



Approved by: IACUC COMMITTEE

Date: 3/21/24

Next Review: Triennial Review

Policy on Reporting Adverse Events, Animal Welfare Concerns, and Non-Compliances

1.0 Purpose

The University of South Alabama (USA) is committed to protecting the welfare of animals used in research and teaching. On rare occasion, the use of animals in the biomedical setting can result in adverse events or unanticipated consequences, potentially affecting animal welfare. This policy aims to offer guidance on how and when to report these events and to detail the steps by which the IACUC will investigate these reports. This policy also addresses what actions may follow the event of a confirmed noncompliance or adverse event.

2.0 Applicability

This policy applies to all persons responsible for conducting animal research, teaching, training, breeding, and related activities involving live vertebrate animals and conducted at or under the auspices of the USA.

3.0 Definitions

Adverse event- An unanticipated event affecting animals covered by an IACUC-approved protocol. Examples include unexpected phenotypes affecting clinical animal welfare, increased incidence of animal morbidity and/or mortality as a result of an IACUC-approved experimental protocol (i.e., more than what is described in the IACUC protocol), any event that impacts personnel health and safety, and physical plant failure that has the potential to affect animal welfare.

Animal welfare concern- Deficiencies in the care/treatment of animals. Examples include failure of husbandry staff to complete daily observations/husbandry, failure of LVTs and animal care staff to carry out veterinary orders, and failure of research staff to complete and document post-procedure care.

Noncompliance- A deviation from policies or procedures without prior approval. Examples include the conduct of animal activities before IACUC approval, failure to correct deficiencies identified by the IACUC, initiation of a significant change to an IACUC-approved protocol without prior IACUC approval of the proposed change via amendment of the protocol, failure of personnel to complete IACUC-required training before animal use.

4.0 Policy

The USA follows the guidelines for prompt reporting as outlined by AAALAC and OLAW.

5.0 Procedures

Reporting of animal welfare concerns-

Research and animal care staff must report adverse events, animal welfare concerns, and/or noncompliance to the Attending Veterinarian (AV), Institutional Official (IO), or IACUC. Reports are expected to be made within 72 hours of the incident/event, or sooner depending on perceived severity. Reports can be made anonymously, and the reporting individual is protected from discrimination and reprisals. The Animal Welfare Policy Statement contains contact information posted throughout the vivarium, at the entry to laboratories where procedures take place, and ABSL-3. It is also located on the IACUC website:

<https://www.southalabama.edu/departments/research/compliance/animalcare/resources/animal.welfare.policy.statement.07.08.21pdf.pdf>

Reports can also be made by calling the "whistle-blower hotline" or through the online EthicsPoint portal:

<https://secure.ethicspoint.com/domain/media/en/gui/60474/>

Investigation of reports-

If an animal is in **immediate danger**, the AV has designated program authority and can take **any necessary action to protect the animal's welfare and safety**. This includes humane euthanasia of the animal, if applicable. In this case, the AV will immediately report the incident to the IO and IACUC Chair (Vice-Chair if the Chair is not available).

The IACUC investigates all reports. The Chair will appoint two voting members of the IACUC to meet and gather information regarding the report. The two voting members will present the report and any pertinent information to the IACUC at the next meeting of the full Committee. Depending on the nature of the report, the Chair may request a meeting of the IACUC before the next regularly-scheduled meeting. The IACUC will vote on how to proceed. Potential consequences for a confirmed noncompliance or adverse event include but are not limited to suspending all animal activities, re-training of involved individuals, and reporting to the funding agency.

Reporting to OLAW, AAALAC, and/or the USDA-

For PHS-funded animal activities, as per PHS Policy, section IV.F.3., the IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken concerning any serious or continuing noncompliance with the PHS Policy, any serious deviations from the provisions of the Guide, or any suspension of an activity by the IACUC. Typically, a preliminary report is made by the AV via phone or

email within 72 hours of the incident and the final report is made in writing by the IO.

Any report made to OLAW is also reported to AAALAC.

When the animal activities are not PHS-funded, the Attending Veterinarian will promptly provide AAALAC and the USDA, if applicable, with a full explanation of the circumstances and actions taken concerning any serious or continuing noncompliance with the Animal Welfare Act, if appropriate, or the AAALAC Program Description; any serious deviations from the provisions of the Program Description; or any suspension of an activity by the IACUC.

The University of South Alabama IACUC uses criteria detailed in NOT-OD-05-034 as guidance in deciding on prompt reporting requirements to AAALAC, OLAW, and/or the USDA for all animal activities:

A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3, fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussions and will guide concerning specific situations. Situations that meet the provisions of IV.F.3 and are identified by external entities such as the United States Department of Agriculture or the Association for Assessment and Accreditation of Laboratory Animal Care International or by individuals outside the IACUC or the institution are not exempt from reporting under IV.F.3.

Examples of reportable situations:

- *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;*
- *conduct of animal-related activities without appropriate IACUC review and approval;*
- *failure to adhere to IACUC-approved protocols;*
- *implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;*
- *conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);*
- *conduct of official IACUC business requiring a quorum (full Committee review of activity by IV.C.2 or suspension by IV.C.6) in the absence of a quorum;*
- *conduct of official IACUC business during a period of time that the Committee is improperly constituted;*
- *failure to correct deficiencies identified during the semiannual evaluation in a timely manner;*
- *chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;*

- *participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.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);*
- *failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);*
- *failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);*
- *failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or*
- *IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.*

6.0 Enforcement

This policy is under the authority of the IACUC and communicated through the Office of Research Compliance and Assurance. The IACUC has the authority to enforce the provisions of this policy and, if necessary, suspend research or implement appropriate sanctions.

7.0 Related Documents

Notice Number: NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>

AAALAC: Managing and Reporting Adverse Events

<https://www.aaalac.org/accreditation-program/faqs/#H2>

OLAW: Reporting Noncompliance

<https://olaw.nih.gov/guidance/reporting-noncompliance.htm>