RADFORD UNIVERSITY
Research Compliance Office

Institutional Animal Care and Use Committee (IACUC)

TITLE: Adverse Events	**Effective Date:** 28-February-2022
IACUC POLICY: 004 **REVISION:** 0	**Last Revised:**
SCOPE: This process applies to submission of all IACUC protocols	**Review Date:**
PURPOSE: To define an accepted process for reporting of adverse events pertaining to vertebrate animals	
KEYWORDS: IACUC, Adverse events, AE, Vertebrate animals	
Policy Owner: Research Compliance Office Radford University **Policy Contact:** Anna Marie Lee, Research Compliance Manager, alee16@radford.edu or irb-iacuc@radford.edu	

1. BACKGROUND

The IACUC is under a federal mandate to monitor all research activities related to animal use. To assist the IACUC in fulfilling this requirement, all suspected Adverse Events (AE) should be reported in a timely manner.

This includes an email report of the adverse event to the Attending Veterinarian, the IACUC Chair, and Research Compliance Office within 72 hours followed by a written report within 10 business days. Verbal reporting can be made to the Attending Veterinarian, the Research Compliance Office, or the IACUC Chair who will communicate to the other two individuals. Incoming AEs submitted anonymously via the whistle blower form will be handled by the Research Compliance Office, who will then notify the IACUC Chair, Attending Veterinarian, and the PI.

2. POLICY

An Adverse Event is the occurrence of an unforeseen event or outcome that negatively impacts the health or welfare of research animal(s), involving pain, distress, and/or death of the animal. By definition, AEs are not identified as potential risks or outcomes in the approved IACUC protocol.

**Adverse consequences that can be expected as part of a research model, which are included on each IACUC approved protocol, do NOT need to be reported.*

The IACUC expects that **everyone** involved in the care and use of animals is aware of the need to report and procedure to report adverse events and/or unanticipated outcomes. Reporting must be in a timely manner to identify ongoing trends, to ensure adequate veterinary care and to minimize the effect on animal welfare.

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Examples of events **that ARE required to be reported** include:

- Animal morbidity or mortality in excess of that described in the IACUC approved protocol.
- Unforeseen events that lead to the harm of the animal(s) or that cause obvious distress not justified and approved in the protocol.
- A cohort of animals dies during experiments because of equipment or power failure.
- A cohort of animals experience unexpected and/or higher than expected morbidity or mortality following a procedure.

The intent of this policy is to outline the reporting of adverse events related to the use of vertebrate animals in research at Radford University.

Appendix A
Adverse Event (AE) Reporting Form

REVISION HISTORY:

Revision	Summary of Revisions	Revision Date

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ADVERSE EVENT REPORT FORM

Principal Investigator:
Protocol Number:
Protocol Title:
Grant/Funding Information:
Species:

Adverse Event/Unanticipated Problem Description			
Date of Event/ Problem:		**Date of Report:**	
Location of Event:			

**** For emergency adverse events, contact the Veterinarian and then complete the form. ****

Briefly Describe The Situation. What Happened Where And Why?

Describe The Cause As Completely As Possible.

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What Actions Were Taken And When?

Briefly Describe The Follow-Up. Explain What Will Be Done To Avoid, Reduce, Or Minimize The Occurrence If Incident In The Future.

Person Reporting The Event (not required if reporting anonymously):

Report Submitted To:

___ Research Compliance Office
___ Attending Veterinarian
___ IACUC Chair