



THE UNIVERSITY OF TOLEDO

SUBJECT: IACUC Standard Operating Procedure for Handling Allegations of Non-Compliance

DATE: July 21, 2021

University of Toledo (UT) Standard Operating Procedure for Handling Allegations of Non-Compliance with Animal Research Guidelines, Regulations and Policies

1. Introduction

This document describes the process that the University of Toledo (UT) Institutional Animal Care and Use Committee (IACUC) follows for allegations and findings of non-compliance with policies and regulations governing research, teaching and training involving animals.

The UT IACUC is responsible for review of all investigations involving animals in accordance with the Public Health Services (PHS) Policy on Humane Care and Use of Laboratory Animals, Animal Welfare Act, the Guide for the Care & Use of Laboratory Animals, and the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. The primary concern of the IACUC is to ensure the humane care and use of animals.

The IACUC encourages those who are aware of, or concerned about the potential for non-compliance, to report their concerns to the IACUC as set forth in this SOP.

2. Definitions

Allegation of non-compliance: An unconfirmed report of non-compliance with applicable federal, state, or local laws or regulations, IACUC SOPs, or with an approved IACUC protocol.

Complainant: The individual who presents an allegation of non-compliance. Such an allegation of non-compliance must be made in good faith and with a reasonable basis for believing that the non-compliance occurred.

Non-compliance: The failure (intentional or unintentional) to comply with applicable federal, state, or local laws or regulations, IACUC Guidelines/SOPs, and/or with an approved IACUC protocol.

Respondent: The person against whom an allegation of non-compliance has been made.

Continuing non-compliance: Additional non-compliance within the same protocol over a period of two years.

Serious non-compliance: Non-compliance that has resulted in or has the potential to result in harm or death to an animal or the conduct of significant animal research without IACUC approval.

Significant animal research: research procedure that would require at least designated member review if added to or part of an amendment.

3. Non-compliance

Non-compliance may be minor or serious, sporadic or continuing. The degree of non-compliance is evaluated on a case-by-case basis, taking into account considerations such as to what degree the animals were harmed or placed at an increased risk and the willfulness of the non-compliance.

Examples of non-compliance include, but are not limited to the following:

- a) Conduct of animal-related activities without appropriate IACUC review and approval;
- b) Failure to adhere to IACUC-approved protocols;
- c) Implementation of any significant change to IACUC-approved protocols without prior IACUC approval (e.g., conducting an unapproved surgical or non-surgical procedure);
- d) Conduct of animal-related activities beyond the expiration date established by the IACUC protocol;
- e) Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained;
- f) Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures), as stipulated in the approved IACUC protocol, at a minimum;
- g) Failure to maintain appropriate and accurate animal-related records (e.g., identification, medical, husbandry);
- h) Exceeding animal numbers in an IACUC-approved protocol without filing an amendment to the protocol
- i) Failure to conduct euthanasia in an approved manner or failure to perform secondary method to assure death
- j) Performing a procedure in such a manner that animals endure distress, pain, or suffering that is not addressed in the approved protocol
- k) Failing to report adverse event(s) or unanticipated problems within a period of two business days;
- l) Not following safety procedures such that personnel are unknowingly exposed to hazards (e.g. dangerous chemicals, radioactivity, biohazards)
- m) Interfering with the veterinary staff and/or failing to adhere with veterinary-mandated instructions

Only the IACUC and/or the Institutional Official may make the determination of non-compliance based on the recommendation of the Inquiry outcome. If a finding of non-compliance is determined to be serious and/or continuing, the same shall be reported to the Office of Laboratory Animal Welfare (OLAW) as stated below.

4. Reporting Allegations of Non-compliance

Allegations of non-compliance may be made known to UT in several ways, including but not limited to:

- a) Reported by the OLAW to UT;
- b) New IACUC applications or continuing reviews submitted to the IACUC may reflect instances of non-compliance in the conduct of previously IACUC approved protocols;
- c) During Semi-annual site visits;

- d) During post-approval monitoring of the research project by IACUC Office;
- e) Reports from collaborators, study personnel, or employees (including DLAR staff); or
- f) Complaints from anonymous sources.

Per IACUC Whistleblower policy, it is a violation for any individual to engage in retaliatory acts against any individual who reports an incident of non-compliance or assists or participates in a proceeding or investigation relating to allegations of non-compliance.

5. Inquiry Process for Evaluating Allegations of Non-compliance

Confidentiality will be maintained throughout the investigation. This will be achieved by restricting the dissemination of information about the allegation, the course of the investigation and its outcome. Additionally, good faith efforts to maintain the confidentiality of the identity of the Complainant, where possible. Due to the nature of the investigation, confidentiality cannot always be assured, however, when it becomes necessary to reveal the name of the Complainant, he or she will be notified prior to the identity being revealed.

a) Receipt of Allegation and Potential Protocol Hold

Upon receiving an allegation of non-compliance, the IACUC chair, IACUC Administrator, and the Attending Veterinarian shall confer as to whether the allegation is of such a nature that it warrants a temporary administrative hold of the protocol at issue pending review. If so, the IACUC chair (or his/her designee) shall advise the PI/Respondent of the allegation of non-compliance and that the protocol is on hold pending completion of the Inquiry.

b) Completing an Inquiry

During an Inquiry a thorough and timely investigation will be conducted by DLAR personnel and/or IACUC Administration of whether there was/is, in fact, a situation of non-compliance and whether it was/is serious and/or continuing. The Inquiry may include, but is not limited to:

- Requesting a written response from the respondent regarding the allegation;
- Interviewing members of the research team, the respondent, the complainant; and/or
- Conducting an unannounced laboratory visit

6. IACUC Process for Allegations of Non-compliance

Following the Inquiry, all Allegations that were deemed to be non-compliance will be brought forth to the full IACUC.

a) Non-compliance that is determined to be Not Serious and Not Continuing

The individuals involved in the Inquiry will convene a full IACUC meeting and the IACUC shall determine what actions to take to protect the welfare of animals. These actions may include, but are not limited to:

- Sending a letter of reprimand to the respondent and the PI, if appropriate, (potentially copied to their respective department chair, dean, institute and/or center director, faculty advisor (student research) and research compliance coordinator);
- Educating the respondent and the PI, if appropriate, as well as the department, institute or center staff; and/or
- Requiring that the respondent or the PI, if appropriate, create a plan of action to remedy the non-compliance.

b) Non-compliance that is determined to be Serious and/or Continuing

The individuals involved in the Inquiry will convene a full IACUC meeting, and the IACUC shall officially vote to establish if the complaint represents Serious or Continuing non-compliance. Then they will determine what actions to take to protect the welfare of the animals.

- Serious but not Continuing non-compliance results in a letter to the investigator, departmental chair, and the IO. It should also include one of corrective actions below, dependent upon the nature of the incident.
- Continuing noncompliance results in a letter to the investigator, departmental chair, and the IO. It will also include at least one of the following corrective actions:
- Possible corrective actions:
 - i. Requesting that the PI provide a corrective action plan;
 - ii. Educating the respondent and the PI, if applicable, and/or all research staff;
 - iii. Suspending or terminating the study;
 - iv. Conducting random audits of the studies conducted by the respondent or the principal investigator and/or all research staff;
 - v. Modifying the research protocol;
 - vi. Recommending to the IO the confiscation of all data collected during the period of non-compliance
 - vii. Recommending to the IO, as relates to the respondent or the PI, if applicable, suspension or revoking the privilege to conduct animal work as a PI or Co-PI or serve as a faculty advisor of student research at UT; and/or
 - viii. Referral to other organizational entities (e.g., General Counsel, Human Resources).

The IACUC must report to OLAW, AAALAC, and USDA (if the issue involved a USDA-covered species) under applicable law and regulations if the issue is Serious and/or Continuing.

The suspension may be lifted following a vote at meeting of the IACUC with a quorum.

7. Appeal.

The PI or research staff will have approximately 14 days to appeal the IACUC decision in writing. The appeal should be based on presentation of new information or unusual circumstances not previously mentioned at time of inquiry. The appeal will be considered during the next scheduled IACUC meeting, and the PI may be invited to attend, or may request to speak. The investigator(s) will be notified within 5 business days of the FINAL decision of the IACUC. Written notice of process and findings will be sent to the person who submitted the original complaint within 30 days.