



University of Maryland College Park Animal Care and Use Standard

Adverse Event Reporting

Purpose: This standard defines Adverse Events (AE) and AE reporting and reviewing requirements.

Background: Experimental manipulation of animals in research, testing or teaching may occasionally result in serious, unanticipated, or adverse clinical consequences. Unexpected events unrelated to the protocol may also adversely impact animals. Effective communication between researchers, veterinarians, and animal care staff is crucial for clear and timely management of animal disease, injury, adverse outcomes or other adverse events. The clinical veterinary staff and the IACUC must be aware of adverse events that involve animals owned or housed by University or listed on University of Maryland-College Park (UMCP) IACUC-approved protocols. The veterinary staff must be informed to ensure appropriate animal care and follow up. The IACUC must be informed as partial fulfillment of the institution's obligations of effective animal care and use oversight. Adverse events may be protocol-related or non-protocol-related. A reporting system facilitates improved monitoring of problem areas (including trends), helps ensure appropriate follow-up and resource allocation when problems are identified, and harmonizes expectations for research, veterinary and animal care staff, and the IACUC, with the ultimate goal of improving animal welfare.

Definition: An Adverse Event (AE) is any event that harmed or posed a threat of harm to an animal owned by or housed at UMCP or covered by a UMCP animal care and use protocol that meets the following conditions:

1. The event is research-related but is not identified in the approved protocol or is occurring at a rate or severity higher than is indicated in the approved protocol; or
2. The event is not research-related, but is unanticipated or results from a facility, physical plant, equipment, or personnel failure, malfunction, or mistake.

Adverse events and unexpected outcomes include any instance of unfavorable or unanticipated (not in the approved protocol) signs or outcomes such as suboptimal well-being (e.g., poor welfare), phenotypic alterations to genetically-modified animals that adversely impact their welfare, animal death, disease, distress, or trauma that was not the anticipated result of approved protocol or SOP activity. They also include unexpected events that put the animals at risk.

Standards: Adverse events involving animals owned by or housed at UMCP or covered under a UMCP IACUC-approved animal use protocol must be reported promptly (immediate notification with follow-up as needed) to the veterinary staff and the IACUC. The Attending and/or Facility Veterinarian, in conjunction with the PI, shall determine appropriate animal treatment as needed. The IACUC shall determine which events/outcomes must be reported to oversight agencies, whether protocol modifications are required (e.g., changes in procedures, monitoring, humane endpoints, etc.), whether SOP changes are necessary, or whether specific corrective actions, beyond those which may be PI-generated, are required to ensure animal well-being.

Methodology: When an AE or unanticipated outcome occur involving animal(s) under a UMCP-approved protocol or SOP, the personnel working with, providing care for, or assuring treatment of animals shall:

1. *Ensure animal care:* provide immediate ‘first-aid’ (to the level that they are qualified/have clearance) to alleviate animal pain or distress then notify the veterinary staff.

2. *Notify the veterinary staff:* contact the University Attending Veterinarian or the facility veterinarian to ensure the injured, diseased, or distressed animal receives definitive care for the injury or disease. Veterinarians shall prescribe and/or provide appropriate veterinary care, based on their assessment of the patient’s condition and perform euthanasia and necropsy as needed. Therefore, regardless of severity, all issues relating to sub-optimal health, disease, injury, or well-being of UMCP animals must be conveyed to the supporting veterinary staff.

Veterinarian On-Call: 301-458-5047

Veterinarian email reflector: vets@umd.edu

3. *Inform the IACUC:* notify the IACUC of the adverse event. Initial information may be incomplete, but notification should be immediate, or as soon as possible after identifying the AE, providing initial animal care and contacting the veterinary staff. Additional details may be provided at a later date as they become known.

a. If Protocol-Related: In addition to informing the veterinary staff, the Principal Investigator (PI) must also inform the IACUC in a timely manner of any protocol-related AE events or conditions. The PI may delegate this task to a member of their research team but retains responsibility to ensure prompt and accurate reporting.

b. If Non-Protocol-Related: The individual with primary animal care responsibility (including research or animal care staff) has primary responsibility for informing the IACUC of any AE or unexpected events or outcomes. However, any individual with knowledge of an AE is obligated to ensure that the IACUC has been notified.

4. IACUC notification may be by phone or in writing (including via email). Adverse Event reports may be made to the following:

IACUC Office: 301-405-7295/3451/4792

IACUC email reflector: iacuc@umd.edu

5. Adverse event reporting, review of circumstances surrounding AEs and subsequent determination of actions necessary to prevent additional problems are intended to be interactive processes with the research or facility staff, veterinary staff and the IACUC to facilitate research effectiveness and improve animal welfare. On behalf of the IACUC or as directed by the IACUC Chair, the IACUC Manager or Post-Approval Monitoring (PAM) Coordinator will alert the IACUC Chair and Attending Veterinarian (as necessary), review the initial notification, and gather all available information to present for IACUC review. The IACUC staff (generally the PAM Coordinator) will track AEs and identify trends to serve as a potential basis for training initiatives, resource allocation and/or standards or SOP development. The full IACUC will be notified of AEs and proposed corrective plans at regularly scheduled meetings to identify trends or problem areas and to determine further appropriate action(s) it may deem necessary for these events.