Office of Research, Grants and Contracts
Standard Operating Procedures (SOP)

SOP Title	Reporting Adverse Events and Unanticipated Problems				
Date Last Revised	09/14/2017	**Date Created**	08/02/2017	**Revision #**	
SOP Number	15	**Required by:**	☐OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☒Researcher	☐Institutional		
Subgroup	☐ NKU Compliance	☐IRB	☒IACUC	☐IBC	

1.0 PURPOSE

To standardize the procedures for reporting adverse events or unanticipated problems for IACUC approved protocols.

2.0 GENERAL INFORMATION AND SCOPE

Everyone involved in the care and use of animals must review the procedure for reporting adverse events and/or unanticipated problems. Reporting must be in a timely manner to identify ongoing trends, to ensure adequate veterinary care and to minimize the effect on animal welfare.

Adverse Event/Unanticipated Problem – Defined as any unexpected animal welfare issue (death, disease, or distress) or human health risk (zoonotic disease or injuries). Examples of adverse events and/or unanticipated outcomes include:

- Unexpected clinical signs, either related or unrelated to a protocol procedure
- Unexpected euthanasia that is not part of the approved animal activities
- Increased or unexpected morbidity or mortality
- Surgical complications such as anesthetic deaths, infection or wound dehiscence
- Phenotypes associated with transgenic animals (e.g., tumor development, early death) that negatively impact the welfare of an animal
- Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire) that negatively impact the welfare of an animal

Adverse events and/or unanticipated problems do not include those described in a protocol or revision, as they are potentially expected from the animal activities. In addition, animals removed from study or euthanized under early removal criteria are not considered adverse events and/or unanticipated outcomes, as they are potentially expected from the animal activities.

3.0 PROCEDURES

A. REPORTING ADVERSE EVENTS/UNANTICIPATED PROBLEMS

When an AE or unanticipated outcome occur involving animal(s) under a NKU approved protocol, the personnel working with, providing care for, or assuring treatment of animals shall:

1. *Ensure animal care:* provide immediate 'first-aid' (to the level that they are qualified/have clearance) to alleviate animal pain or distress then notify the veterinary staff.

2. *Inform the IACUC*: notify the IACUC of the adverse event/unanticipated problem. Initial information may be incomplete, but notification should be immediate, or as soon as possible after identifying the AE/unanticipated problem, providing initial animal care and contacting the veterinary staff. Additional details may be provided at a later date as they become known. If necessary, the IACUC may request that the PI contact the IACUC Veterinarian.
    - IACUC notification may initially be by phone or in writing (including via email) but a final report must be documented on the NKU Adverse Event/Unanticipated Problem Reporting Form.

B. IACUC ACTION

- After receiving a report of an adverse event or unanticipated problem, the IACUC Administrator will log the event/problem following appropriate in-office procedures including contacting the IACUC Chair and IACUC Committee
- The IACUC chair may inform the IACUC veterinarian if the AE/unanticipated problem impact the health and/or welfare of research animals.
- Based on the report, the IACUC may re-review the protocol, request modifications or other corrective actions such as additional training or enhanced post-approval monitoring.
- The IACUC and/or the PI will report the AE/unanticipated problem to external agencies if required.

4.0 REFERENCES

Guide for the Care and Use of Laboratory Animals Eighth Edition

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	11/01/2017	☐
IACUC Chair	☒	11/01/2017	☐
Institutional Official	☐		☒

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒		☐	
IACUC Chair	☐		☐	
Institutional Official	☐		☐	