INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POLICY
Adverse & Unanticipated Outcomes Reporting
Approval Date: *7/25/2024*
Next Review Date: 7/25/2027
Previous Approval Date(s): 3/6/2023

PURPOSE

The purpose of this policy is to provide guidance on determining what, when and how concerns regarding animal welfare should be reported.

DEFINITIONS

1) Adverse event – An unexpected incident that negatively affects the health or welfare of animals.
2) Unexpected outcome – An unanticipated result of IACUC-approved animal activities.

Examples of IACUC-reportable unexpected outcomes may include, and are not limited to:

• Animal morbidity or mortality occurring at a higher frequency than expected.
• Unanticipated debilitating defects discovered after creating or breeding genetically modified animals.

Reportable adverse events include conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals.

REPORTING REQUIREMENTS

The IACUC is required to monitor all research activities related to animal use at SUNY Downstate Health Sciences University (Downstate). To assist the IACUC in fulfilling this requirement, all adverse/unanticipated outcomes should be reported in a timely manner. Principal investigators (PIs) have an obligation to report an adverse event within three business days of discovery of the adverse event. Reporting is not intended as a punitive action against investigators, but an effort to facilitate research effectiveness, communication and improve animal care.

Following a discussion by the IACUC, a determination will be made whether the event is significant or serious enough to be reportable to outside agencies or institutions. Notification to the appropriate agencies will occur after a full discussion by the IACUC.

When to report

Examples of events that are required to be reported:

1) Animal mortality or morbidity as a result of experimental conditions or outcomes not described in the approved IACUC protocol.
2) Animal mortality or morbidity in excess of that described in the approved IACUC protocol.
3) Animal mortality or morbidity in excess of humane endpoints described in the approved IACUC protocol.

4) Unforeseen events that lead to the harm of the animal(s) or that cause obvious distress not justified and approved in the protocol, such as
   a) Unexpected phenotypes of genetically modified animals,
   b) Any non-human primate injury which requires veterinary intervention such as suturing, or
   c) Protocol procedure complications.
5) Unforeseen events that lead to the harm of the animal(s) or that cause obvious distress not associated with the approved protocol, including events associated with
   a) Animal housing and environmental conditions (e.g., mechanical or electrical failures, escape from primary containment, insufficient food or water),
   b) Failure of IACUC personnel to carry out veterinary care,
   c) Hazardous material contamination (e.g., water or food supply contamination, spills/exposures, radiation leak), or
   d) Natural disasters.

Examples of events that are not required to be reported:

1) Death or morbidity of animals described as expected in the approved IACUC protocol.
2) Injury/illness unrelated to approved procedures and being treated by the clinical veterinarians.
3) Phenotypic abnormalities described in the approved protocol, common phenotypic abnormalities described in the literature (e.g., ulcerative dermatitis in specific strains), or phenotypic abnormalities that have no negative impact on animal welfare.

What to report

Complete and submit an Adverse/Unanticipated Event Report form to capture this information is included and on the IACUC website. IACUC Adverse Event Report form can be found here.

Reports should include the following information:

1) PI name and Protocol number
2) Date/time of finding
3) Location of event
4) Species involved
5) Number of animals (cage card numbers if available)
6) Brief description of the event
7) Name and contact information of person reporting event (Not required if individual wishes to remain anonymous)

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Investigator Reporting Procedures

The PI must ensure that written notification of adverse events is submitted to the Office of the IACUC. In addition to the Adverse Event Report, the PI should attach any additional information necessary in evaluating the adverse event. For protocol-related adverse events, the Principal Investigator (PI) is responsible for reporting. If the PI is not available, research personnel (preferably senior project personnel) should report to IACUC.

How to report

Reporting of potential adverse/unanticipated outcomes can be made in person, by phone, or by email to any of the following entities. Individuals making reports may remain anonymous and are protected from reprisals when reporting in good faith.

1) Division of Comparative Medicine – DCM@Downstate.edu

2) The Office of the IACUC – IACUC.Welfare@Downstate.edu

3) The IACUC Chair – IACUC.Chair@Downstate.edu

4) SUNY Office of Compliance and Audit Services: To make an anonymous report regarding any concerns, use either of these methods for reporting: Phone: (877) 349-SUNY (7869) or Web-based reporting: **Compliance Help Line**: https://www.compliance-helpline.com/downstate.jsp

5) Speak Up RF - Ethics Hotline online at www.rfsuny.org/speakuprf-ethicshotline or by calling 800-461-9330 or via text message to 518- 351-6827.

SUNY Downstate Health Sciences University maintains strict confidentiality regarding the source of concerns and prohibits discrimination and reprisal for reporting good faith concerns.