Introduction: Safeguarding animal welfare is the responsibility of every individual associated with the Animal Care and Use Program. The use of animals in research, testing, or teaching may occasionally result in adverse events (AEs), abnormal animal behaviors/conditions, or other incidents that impact or have potential to compromise animal welfare. Federal regulations and professional standards require that such situations are promptly and appropriately reported to the veterinary staff and, in certain cases, to the IACUC.

Prompt reporting upholds the commitment of the IACUC, investigators, and the institution to engage in high-quality research and support the welfare of all animals on a protocol. Reporting allows for the timely delivery of care to affected animals; enables collaboration by the IACUC, investigators, and animal care staff to identify and implement changes to decrease risk of recurrence; and enhances cooperation among investigators, veterinary care staff, and the IACUC with the ultimate goal of improving research quality and protecting animal subjects.

I. Definitions of Reportable Situations

A. An incident is any event that does not immediately impact animal welfare but has the potential to do so.

B. Abnormal behavior/conditions are signs of unusual behavior or injury, illness, or deaths unrelated to study procedures.

C. An adverse event (AE) is an unexpected event that leads to harm (pain, distress, or morbidity), or endangers the well-being of animals on an IACUC protocol. By definition, AEs are not identified as potential outcomes in the approved IACUC protocol. An AE may be protocol-related, intrinsic to the animal population studied (e.g., specific feature associated with engineered genotypes), or it may be the result of conditions external to the protocol, such as shipping, physical plant malfunctions, or weather events. An AE may also have an impact on personnel health and safety.

Although the cause may not be immediately known, a variety of situations may precipitate an AE. Examples of such causes include, but are not limited to:

1. Unforeseen features intrinsic to the animal
2. Human error / accidents
3. Deviation from activities or procedures approved on the protocol
4. Deviation from an IACUC Policy/Guideline/SOP (without an IACUC-approved exception)
5. Equipment malfunction or failure
6. Natural disasters
7. Facility-related emergencies (power outage; plumbing issues/leaks causing flooding; fire; etc.).
8. Environmental hazards (disease outbreaks; zoonosis exposure; infestations of mold, pests, etc.)

II. Examples of situations that must be reported
A. Animal mortality or morbidity not described or in excess of that described in the approved IACUC protocol.
B. Events that lead to animal harm or that cause obvious distress not justified and approved in the protocol.
C. Phenotypes associated with transgenic animals (e.g., tumor development, early death) that negatively impact the welfare of an animal.
D. Surgical complications such as anesthetic deaths, infections, or wound dehiscence.
E. Unexpected clinical signs potentially related to a protocol procedure.
F. Injury or illness unrelated to study procedures (e.g., age-related mortality, etc.).

III. Examples of situations that are not required to be reported

A. Injury/illness unrelated to approved procedures and being treated by the clinical veterinarians.
B. Death or morbidity of animals as expected and described in the approved IACUC protocol.

IV. Procedures for Reporting Adverse Events, Abnormal Behaviors/Conditions, and Incidents

When any situation jeopardizes animal welfare, the project personnel or animal care staff must follow the procedures outlined below:

1. If warranted, immediate care must first be provided to the animal(s). If pain or distress cannot be relieved, the animal should be humanely euthanized. Consult an Animal Care Technician or the Attending Veterinarian to coordinate an appropriate response. All steps should be taken to remedy the situation to prevent further harm to other animals.
2. The Attending Veterinarian and Vivarium Staff (vivarium@uncc.edu) must be notified immediately to ensure that the situation is managed and, if animals are affected, that animals receive appropriate veterinary care and monitoring. Any clinical issue, regardless of the severity, must be reported to the Veterinarian.
3. The Veterinarian will provide guidance regarding whether the reported situation constitutes an AE and therefore requires submission of an AE report (see Appendix A).
   a. Within 48 hours of an AE, the Principal Investigator (PI) will email a written report (Appendix A) to the Attending Veterinarian for review. Copy the report to the IACUC (uncc-iacuc@uncc.edu) and Vivarium (vivarium@uncc.edu). If the PI is not available, a senior investigator may report the AE, copying the PI. If the AE is related to husbandry or the facility, the Attending Veterinarian will submit the AE report.
   b. The Veterinarian will review and sign the report before forwarding to the ORPI for distribution to the IACUC.
   c. The IACUC is responsible for determining whether additional steps are necessary to ensure animal welfare. Depending on the nature and severity of the AE, the IACUC may take immediate action or defer discussion to the next meeting.
   d. Some regulatory or funding agencies may require an institutional report of AEs. The ORPI will report AEs as required by regulation.

Supplemental information may be requested by the IACUC at a later date.

V. Failure to Report AEs

The IACUC views the failure to report an AE by animal research participants as non-compliance. Such failures will be addressed by the IACUC on a case-by-case basis.

References


Mohan, S., Hampton, L. & Silk, S. Adverse events at research facilities. Lab Anim 46, 244–249 (2017). https://doi.org/10.1038/lababn.1278
APPENDIX A

Animal Care and Use Program

ADVERSE EVENT REPORTING FORM

**PROTOCOL INFORMATION**

<table>
<thead>
<tr>
<th>Protocol Title:</th>
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<tr>
<td>Protocol ID:</td>
<td>Principal Investigator:</td>
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</table>

**Event Information (date and room/location)**

**Description of Animal(s) Involved**

**Personnel Involved**

**Personnel Training Relevant to Protocol Procedures**

<table>
<thead>
<tr>
<th>Name</th>
<th>Topic</th>
<th>Date</th>
<th>Trainer</th>
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**Incident Description (narrative)**

**Corrective Action Plan (if applicable)**

**PI Signature**

**Date**

**AV Signature**

**Date**