**IACUC Policies**

**Adverse Event Reporting**

**Date adopted: February 13, 2024**

**Policy:**

Reporting significant and unanticipated adverse events (AE) fosters protection, integrity and creditability of the institution while also demonstrating a culture of care. Principal Investigators should seek guidance from the Attending Veterinarian (AV) when adverse events occur. The AV will assist in assessing the situation, seeking a resolution, and help with reporting, if necessary. Consultation with the AV MUST occur when pain or distress is beyond the level anticipated in the approved animal use protocol or when interventional control (such as administration of analgesics) is not possible. **The completion of the** [**Adverse Event Form**](https://www.umt.edu/research/compliance/iacuc/forms/adverse-event-form.php) **is mandatory** for reporting of any unforeseen or negative incidents impacting animals involved in research, testing, or educational activities.

**Definitions and Examples:**

**Unanticipated or adverse event:** Any event that is not consistent with IACUC-approved expected outcomes that results in unexpected animal welfare issues such as: distress, increase in pain, disease, or death.

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

* **Unexpected animal death or injuries related to approved animal activities.**
* **Distress, disease, or death due to equipment failure or natural disaster.**
* **Unexpected injuries or reactions related to approved protocol activities such as: allergic reactions, broken limbs, complications during or recovering from procedures, unanticipated reactions due to exposure of experimental compounds, or sudden death.**
* **Unanticipated life threatening or debilitating birth defects discovered after generating or breeding genetically modified animals.**
* **Increase in death rate beyond expect outcomes related to approved animal procedures.**

**Expected outcomes/events that *may* not need to be reported:** An expected outcome is an already anticipated result of approved protocol activities. These outcomes do not need to be reported if they fall within the anticipated frequency of occurrence as defined in the approved AUP, and protocol personnel are following the animal monitoring procedures and humane endpoint determinations, as outlined in the protocol.

* **Certain frequency of morbidity or mortality that may be expected with a particular procedure, such as a surgery or disease model.**
* **Ulcerative dermatitis, barbering, blepharitis (granulated eye lids), not related to study activities/procedures.**
* **Anticipated events as a result of breeding.**

**Policy Procedure:**

1. If AE is noticed by LAR staff, PI and contact name on cage card will be notified via email. LAR staff will request that PI/research staff complete UM online [Adverse Event Form](https://www.umt.edu/research/compliance/iacuc/forms/adverse-event-form.php)  within 24 hours of notification. LAR staff will also copy IACUC Manager and AV on initial email.
2. If AE is noticed by PI or research staff, the [Adverse Event Form](https://www.umt.edu/research/compliance/iacuc/forms/adverse-event-form.php)  must be completed within 24 hours of AE discovery. Research staff can also reach out to AV via phone for immediate assistance, if necessary.
3. When an AE form is completed and submitted by PI/research staff, the IACUC Manager and AV will be notified electronically and will follow-up with PI and/or research staff.
4. The AV and/or the IACUC Manager will determine if the AE is a reportable incident with Office of Laboratory Animal Welfare (OLAW), United States Department of Agriculture (USDA), and/or AAALAC.
5. AE reports will be filed in the PI-specific online BOX folder for future access.
6. If AE is reportable, the PI will be notified by the IACUC manager. The IACUC manager and AV will work with PI to generate the necessary report to federal or accrediting agency (OLAW, USDA and/or AAALAC). Reports will be filed to necessary agencies by the IACUC Manger.
7. When necessary, the AV and/or the IACUC Manager will consult with the PI to address any needed modifications or potential amendments that may be required to approved animal use protocol.