

UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	IACUC - 002
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Procedure Title:	Noncompliance

1.0 Objective

- 1.1. To describe the policies and procedures the Institutional Animal Care and Use Committee (IACUC) and the Office of Research Integrity and Outreach (ORIO) follow for handling allegations of noncompliance.

2.0 General Description

- 2.1. The primary responsibility of the IACUC is to ensure the humane care and use of animals. In performing that responsibility, the IACUC addresses allegations of noncompliance with federal and state regulations and institutional policies and procedures governing the conduct of research, teaching, and training involving animals.
- 2.2. ORIO staff, IACUC members, or IACUC consultants do not participate in alleged noncompliance reviews if they have a financial or institutional conflicting interest or are personally involved in the research.

3.0 Definitions

- 3.1. **Allegation** is a disclosure of possible noncompliance by a respondent to the Research Compliance Administrator (RCA) by any means of communication.
- 3.2. **Complainant** is a person who makes an allegation and need not be a member of the University of Southern Maine (USM) Community.
- 3.3. **Continuing noncompliance** is a knowing, intentional, or reckless persistent failure to adhere to the laws, regulations, or policies governing animal research. The IACUC may take into consideration the volume and complexity of a researcher's activities in making the designation of continuing noncompliance.

- 3.4. **Noncompliance** is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to the conduct of research involving animals.
- 3.5. **Principal Investigator (PI)** of an IACUC protocol is the person who has the responsibility and authority to direct the animal activities on the protocol.
- 3.6. **Respondent** is a person who is the subject of an allegation and must be a member of the USM Community at the time the alleged noncompliance occurred.
- 3.7. **Serious noncompliance** is a failure to adhere to the laws, regulations, or policies governing animal research and which places animals at a greater risk of harm than would otherwise exist under the IACUC-approved protocol, or the conduct of animal research without IACUC approval.

4.0 Responsibility

- 4.1. Execution of SOP: IACUC Chair, IACUC Members, ORIO Staff, RCA, Investigators, and Research Personnel.

5.0 Procedure

5.1. Submission and Screening of Allegations of Noncompliance

- 5.1.1. Anyone may submit allegations of noncompliance involving animal research to the RCA or Assistant Provost for Research Integrity verbally or in writing. Anyone who wishes to make an anonymous allegation should follow the procedure set forth in Section 6.3 of the USM Alleged Research Misconduct Policy RCR-101. The RCA/ORIO/IACUC shall maintain confidentiality regarding the identity of the person submitting the allegation to the extent possible.
- 5.1.2. The RCA screens the allegation of noncompliance to determine whether the protocol(s) affected is supported by federal funds.
- 5.1.3. The RCA also determines whether the protocol has issues pertinent to other research review committees (radiation committee or IBC).
- 5.1.4. If the alleged violation involves a reportable disease the RCA shall notify the attending veterinarian immediately.

5.2. Preliminary Assessment of Allegation

- 5.2.1. The RCA reviews all allegations to determine whether the facts justify the allegation (i.e. whether there is credible information to justify a review).
- 5.2.2. If the RCA deems an allegation unjustified (i.e., there is no credible information to justify a review), the RCA communicates this determination in

writing to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent). Upon resolution of the issue, the RCA provides an oral and/or written summary of the resolution to the applicable IACUC at the next convened IACUC meeting.

- 5.2.3. If the RCA determines that an allegation is justified but is minor or administrative in nature, he/she manages the concern through communications with the investigator. The RCA communicates this determination in writing to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent). Upon resolution of the issue, the RCA provides an oral and/or written summary of the resolution to the applicable IACUC at the next convened IACUC meeting.
- 5.2.4. If the RCA determines that an allegation is justified, the RCA forwards the allegation materials to the IACUC Chair or designee for review. The RCA shall determine whether an allegation is justified if, in his or her judgment: the alleged conduct could constitute noncompliance and there is credible information to support further review.
- 5.2.5. If the IACUC Chair deems the allegation unjustified, the RCA communicates this determination in writing to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent). Upon resolution of the issue, the RCA provides an oral and oral or written summary of the resolution to the applicable IACUC at the next convened IACUC meeting.
- 5.2.6. If the IACUC Chair determines that an allegation is justified, the RCA initiates an inquiry into an allegation.

5.3. Initiating an Inquiry into an Allegation

- 5.3.1. If the IACUC Chair determines that an allegation is justified, the RCA notifies the investigator. If the allegation involves co-investigator(s) or research personnel, the RCA also contacts these individuals (by phone, email, or letter).
- 5.3.2. The IACUC Chair appoints the RCA and/or designee(s) to gather information pertaining to the nature of the allegation. The RCA may compare the protocol procedures approved by the IACUC to the procedures followed by research personnel in conducting the study.
- 5.3.3. When appropriate, the RCA interviews the complainant or, in cases where the complainant requests anonymity, the individual who received the original allegation interviews the complainant. The interviewer prepares a summary of the interview and gives the complainant the opportunity to comment on the written summary. In some cases, the complainant may have already

submitted a written complaint, which the RCA then verifies. The RCA may request additional information from the complainant.

- 5.3.4. When appropriate, the RCA interviews the respondent and gives him/her the opportunity to comment on the allegation and provide information. The RCA prepares a summary of the interview and gives the respondent the opportunity to comment on the summary. The respondent may submit a written rebuttal to the complaint, which the RCA verifies. The RCA may request additional information from the respondent.
- 5.3.5. Depending on the nature of the allegation and the information collected during the interviews, the RCA may interview other individuals. The RCA may also examine research data (both published and unpublished), the applicable approved IACUC protocol, and any other pertinent information.
- 5.3.6. When appropriate, the RCA prepares a summary report for the convened IACUC. The report may consist of a summary of the allegations, abstract of interview(s), and copies of pertinent information or correspondence. The report may or may not include recommendations for IACUC action. In some cases, the RCA simply meets with the convened IACUC and submits the documentation gathered during the investigation without a written report.

5.4. Review Procedures

- 5.4.1. The RCA advises the IACUC regarding the applicable University and federal regulations, assists the IACUC in documenting the review, answers questions about the review process, maintains the records as required by state and federal laws, and serves as a liaison with the funding agency or agencies.
- 5.4.2. The IACUC reviews the material presented by the RCA at a convened meeting at which a quorum is present. The materials provided include the summary report of the noncompliance and the protocol if applicable. The convened IACUC determines whether to request additional information or whether to interview additional witnesses. The IACUC may give the respondent the opportunity to meet with the convened IACUC before it takes final action.

5.5. Review Outcomes/IACUC Actions

- 5.5.1. The convened IACUC makes the determination whether the allegation is substantiated, and if so, whether the noncompliance is serious or continuing or both based on the materials compiled during the inquiry. If the noncompliance is serious or continuing or both, the Institutional Official (IO), with the assistance of the RCA, reports the incident(s) to the applicable federal agency.
- 5.5.2. The convened IACUC may take a variety of actions, depending on the outcome of the review, including, but not limited to, the following:

- 5.5.2.1. Approve continuation of research without changes;
- 5.5.2.2. Request formal educational intervention;
- 5.5.2.3. Request minor or major changes in the research procedures;
- 5.5.2.4. Require the investigator create a plan of action to remedy the noncompliance;
- 5.5.2.5. Require monitoring of research;
- 5.5.2.6. Suspend or terminate IACUC approval/disapprove continuation of the study;
- 5.5.2.7. Require audits of other active protocols of the investigator;
- 5.5.2.8. Disqualify the investigator from conducting research involving animals at the University;
- 5.5.2.9. Determine that the investigator may not use the data collected for publication;
- 5.5.2.10. Request that the investigator inform publishers and editors if he/she has submitted or published manuscripts emanating from the research; and/or
- 5.5.2.11. Referral to other university departments such as General Counsel or Human Resources.

5.5.3. The RCA informs the following individuals of the allegation(s), the review process, and the findings of the review.

- 5.5.3.1. Investigator;
- 5.5.3.2. Complainant;
- 5.5.3.3. Research Integrity Officer;
- 5.5.3.4. Department Chair;
- 5.5.3.5. Dean;
- 5.5.3.6. Human Resources;
- 5.5.3.7. Provost;
- 5.5.3.8. Office of Laboratory Animal Welfare;
- 5.5.3.9. United States Department of Agriculture;
- 5.5.3.10. Association for the Assessment and Accreditation of Laboratory Animal Care;
- 5.5.3.11. Sponsor; and/or
- 5.5.3.12. Other administrative personnel as appropriate.

5.5.4. The RCA resolves questions or concerns raised by an investigator regarding the outcome of a specific IACUC noncompliance review through direct communication with the investigator.

5.6. Re-evaluation/Appeal of IACUC Decisions

5.6.1. The investigator may submit new information or concerns of due process in writing to the IACUC within thirty of the IACUC's decision. The investigator may specify the nature of any claimed procedural error or the perceived unfairness of sanctions issued.

5.6.2. The IACUC limits concerns to a review of the procedures employed to reach the decision (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances against sanctions imposed as a result of a finding of noncompliance.

5.7. The re-evaluation/appeal process shall be a continuation of the original review record.

6.0 References

6.1. PHS Policy on Humane Care and Use of Laboratory Animals IV.F.3; NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS policy on Humane Care and Use of Laboratory Animals; 9 CFR §2.31 (d)(7)