University at Buffalo Institutional Animal Care and Use Program
Policy on Adverse Event Assessment and Reporting for Animal Research

Purpose

This policy describes the process and expectation for timely reporting and evaluation of adverse events in activities involving animal research.

Background

Use of animals in research or teaching may result in unexpected adverse events (UAEs). Unexpected events unrelated to the protocol may also negatively impact animals. Prompt and effective communication between researchers, veterinarians, animal care staff and the Institutional Animal Care and Use Committee (IACUC) is crucial for clear and timely management of animal disease, injury, adverse outcomes, or other adverse events and is required by The Guide for the Care and Use of Laboratory Animals[1]. Activation of adverse event assessment and reporting plans (by the IACUC) is a condition of maintaining AAALAC Accreditation.

The IACUC expects that everyone involved in the care and use of animals be aware of the need to promptly report issues and be trained on this procedure. Reporting is not intended as a punitive action against investigators, but rather is an effort to improve overall research and animal welfare. Some adverse events require prompt reporting to regulatory, funding and/or accrediting agencies, so timely notifications are essential.

Definition of an Unexpected Adverse Event (UAE)

An unexpected adverse event (UAE) is any occurrence of an unforeseen event that negatively impacts the health or well-being of research Unexpected adverse events are those not identified as potential risks, expected phenotypes or experimental outcomes in the approved IACUC protocol. They also include natural disasters, accidents and mechanical failures that result in actual harm or death to animals.

Examples of unanticipated adverse events and incidents requiring notification to LAF Veterinary Staff and the IACUC include but are not limited to:

- Unexpected clinical signs potentially related to a protocol procedure that are not currently described as expected adverse events in the protocol.
- Expected clinical signs related to a protocol procedure that are occurring at an increased rate or severity from what is described in the protocol.
- A significant increase in morbidity or mortality related to protocol procedures (e.g. 20% death during a procedure is expected but 40% death is occurring).

Effective Date: 12/18/2023
Next Review Date: 12/2026
First Approved: 12/2023
Revised: --

- Phenotypes associated with transgenic animals (e.g. tumor development, neurological conditions, fertility issues, skin conditions, early death) that negatively impact the welfare of the animal, but are not stated in the protocol.
- Accidents, unrelated to the research protocol, that negatively impact animal welfare.
- Facility or weather-associated events (HVAC, power failure, flooding, fire) that negatively impact the welfare of an animal.
- A high rate of surgical complications such as anesthetic deaths, infections or wound dehiscence.

Examples of events that are not required to be reported as unanticipated or adverse events.

- Injury/illness unrelated to approved procedures and being treated by clinical veterinarians.
- Death, illness, or morbidity of animals that occurs as described in the approved IACUC protocol.

Researcher Reporting Policy

This section describes what must be done by researchers upon occurrence of a UAE.

1) All unexpected adverse events must be immediately reported to the LAF Director or a Clinical Veterinarian.
    a. LAF Director Dr. Jennifer Peirick
    Phone: (716) 803-5985 Email: jpeirick@buffalo.edu

    b. Clinical Veterinarian Dr. Jolie McCutcheon
    Phone: (716) 536-4933 Email: joliemcc@buffalo.edu

    c. Clinical Veterinarian Dr. Amy Snyder
    Phone: 716-339-5387 Email: snyder38@buffalo.edu

2) An Unexpected Adverse Event (UAE) Form must also be submitted to the IACUC at iacuc@research.edu within 72 hours of the event or whenever a problematic trend in morbidity, mortality or complication rate is recognized.

Institutional Review and Reporting Policy

This section describes the process followed by the IACUC and Institution upon receipt of a report of a UAE.

IACUC Review of UAEs

1. All UAE Forms will be reviewed at the next IACUC meeting by the full committee.
2. The IACUC will review the event and the associated IACUC protocol (if relevant), then vote to determine whether the reported event meets the definition of a UAE.

3. The IACUC will deliberate and vote upon recommendations for actions that may include:
    a. Retraining on specific procedures.
    b. Pilot studies to refine outcomes.
    c. Protocol amendments to describe and justify newly recognized adverse events secondary to procedures, disease models or newly recognized phenotypes. Amendments must outline monitoring, management of adverse clinical signs and humane endpoints.
4. PIs (or UB Facilities, LAF, etc.) will receive official communication from the IACUC outlining determinations and recommendations.

Reporting UAEs to Outside Agencies

Reporting of UAEs may be required depending on the circumstances.

1) **Office of Laboratory Animal Welfare** (**OLAW**)
    a) Reporting is required for **PHS-funded animal activities IF the UAE includes a protocol noncompliance or suspension** (this will often not be the case). PHS-funded animal activities include those funded through: NIH, NSF, NASA, DOD and VA.
    b) Reporting to OLAW is required for these types of noncompliance (see IACUC Policy for Handling Protocol Noncompliance:
        i) **Serious** or **Continuing** Noncompliance with PHS Policy
        ii) **Serious** deviation from The Guide.
        iii) **Suspension** of an activity by the IACUC

2) United States Department of Agriculture (USDA)
    a) Reporting is only required if animal activities involve species covered by the Animal Welfare Act (hamster, rabbit, pig, sheep, dog, chinchilla, ferret, etc.)
    b) Reporting to USDA is required **only if UAEs are associated with**:
        i) **Suspension** of a protocol by the IACUC
        ii) **Failure to adhere to a plan to correct a significant deficiency**.

3) Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC)
    a) Prompt reporting of UAEs to AAALAC is required when:
        i) UAE results in **negative consequences to animal welfare**
        ii) UAE results in **negative consequence to human health (safety)**
    b) Reports may be made using the online Adverse Event Report available through the Unit Login.

University at Buffalo
The State University of New York

Office of Research Compliance
Institutional Animal Care and Use Committee (IACUC)

Unanticipated Adverse Event (UAE) Form

This form must be scanned, and a copy of this form must be emailed to iacuc@reasearch.buffalo.edu within 72 hours of the occurrence of an event or whenever a problematic trend in morbidity, mortality or complication rate is recognized.

Use this form to help summarize suspected adverse events, defined as unexpected incidents that harm or endanger the well-being of animals or humans at a research facility. All parties involved in the care and use of animals at the University at Buffalo are responsible for notifying the UB IACUC. You may discuss incidents anonymously with the IACUC administrator at 716-829-3977.

Date of the Adverse Event:	Date of the Report:
Contact Email of the Person Reporting:	Veterinarian contacted (name, date of contact):
Principal Investigator (PI):	IACUC Protocol Number:
Location of the Incident: i.e. building and room #	Number and Species of Animals Affected:
Date and Approximate Time of the Finding:	
Describe what happened and the outcome: e.g., treated/recovered, treated/euthanized, fatal, etc.	

Effective Date: 12/18/2023
Next Review Date: 12/2026
First Approved: 12/2023
Revised: --