Standard Operating Procedure

Wake Forest Institutional Animal Care and Use Committee

Effective: 24 July 2012

TITLE: Reporting of Adverse Events to the IACUC

SCOPE
This SOP applies to all animals used in research, training or teaching at Wake Forest University.

PURPOSE
This SOP establishes that the WFU IACUC will be notified of adverse events in order to ensure that animals receive appropriate and timely care

STANDARD OPERATING PROCEDURE
This SOP requires that principal investigators of approved IACUC protocols promptly report adverse events (AE) to the IACUC. A detailed definition of adverse events and reporting procedures are contained in the associated set of Frequently Asked Questions (FAQ). Broadly, Adverse Events are any unanticipated event that results in increase pain, distress or health risk to the animals.

FAQ for Adverse Events in Animals

1. What is an animal adverse event (AE)?

An AE is any occurrence that has a negative impact on animal welfare (usually involving pain, distress or death of an animal), the possibility of which was not described in the approved IACUC Protocol or its subsequent modifications.

2. Why should AEs be reported?

Reporting AEs assists PIs, animal care staff and the Attending Veterinarian to find the cause and to prevent recurrence.

From a regulatory aspect, the purpose of AE reporting is to document at the level of IACUC, in accordance with its federally mandated role of oversight, that adverse events have been fully addressed by the research team and veterinary staff as they occur. Furthermore, it ensures that the appropriate institutional resources are made available to the research group to address the AE. Timely reporting demonstrates the commitment of the research team to provide the highest quality animal care by engaging all available resources.

If AEs are not appropriately addressed in a timely manner, the IACUC has the responsibility and authority to protect animal subjects with actions up to and including the suspension of approved protocols. Failure to report adverse events is noncompliance with IACUC SOP

3. Who should report AEs and When?

PIs and Animal Facility Directors should report to the IACUC as soon as they become aware of an event that may impact animal welfare. A preliminary report should be completed within 7 calendar days after the event. The final report should be made as soon as all necessary details are known and after consultation with veterinary staff. Note: there are instances where a preliminary report is not needed. In such cases, the Final Report should be submitted within 7 calendars day after the event.

4. What qualifies as an AE?

When in doubt, call the Animal Facility Director or the IACUC to discuss the event. Unexpected events or problems are considered AEs if they affect greater numbers of animals than anticipated, have a negative impact on other animals or activities, or reflect a situation that could become more severe in the future. A report is not required if the event and its management are described in the approved IACUC protocol.

5. What types of events must be reported?

- Morbidity or mortality resulting from complications not described in the IACUC protocol.
- Greater number of mortalities, more severe responses, or when animals appear to be in more pain or distress than expected/described in the IACUC protocol. For example, a report would be required, if 10 % of animals die following surgery when a 5% mortality rate was indicated in the approved protocol.
- Allergic reaction to a treatment; inadequate anesthesia; development of an unexpected infection following surgery or treatment.
- Facility or equipment failure that has a negative impact on animal welfare. Loss of electrical power impacting HVAC function or water supply; restraint equipment malfunction; biohazard containment failure. Facility design, husbandry or postoperative care that has a negative impact on animal welfare
- Entrapment; overexposure to heat source(s); inadequate analgesia or antibiotic use.

6. What events do not need to be reported?

Injury or illness unrelated to approved procedures and being treated by the attending veterinarian or designee. Events that are described in the approved protocol that occur at rates that are equal or below the rates indicated in the approved protocol.

7. What information needs to be reported?

The Adverse Event Forms should be used to submit a report. The forms are available on the IACUC website (see Related Documents). Information required includes the project title and IACUC protocol number; the PI's name; the date, time, location and nature of the event; the number and species of animals involved; the WFU animal ID # (for USDA regulated species), measures taken at the time to minimize impact on animal welfare; the actual or potential impact of the event on animal welfare and study outcomes; and immediate and long-term steps being taken or considered to prevent recurrence of the event. The name of the person reporting the adverse event is also required.

8. How should reporting proceed?

a. In an emergency, contact a staff veterinarian immediately.

b. Consult with the Animal Facility Manager to provide any necessary changes in animal care.

c. If unsure, communicate as soon as possible with the O & O Office by phone or email to receive instruction. If needed, submit a preliminary report to the O & O Office within 7 calendar days of the event.

d. Work with veterinary staff to complete a final report including a Corrective Action Plan, as needed, and submit it by email to the O & O Office

e. An AE Review team will review the report and seek further clarification or sign off that it has been fully resolved.

f. The report will be included in the agenda for the next IACUC meeting and the IACUC Chair will request further clarification or sign off that the event has been accepted by the IACUC, thereby closing the issue.

g. An AE Acceptance notification will be sent to the PI.

9. What will the IACUC do with the report?

Most of these reports will be informational to the full IACUC; others may require further action. Amendments to approved protocols may be necessary to modify procedures based on knowledge gained from adverse events. In some cases, it will be advisable for PIs to voluntarily halt certain animal procedures until an event is fully addressed. As official IACUC documents, these reports are not public because Wake Forest is a private institution. However, the documents must be available to USDA representatives and other regulatory officials upon request.

RELATED DOCUMENTS
Adverse Event Report Form

APPROVALS
Issues: 07/20/10, 07/24/12

ADVERSE EVENT (AE) REPORT FORM

FOR ANIMALS USED IN RESEARCH &TEACHING AT WAKE FOREST UNIVERSITY

A report (either Preliminary or Final) should be submitted within 7 calendar days of the adverse event. Send to Colleen Bennett, Outreach & Oversight Office (cobennet@wakehealth.edu).

1. Consult with ARP veterinarians immediately if existing animals related to this AE continue to have health abnormalities. Consult with the ARP Operations Manager if there are any necessary changes to animal care.
2. Work with veterinary staff to complete this report including a Corrective Action Plan
3. See FAQs for help defining AE or contact Colleen Bennett, Oversight & Outreach Office (cobennet@wakehealth.edu)

If all the information needed to describe the Adverse Event and determine an appropriate Corrective Action Plan (CAP) is known, go directly to Section 2 and complete the **Final Adverse Event Section.**

Complete and submit the **Preliminary Adverse Event Section** only if additional information is needed to determine the cause of the AE or for the CAP (eg. Necropsy Reports, test results, etc.).

A Final Report must be completed once all the information has been obtained.

Section 1 Preliminary Adverse Event Report Section

Protocol # and Title	
Principal Investigator	
Individual submitting report/Contact information	
Species involved and # of animals. (Include the WFU animal ID# for USDA regulated species)	
Brief description of incident	
Preliminary considerations as to cause	
Timeframe for Final Report Submission	

Section 2 Final Adverse Event Report Form

Protocol # and Title:

Principal Investigator:

Individual submitting report:

Name:
Project role:
Contact information (phone, pager, etc.):

Reason for submission:

- ☐ Higher than expected levels of mortality than approved in the IACUC protocol
- ☐ Mortality due to complications unanticipated in the approved protocol
- ☐ High "cluster" mortality (Cluster mortality is defined as a grouping of animal deaths occurring closely together, significantly above anticipated study loss levels)
- ☐ Morbidity/non-fatal complications significantly beyond that anticipated in the approved protocol, especially those creating difficult to manage levels of pain and distress.
- ☐ Other (list)

Briefly summarize the Adverse Event

a) species involved:

b) number of animals impacted:

c) WFU animal ID# (USDA regulated animals):

d) date or date range of incident(s):

e) Write a short narrative describing the adverse event(s) occurring (please also list and compare with the anticipated nature and frequency/rate of morbidity or mortality described in the currently approved protocol)

f) Attach any diagnostics, data or reports that may help further explain the cause(s) of the adverse events if applicable

Has there been prior communication or consultation with the ARP veterinary staff concerning this or similar adverse events? ____Yes ____No If yes, please provide any salient details.

In the box below, describe the proposed Corrective Action Plan (CAP) to reduce or prevent future morbidity or mortality:

Please note in conjunction with adverse event filing:

a) All Adverse Event report summaries are reviewed by the full IACUC. The committee maintains the right of final approval of the CAP and may require additional stipulations in the project
b) Proactive feedback to the ARP on the success of the CAP in reducing or eliminating additional morbidity and mortality is encouraged.