

Animal Care & Use Program Policy



Review and Reporting of Animal Welfare Concerns

Research Integrity Office

iacuc@ohsu.edu

westcampusiacuc@ohsu.edu

CWC Office: 503.494-8408

WC Office: 503.466.3800

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Background

“As an agent of the institution, the IACUC shall with respect to PHS-conducted or supported activities...review concerns involving the care and use of animals at the institution” (PHS Policy IV.B.4).

“The IACUC through the Institutional Official (IO), shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a. Any serious or continuing noncompliance with PHS policy;
- b. Any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals” (PHS policy IV.F.3).

Scope

This policy defines the process by which concerns are evaluated and reported to the Institutional Official (IO), who is the Senior Vice President for Research.

Definitions

Noncompliance: Failure to follow regulations, institutional policies, and/or the requirements or determinations of the IACUC, including animal-related activities not on the approved protocol.

Serious Deviations: Noncompliance with the standards set forth in the *Guide* that adversely affects the safety, welfare, or responsible care and use of animals.

Continuing Noncompliance: A pattern of repeated noncompliance that is likely to continue without intervention or failure to work with the IACUC to resolve the noncompliance.

Serious Noncompliance: Noncompliance that adversely affects the safety or welfare of animals or humans.

IACUC Leadership Team (ILT): Composed of the Research Integrity Officer (RIO), the Attending Veterinarian (AV), and the IACUC Chair from both the Central and Waterfront and West Campuses.

Policy

The IO will report to the appropriate federal agencies, as applicable, any serious or continuing noncompliance and/or serious deviations from the provisions of the *Guide*.

Procedure

- I. Any individual having an animal welfare concern at OHSU must promptly report that concern. Each OHSU campus provides mechanisms for reporting animal welfare concerns. The mechanisms for reporting will be posted in prominent locations identified by the IACUC on each campus and on applicable OHSU websites. Animal welfare concerns may be reported to any of the following individuals or offices:
 - a. Reporting to IACUC Chair, Research Integrity Officer (RIO), or Attending Veterinarian
 - b. West Campus Animal Concerns line 503.629.4111
 - c. OHSU Integrity Hotline 877.733.8313

- d. OHSU Integrity Office 503.494.8849
 - e. OHSU Integrity Hotline
- II. The information provided in a report should be as specific as possible with regard to the date, time, species involved, names of the relevant OHSU personnel, and any other supporting information.
 - a. No OHSU Member will be subject to any reprisal for reporting, in good faith, violations of any regulations or standards under the Animal Welfare Act, PHS Policy, or any other applicable regulation.
 - III. Any issue that may represent potential noncompliance shall be addressed by the RIO on the appropriate campus who will evaluate the issue in accordance with the Integrity Office standard procedure for investigating concerns. The following individuals may be involved: the other RIO; Attending Veterinarian; IACUC Chair and/or IACUC members; or others, as appropriate.
 - IV. At the conclusion of the evaluation, the ILT will develop a mitigation plan that defines corrective actions necessary to address the issue and minimize the possibility of reoccurrence. The mitigation plan will be presented to the IACUC for acceptance or for modification to include additional mitigation steps. The RIO will ensure that all appropriate mitigation steps have been implemented.
 - a. If the animal welfare concern involves an IACUC protocol, the IACUC will decide how to proceed. This may include notification to the department head, additional training, and/or suspension of the protocol.
 - b. Suspension or termination of the protocol will be determined at an IACUC meeting in accordance with OHSU policy and procedures.
 - V. The RIO and Chief Integrity Officer will send issues that represent serious deviations, or serious and/or continuing noncompliance to the IO for reporting to federal agencies, as appropriate.
 - VI. The RIO will prepare the necessary reports.
 - VII. Any required notification and communication with external funding agencies will be done by the OHSU Senior Director, Office of Proposal and Award Management (OPAM).
 - VIII. Reports to accrediting agencies such as AAALAC will be made as appropriate.
 - IX. The outcome of any serious and/or continuing noncompliance and/or serious deviation, including the final report to OLAW and the OLAW response, will be reported to the IACUC by the RIO.

Authority

Notice NOT-OD-05-034 Guidance on Prompt Reporting to OLAW

PHS Policy on Humane Care and Use of Laboratory Animals

Guide for the Care and Use of Laboratory Animals (2011, 8th edition)