UNIVERSITY OF NORTH CAROLINA
CHARLOTTE
ANIMALC CARE AND USE PROGRAM

SOP: Reporting Non-Compliance, Adverse Events, Abnormal Behaviors/Conditions, and Other Incidents

Objective:	To describe procedures for reporting situations that have actual or potential adverse effects on animal welfare
Author:	Office of Research Protections and Integrity (ORPI)
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I. 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; enhances cooperation among investigators, veterinary care staff, and the IACUC to identify and implement changes to decrease risk of recurrence with the ultimate goal of improving research quality and protecting animal subjects.

II. Definitions

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

B. 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.)

C. **Attending Veterinarian (AV)** means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates.

D. An **incident** is any event that may immediately impact animal welfare or have the potential to do so.

E. **The Institution or the University** refers to the University of North Carolina at Charlotte.

F. The **Institutional Animal Care and Use Committee (IACUC)** is responsible for ensuring the protection and care of vertebrate animals used in research studies at UNC Charlotte.

G. **The Institutional Official (IO)** is the individual who is legally authorized to act for the institution and on behalf of the institution.

H. **Non-Compliance** is not following federal, state, local laws, guidelines or University policies, guidelines, or SOPs. AE's and non-compliance incidents can be the same incident, can overlap, or may be mutually exclusive. Non-compliance can lead to an AE. An AE is not always due to non-compliance.

Examples include (but are not limited to):

1. Lack of an IACUC approved protocol (where handling and care of the animals is unknown).
2. An incident where regulations are not followed, but it does not directly impact animal welfare.

I. **Office of Research Protections & Integrity (ORPI)** provides oversight, education, and support for integrity and compliance issues related to research at UNC Charlotte.

J. **Principal Investigator (PI)** is charged to conduct objective research that generates independent, high quality, and reproducible results.

K. **Reportable Situation** is an event that rises to the level of non-compliance and must be documented, mitigated, and reported to regulatory authorities.

III. Examples of incidents 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.).

G. Non-compliance issues that put animals or humans at risk.

H. Vertebrate Animals and Cephalopods used on campus without prior IACUC approval.

IV. 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.

Note: With Category E and Pilot Studies, a separate 90-day report will be required.

V. Procedures for Reporting Non-compliance, Adverse Events, Abnormal Behaviors/Conditions, and Incidents

When any situation jeopardizes animal welfare, the project personnel, or animal care staff, or deviates from regulations required by law or by the Institution, the Office of Research Protections and Integrity (ORPI) staff will follow the procedures outlined below:

A. Acute Triage and Treatment of Animals
   1. The Attending Veterinarian and Vivarium Staff (vivarium@charlotte.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.
   2. **Any Adverse Event or non-compliance incident regarding animals in activities at UNC Charlotte, regardless of the severity, must be reported to the Veterinarian.**
   3. The Attending Veterinarian will determine the best course of action for the animals involved in the incident.
   4. 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. An Animal Care Technician (and the Attending Veterinarian) will coordinate an appropriate response. All steps should be taken to remedy the situation to prevent further harm to other animals.

B. The AV will provide guidance regarding the reported AE or non-compliance situation and determine if it rises to the level of requiring submission of a report.
   1. In his role, he may consult with regulatory authorities.
   2. The AV will notify the ORPI of his decision.

C. Within 72 hours of a known AE or non-compliance incident, and after consultation with the AV, the ORPI will contact the party(ies) involved to initiate a review and report.

D. Adverse Event Reports (Appendix A)
   1. The Principal Investigator (PI) will email a written report (Appendix A) to the Attending Veterinarian and IACUC Coordinator (uncc-iacuc@charlotte.edu).
   2. If the AE occurred in the vivarium, the Vivarium Manager (vivarium@charlotte.edu) will also receive the email for review.
   3. If the PI is not available, a senior investigator can make an AE report, copying the PI.
   4. If the AE is related to husbandry or the facility, the Attending Veterinarian will submit the AE report.
   5. If the AE is a whistleblower situation, an anonymous report will be written and sent to the ORPI. An ORPI member will forward it to the Attending Veterinarian, IACUC Coordinator, and the Vivarium Manager (when warranted).
   6. AE Reports will be signed by the AV and the PI, and PI supervisor(s) (when applicable).

E. Non-Compliance Reports (Appendix B)
   1. A written report (Appendix B) will be completed by the IACUC Coordinator or the Attending Veterinarian.
   2. If the non-compliance incident is related to husbandry or the facility, the Attending Veterinarian will submit the non-compliance report.
   3. The AV and the IACUC Coordinator will retain copies of the document.
   4. If the non-compliance incident occurred in the vivarium, the Vivarium Manager (vivarium@charlotte.edu) will also receive notification of the incident.
   5. The PI will receive a copy of the non-compliance report.
   6. Non-compliance reports will be signed by the AV.

F. The Attending Veterinarian will have ultimate authority in decision making and will sign the report before forwarding/returning it to the ORPI.

G. The AV, IACUC Coordinator, Director of ORPI, and Vivarium Manager (when applicable) will review and discuss the situation.

H. If the Veterinarian determines that the AE or non-compliance incident is reportable or rises to the level of a programmatic compliance issue, the report will be sent from the ORPI to the full IACUC for review.

I. If deemed appropriate and necessary, the ORPI (via the IACUC Coordinator) will contact the proper regulatory authorities with an initial (verbal) report.

J. The IACUC will convene and determine additional steps, as necessary, to ensure animal welfare and/or compliance. Depending on the nature and severity of the AE or non-compliance incident, the IACUC may take immediate action or defer discussion to the next meeting.

K. The IACUC will determine what actions will be needed for improved adequate and humane animal care and welfare and/or compliance.

L. Some regulatory and/or funding agencies may require a formal, written, institutional report of the AE or non-compliance incident.
    1. A formal written report will be sent to the proper authorities as required by regulation.
    2. This formal report will be sent to the IO, and through them to regulatory authorities.

M. Supplemental information may be requested by the IACUC or Attending Veterinarian at any time, including at a later date.

VI. Failure to Report AEs or non-compliance incidents

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 and in accordance with federal, state, and local laws & regulations and University policies.

References

National Research Council. *Guide for the Care and Use of Laboratory Animals: Eighth Edition*. Washington, DC: The National Academies Press, 2011.

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Office of Laboratory Animal Welfare, Public Health Service. Public Health Service Policy on Humane Care and Use of Laboratory Animals. Washington, D.C.: Department of Health and Human Services. Revised August 2002.

Office of Laboratory Animal Welfare, Public Health Service. "*Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*" (NOT-OD-05-034). Released February 24, 2005.

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Revision History

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Administrative changes October 1, 2022
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APPENDIX A

UNIVERSITY OF NORTH CAROLINA
CHARLOTTE
ANIMAL CARE AND USE PROGRAM

ADVERSE EVENT REPORTING FORM

PROTOCOL INFORMATION

Protocol Title: _____

Protocol ID: _____ Principal Investigator: _____

Event Information *(date and room/location)*
Description of Animal(s) Involved
Personnel Involved

Personnel Training Relevant to Protocol Procedures			
Name	***Topic***	***Date***	***Trainer***

Incident Description *(narrative)*
Corrective Action Plan *(if applicable)*

_____ _____
PI Signature Date

_____ _____
AV Signature Date

APPENDIX B

UNIVERSITY OF NORTH CAROLINA CHARLOTTE

ANIMAL CARE AND USE PROGRAM

NON-COMPLIANCE REPORTING FORM

Event Information *(date/location)*
Description of Animal(s) Involved
Personnel Involved
Incident Description *(narrative)*
Compliance Deviation(s) *(List: Law, Policy, Guideline, or SOP)*
Corrective Action Plan *(if applicable)*

PROTOCOL INFORMATION (if applicable)

Protocol Title: _____

Protocol ID: _____ Principal Investigator: _____

_____ _____

AV Signature Date

_____ _____

Principal Investigator Date