INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POLICY
Adverse & Unanticipated Outcomes Reporting

Approval Date: 3/6/2023
Next Review Date: 3/6/2026

DEFINITIONS

Adverse/Unanticipated Outcome: An adverse and unanticipated outcome is the occurrence of an unforeseen event that negatively impacts the welfare of research animal(s), involving pain, distress, and/or death of the animal. By definition, these are not identified as potential risks or outcomes in the approved IACUC protocol (e.g., part of the risk vs. benefit analysis section of the protocol form).

REPORTING REQUIREMENTS

The IACUC is required to monitor all research activities related to animal use at SUNY Downstate Health Sciences University (DHSU). 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.
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, or
    b) 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),
    b) Animal husbandry and veterinary care (e.g., escape from primary containment, insufficient provision of food and/or water, non-response to 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

Office of the IACUC
SUNY Downstate Health Sciences University
450 Clarkson Avenue, MSC 112
Brooklyn, NY 11203-2098

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An Adverse/Unanticipated Event Report form to capture this information is included and on the IACUC website.
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)

IACUC Adverse Event Report form can be found here.

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

The Attending Veterinarian (AV) and the IACUC will work with the researcher to assess the outcome and develop a plan, as needed, for revising the IACUC protocol to ensure the well-being of the animals. During the interim period between notification of the unanticipated outcome and the IACUC's decision, the AV or their designee are authorized to make final decisions regarding care and the humane endpoints for the animal.

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 – 877-349-7869 or Compliance Line

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