condition, PI care, survival surgery, post-procedure care)
- Personnel ignorant of protocol content
- Performing unapproved procedure without causing pain or distress
- Failure to adhere to IACUC expired drug policy without specific exemption
- Controlled substances not secured properly or dispensing logs not kept
- Failure to respond to the IACUC by designated deadlines
- Failure to participate in the semi-annual inspection and/or review process
- Not participating in the Occupational Health and Safety Program where it is mandatory
- Improperly labeled bottles or secondary containers
- Relocating a laboratory without properly notifying the IACUC; research conducted in unapproved areas
- Improper waste disposal practices
- Exceeding the number of animals approved on the study (e.g., breeding colonies)
- Overcrowded animal enclosure(s)
- Improper laboratory or animal facility attire
- Cage cards not containing required information (e.g. date of surgery, chemical administration, tumor inoculation, etc.)
- Failure to maintain cleanliness, hygiene and upkeep of lab space where animal work is done
- Failure to follow established IACUC policy

Levels of disciplinary actions for minor compliance issues:

**First level:** accumulation of 4 points. Those activities related to the infraction will only be allowed to continue with consultation by an individual designated by the IACUC, such as a member of the veterinary staff or personnel associated with the animal resources program. The consultation may include training and written exams. Activities unrelated to the infraction will not be affected.

**Second level:** accumulation of 8 points. Future animal orders and on-hand animal use will not be allowed until the PI provides a written response addressing the specific issues to the satisfaction of the IACUC.

**Third level:** accumulation of 12 points. Noncompliant activities involving the use of animals will be halted immediately until such time as the IACUC can discuss the infraction and develop a recommendation during a normally scheduled (monthly) convened meeting. The Public Health Service, USDA (if applicable), and funding agencies will be notified of the suspension and the resolution if an activity is suspended.

Possible resolutions to a third level penalty include but are not limited to:

- Requiring that animal resources personnel perform the service for a fee
- Permanent suspension of activities using animals
- Permanent suspension of animal use privileges of specific personnel
• Any other action such as those in response to an animal welfare issue.

Repeated offenses will be handled on a case-by-case basis but, once IACUC has notified the PI of remedial action to be taken, repeated infractions will result in additional points, thereby jeopardizing ongoing activities (i.e. animal use privileges, protocol approval).

III. Appeal Process

PIs may appeal the application of points or levels of disciplinary actions taken. To do so, written correspondence must be submitted within two weeks of the action. The correspondence must be addressed to the IACUC Chair and mailed to the IACUC office. Further, it must identify the action they wish to appeal and clearly explain why it should be removed from their record. Appeals will be held and discussed at the next scheduled IACUC meeting after the appeal submission. A decision by the IACUC may only be overturned by the IACUC; there is no further appeal process.

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