Adverse Event Procedure

Purpose: to define an adverse event and formalize the process for handling such events.

Scope: This procedure applies to all members of the animal care and use program.

Definitions

Adverse Event: An unexpected event, outside the scope of an approved IACUC protocol, where an animal is experiencing pain, distress, or death, or where an animal is not responding favorably to the commonly prescribed treatment.

Anticipated Adverse Event: An event described in an approved IACUC protocol that occurs within the expected type and frequency.

Noncompliance: A deviation from an approved protocol, policy, or procedure.

Reporting and Documenting an Adverse Event

Upon discovery of an adverse event, the investigator must *immediately* report the incident to the Attending Veterinarian (AV) for consultation and begin treatment of the animal(s) involved. Within 24-48 hours of the event, the investigator will complete the Adverse Event Form provided on the IACUC website and submit it to the Research Compliance Officer (RCO). Contact information for both the AV and RCO is available on MTSU's IACUC website. The AV should be updated throughout the treatment of the animal(s). If the status of the animal(s) changes after submission of the Adverse Event Form, a revised copy should be submitted. All versions of the form will be retained for the IACUC records.

For anticipated adverse events, a record should be kept to ensure the number and severity of those incidents remain within what was approved by the IACUC. The IACUC may ask to review these records at any time to ensure the research remains in compliance with the protocol's approved activities and attrition rates.

Reviewing Adverse Event Reports

The result of the adverse event is first reviewed by the AV, IACUC Chair and RCO. Details of the adverse event are reviewed by the IACUC at the next meeting following the event. In the case of a serious adverse event, an IACUC meeting may be called to determine if additional investigation is required, per Section XII of MTSU Policy 403, Animal Care and Use in Research and Training.

The nature and outcome of the adverse event will be reviewed against OLAW's Guidance on Prompt Reporting to determine if the incident is reportable as noncompliance. Reporting to OLAW will be managed by the RCO, in collaboration with the IO, IACUC Chair and AV.

Failure to comply with the adverse event policy as described may result in further action. Repeated instances of adverse events may require investigation as described in Section XII of MTSU Policy 403, Animal Care and Use in Research and Training.

Adverse Event Training and Awareness

All faculty working with animals are required to make an Adverse Event Notice flyer available at the research site, including the protocol number, the investigator's name and contact information, as well as information on what to do in case of an adverse event. PIs and animal supervisors are expected to inform all personnel working with animals of the adverse event procedure. Additional training can be provided by the Research Compliance Officer as requested.

Approved by a quorum of IACUC members on March 18th, 2026

Adverse Events Reference Guide

Please refer to sections *Animal Numbers, Methodology,* and *Unrelieved Pain/Distress* of the approved IACUC protocol to determine if the potential adverse event is previously anticipated. As a best practice during protocol preparation, please include sources for predicted animal loss rates or anticipated issues when available.

This is not an exhaustive list. Instead, it should be used as a reference sheet to provide general and species-specific examples of situations in which contacting the Attending Veterinarian to report an adverse event is appropriate.

<u>Major Reportable Events:</u>

- Any activities performed with an animal outside the scope of an approved IACUC protocol
- Any unexpected animal fatality, above what is expected or anticipated by the approved IACUC protocol
    - Exceptions for:
        - Stillborn animals of any species
        - Natural attrition of breeding population mouse pups
        - Rats who die at an expected age
- A negative, unexpected reaction to a medication or treatment administered during a protocol i.e. sores, tumors, swelling, bleeding

<u>Species-Specific Reportable Event Examples:</u>

- Cow
    - Not responding to commonly used medication for a typically treatable illness, i.e. mastitis
    - Animals missing for over 24 hours
- Horse
    - Extended periods of lameness not resolved with rest
    - Not responding to commonly used medication for a typically treatable illness
- Rat
    - Unexpected or unexplained changes in typical behavior
    - Sores, tumors, bleeding etc not attributed to protocol procedures
- Mouse
    - Unexpected or unexplained changes in typical behavior
    - Surgery site complications- non-fatal and fatal
        - Signs of infection
        - Tissue damage incurred from other mice

    - Struggling to recover from surgery
- Field Studies
    - Negative researcher-animal interactions
    - Trapping-related deaths

- INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE -

NOTICE

MANDATORY REPORTING OF AN ADVERSE EVENT

An **adverse event** is an unexpected event, outside the scope of an approved IACUC protocol, where an animal is experiencing pain, distress, or death, or where an animal is not responding favorably to the commonly prescribed treatment.

In the case of an adverse event, please immediately contact Dr. Amy Massengill at

615-429-8930

The adverse event form must be submitted electronically to the Research Compliance Office within 24-48 hours of the incident:

compliance@mtsu.edu

Protocol Number : _____

Principal Investigator : _____

Contact Information : _____

To download a copy of the adverse event form, please visit https://iacuc.mtsu.edu/ > "Working with IACUC" > FORMS & DOCUMENTS

Contact Dr. Annie Galizio, IACUC Chair, for all other concerns.
ann.galizio@mtsu.edu

Both the PHS Policy (IV.C.5) and USDA Animal Welfare Regulations (9 CFR 2.3 (d) (5)) require continued review of previously approved projects. The IACUC, as part of post-approval monitoring, requires investigators to promptly submit an adverse event form for any unexpected injuries to animals during the course of the project.

Institutional Animal Care and Use Committee Adverse Event Form

Mandatory reporting of an adverse event is required by PHS Policy and USDA Animal Welfare Regulation. PHS Policy (IV.C.5) and USDA Animal Welfare Regulations (9 CFR 2.3 (d) (5)) require continued review of previously approved projects. The IACUC, as part of post-approval monitoring, requires investigators to promptly submit an adverse event form for any unexpected injuries to animals during the course of the project.

Definition: An unexpected event, outside the scope of an approved IACUC protocol, where an animal is experiencing pain, distress, or death, or where an animal is not responding favorably to the commonly prescribed treatment.

In the case of an adverse incident, please immediately contact Dr. Amy Massengill, the attending veterinarian ASAP.

Amy.Massengill@mtsu.edu (For General Contact)
615-429-8930 (For Immediate Issues)

Contact Dr. Annie Galizio, IACUC Chair, for all other concerns.
Ann.Galizio@mtsu.edu

All material **must** be submitted electronically to the Research Compliance Office within 24-48 hours of the incident: compliance@mtsu.edu

Institutional Animal Care and Use Committee Adverse Event Form

Principal Investigator:

E-mail:

Department:

Telephone:

Protocol Title:

Protocol Number:

1. **Event Date:**
2. **Severity of Event:** ☐ Moderate ☐ Severe ☐ Fatal
3. **Is this event related to the research?**
4. **Description of Event (include location):**
5. **Is this a recurrent event?** ☐ Yes ☐ No
6. **Cause of Event:**
7. **Changes necessitated by adverse event/injury:** In your opinion, does this adverse event/injury require a change in the protocol? ☐ Yes ☐ No
8. **Have you contacted the veterinarian?** ☐ Yes ☐ No (If not, contact Dr. Amy Massengill at 615-429-8930)
9. **Outcome of Event:**

For IACUC Use Only:

Veterinary Review/ Comment:

Office Action:

☐ Consultation with IACUC Chair; file with protocol-no further action required

☐ Report to IACUC for review and action