



Guidance on Prompt Reporting of Unanticipated Adverse Events Policy

The IACUC Unanticipated Adverse Event Form must be completed for reporting any adverse or unanticipated event affecting animals used in research, testing or teaching.

Principal Investigators should seek assistance from the Attending Veterinarian (AV) when adverse events occur. The AV can assist in assessing the situation, seeking resolutions, and helping with the report. Consultation with the AV **MUST** occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control (such as administration of analgesics) is not possible.

Definition of an unanticipated or adverse event: Any event not consistent with routine expected outcomes that results in unexpected animal welfare issues (death, disease, distress).

Examples of events that **MUST** be reported include, but are not limited to the following:

- Animal death or illness from spontaneous disease not related to activities approved on a protocol.
- Unexpected animal death or injuries related to approved animal activities (e.g., allergic reactions, broken limbs, complications during or recovering from surgery, sudden death). Unexpected death includes an increased number of deaths over what was stated in the approved protocol.
- Death, disease, or distress due to equipment failure or natural disaster.

The Adverse Event must be reported to the IACUC via the Office of Research Compliance verbally or in writing within 24 hours of identification of the event. An [Adverse Event Report Form](#) must be completed and submitted to the IACUC in a timely manner.

Adverse events affecting USDA regulated species require a separate report for each affected animal.

It is Montana State University policy that the procurement, housing, care, and use of animals should conform to the *Guide for the Care and Use of Laboratory Animals* and other relevant federal, state, and university policies and procedures (e.g., USDA, OLAW, AAALAC). The policy applies to all research and teaching involving the use of laboratory animals whether funded from external or internal sources.

References

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Lab Animal Volume 46, No. 6 | JUNE 2017 [Adverse Events at Research Facilities.](#)