Guidelines for Regulatory Reporting of Non-Compliance, Adverse Events, and Assessment of Penalties

This document is intended to provide guidance to both the investigators and the Institutional Animal Care and Use Committee (IACUC) with regard to how issues of non-compliance at the University of Cincinnati’s Animal Care and Use Program will be managed.

1. Incident Specific Non-Compliance

The Public Health Service Policy on Humane Care and Use of Laboratory Animals (revised August, 2002) “PHS Policy” categorizes non-compliant conduct into two categories: “minor” and “significant.” As defined by PHS Policy, a “significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official (IO), is or may be a threat to the health or safety of the animals.”

Significant deficiencies (non-compliances) that were determined by the IACUC and the IO to have been a threat to the health or safety of the animals must be reported promptly to the Association for Assessment and Accreditation of Laboratory Animal Care, Inc. (AAALAC), the Office of Laboratory Animal Welfare (OLAW), and the United States Department of Agriculture (USDA) if applicable.

In addition, serious or continuing noncompliance with the PHS Policy and/or the Guide for the Care and Use of Laboratory Animals (the Guide), and any suspension of an activity by the IACUC may also constitute a significant deficiency even though the health and safety of the animals may not have been threatened. The IACUC, through the IO, is responsible for reporting all such deficiencies. Failure by the University of Cincinnati to submit the required reports can result in the loss of AAALAC accreditation, termination of the PHS Assurance which is required to receive federal funding, termination of the USDA registration, and possible legal action by the federal regulatory agencies.

Non-compliance not posing a threat to the health and safety of the animals still requires prompt attention and resolution, but does not require reporting to the agencies cited above.

Examples of non-compliance based on the standards of AAALAC, OLAW, and the USDA:

A. Significant non-compliance that is reportable

1. Insufficient anesthesia, insufficient analgesia, inappropriate post-operative care, or improper euthanasia which results in pain or distress to the animal, or premature euthanasia of an animal due to failure by the investigative research staff to provide adequate veterinary medical care

2. Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents and mechanical failures, resulting in actual harm or death to animals

3. Conducting animal-related activities or procedures without IACUC approval, or beyond the expiration date of the protocol established by the IACUC

4. Use of surgery or housing area(s) which have not been approved by the IACUC

5. Implementation of any significant change to IACUC approved protocols without prior IACUC approval

6. Exceeding the allotment of animals without prior IACUC approval

7. Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained
8. Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry) 13
9. Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO2) 23
10. Failure of personnel to carry out veterinary orders (e.g., treatments) 14
11. Treatment of sick animals without prior consultation with veterinary staff 15
12. Any items categorized below as “significant non-compliance that is NOT reportable” or “minor non-compliance”, which result in pain, distress or premature euthanasia of an animal
13. Any items categorized below as “significant non-compliance that is NOT reportable” or “minor non-compliance”, which constitute continuing noncompliance at the IACUC’s discretion

B. Significant non-compliance that is NOT reportable
1. Repeated overcrowding of cages and animal pens, without prior IACUC approval 7
2. Failure to use aseptic technique during the performance of survival surgery 16
3. Use of expired drugs or use of non-pharmaceutical grade drugs without prior IACUC approval 17
4. Unapproved transfer of animals from one protocol to another 19
5. Improper transportation of animals 20
6. Participation in animal-related activities by individuals who are qualified and have been appropriately trained but were not added to the appropriate protocol 12

C. Minor non-compliance that is NOT reportable
1. Improperly labeled secondary containers 21
2. Failure to adhere to housing or procedure area specifications as defined by IACUC Policy (e.g., cleanliness) 22
3. Expired drugs found in the laboratory and not labeled “For In-vitro Use Only—Not for use in Animals” 23
4. Mill dates or Expiration dates not properly labeled on feed containers 26

2. Penalties for Non-Compliance
When determining the appropriate penalty to impose or to recommend, the IACUC may consider all of the following factors:
- Extent to which the incident(s) were self-reported by the Principal Investigator (PI) or staff
- Proactive corrective action(s) taken in response to the incident(s)
- Extent to which the incident(s) represent a continuing, or repeated violation
- Extent to which harm to an animal resulted from the incident(s)

While the IACUC will consider self-reporting and proactive corrective actions taken by the investigator in evaluating the non-compliance, these will not impact on reporting to regulatory agencies.

The IACUC will consider the length of time between incidents of non-compliance when developing corrective action and when declaring a series of incidents a continuing non-compliance.

The IACUC may at its discretion impose any of the corrective actions listed below separately or in combination in order to ensure compliance.

A. Corrective Actions for Significant Non-Compliance
- First Offense:
  o Procedures stopped immediately by LAMS vet or emergency meeting of the IACUC
  o A letter to the PI from the IO or Chairperson outlining the problem and requesting a detailed plan of corrective action, unless corrected during inspection
  o PI required to appear before the IACUC to present plans for corrective action
  o Notification to the PI’s department chair or division director
o Possible retraining of laboratory personnel
  o Possible suspension of protocol and or loss of animal use privileges
• Second Offense:
  o Retraining of laboratory personnel
  o PI required to appear before the IACUC to present plans for corrective action
  o Probable loss of animal use privileges
  o Possible suspension of protocol and or loss of animal use privileges
• Third Offense:
  o Probable suspension of protocol and or loss of animal use privileges

Note: Any suspension of a protocol would affect all personnel in the laboratory performing procedures. In some instances, an individual’s animal use privileges to work on any protocol may be revoked.

B. Corrective Actions for Minor Non-Compliance
• First Offense:
  o An email notification on behalf of the IACUC chairperson to the PI outlining the problem and specifying desired corrective action(s)
• Second Offense:
  o A letter from the IO to the PI outlining the problem and specifying desired corrective action(s)
• Third Offense:
  o A letter to the PI outlining the problem and requesting a detailed plan of corrective action, unless corrected during inspection, and a plan for verification
• Fourth Offense:
  o Continuing incidents of minor non-compliance may be upgraded to a significant non-compliance, and would be subject to the penalties and reporting requirements outlined in that section

3. Programmatic Deficiencies
• Failure to correct situations identified in previous IACUC semiannual evaluations as significant deficiencies in a timely manner
• Shortcomings in the programs of veterinary care, occupational health, training, or with the IACUC that are identified during semiannual program review and not corrected within the institutionally determined time frame

The IACUC semiannual evaluations are intended to be tools for institutional self-identification and correction of facility and program deficiencies and therefore are not required to be submitted to OLAW. However, serious problems may be identified during the course of IACUC semiannual evaluations that also qualify for prompt reporting.

A. Corrective Actions for Programmatic Deficiencies
• Programmatic deficiencies must be categorized as acceptable, minor, or significant.
• The corrective action for a significant deficiency must include a reasonable plan to correct the issues as well as a date by which the issue will be corrected.
• Significant programmatic deficiencies must be reported to the applicable regulatory agencies if the deficiency jeopardizes the health and welfare of the animals, or if the institution is unable to meet the correct by date.
1. PHS Policy, IV.B.3
2. AAALAC Rules of Accreditation, Section 2, Standards, Paragraph 7
3. PHS Policy, IV.F.3
4. 9 CFR 2.31(c)3
5. PHS Policy V.A., B., C., 9 CFR 2.38(k)
6. Chapter 3 of the Guide
7. Chapter 2 of the Guide, see IACUC Policy #001
8. PHS Policy, IV.C. and 9 CFR 2.31
9. Ibid.
10. PHS Policy IV.B.7
11. PHS Policy IV.B.7, see IACUC Policy #006
12. PHS Policy IV.C.1.f
13. NOT-OD-05-034
14. Ibid.
15. 9 CFR 2.33(b)(3) and Chapter 3 of the Guide
16. 9 CFR 2.31(d)(ix), see IACUC Policy #016
17. USDA Policy #3, see IACUC Policy #019
18. PHS Policy, IV.C. and 9 CFR 2.31
19. Ibid.
20. Chapter 3 of the Guide, see IACUC Policy #003
21. 29 CFR 1910.1200, see IACUC Policy #017
22. Chapter 2 and 4 of the Guide, see IACUC Policies #012 and #021
23. Chapter 3 of the Guide, see IACUC Policies #4 and #17
24. PHS Policy, IV.F.3 and NOT-OD-05-034
25. Ibid.