**IACUC Policies**

**Guidance on Prompt Reporting of Unanticipated Outcome or Adverse Events in Research Animals**

**Date adopted: May 14th, 2024**

**Policy:**

The purpose of the guidance is to identify responsibilities and reporting requirements of the Institutional Animal Care and Use Committee (IACUC) in the event of an unusual or unexpected death(s), or other adverse events that affects the health or well-being of an animal involved in research, teaching, and testing.

**Definitions:**

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

**Examples of situations the USDA, Office of Laboratory Animal Welfare (OLAW) and/or AAALAC would consider reportable include but are not limited to:**

* Conditions that jeopardize the health or well-being of animals such as,
* natural disasters
* accidents
* physical plant failures
* inadequate veterinary care
* adverse events in the course of research
* Significant animal rights activities (e.g., protests, break-ins, property damage, FOIA and other public records requests)
* Inappropriate euthanasia techniques and/or failure to confirm euthanasia.
* Substantiated complaints or reports regarding animal welfare concerns.
* Internal or external reviews/inspections or other similar reports that document significant adverse events or noncompliance that resulted in animal harm or death; investigations by national oversight bodies; and other serious incidents or concerns that negatively impact animal well-being (e.g., failure to follow the approved protocol which resulted in compromised animal welfare; death during transport).
* Significant human health issue(s) directly related to the animal care and use program.
* Any serious deviation from the Guide
* Any suspension of an activity by the IACUC

**Expected outcomes:** An anticipated result of IACUC-approved animal activities. For example, a certain percentage of morbidity or mortality may be expected with a particular procedure, such as a surgery or disease model. These outcomes do not need to be reported to the IACUC if they fall within the anticipated frequency of occurrence and the procedures are conducted as approved in the Animal Use Protocol (AUP).

**Internal Reporting**: Adverse events, unexpected outcomes, unexpected deaths and animal welfare concerns must be promptly reported to the IACUC Manager and AV following specific reporting requirements in UM’s Adverse Event Reporting Policy5 and the associated [Adverse Event Form](https://www.umt.edu/research/compliance/iacuc/forms/adverse-event-form.php) . Some events may require immediate action by the LAR Manager, LAR staff, IACUC Manager, or AV to protect animal health and welfare in addition to IACUC Committee notification and reporting.

**The process of assessment and reporting includes the following:**

* Once an adverse event, unexpected outcome, or animal welfare concern has been reported to the IACUC Manager and Attending Veterinarian (AV), the IACUC Manager will provide a preliminary report to the Institutional Official (IO), OLAW, USDA, and AAALAC International, if applicable.
* If warranted, the IACUC Chair promptly appoints an individual or subcommittee to investigate the event, unexpected outcome, or concern. The IACUC Chair may also convene an emergency meeting if immediate actions are necessary.
* At a convened meeting of the IACUC with a quorum present, the IACUC reviews the event, unexpected outcome, or concern and:

Decides whether to recommend external reporting through the IO (see below), and

Develops a corrective and preventative action plan, if applicable.

* If external reporting is recommended, the IACUC Manager submits a final report to the IO and includes an explanation of the event and, if applicable, the corrective and preventative action plans.

**External Reporting to OLAW**: In addition to the final report to the IO, PHS Policy1 requires assured institutions to promptly report non-compliance or reportable situations.

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| **OLAW Prompt Reporting Examples2** |
| * Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents,   and mechanical failures, resulting in actual harm or death to animals   * Animal-related activities conducted without appropriate IACUC review and approval. * Failure to adhere to IACUC-approved AUPs * Implementation of any significant change to IACUC-approved AUPs without prior IACUC approval * Conducting animal-related activities beyond the expiration date established by the IACUC * Participation in animal-related activities by individuals who have not been determined by the IACUC   to be appropriately qualified and trained   * Failure to ensure death of animals after euthanasia * Failure of animal care and use personnel to carry out veterinary orders * IACUC suspension or other institutional intervention that results in the temporary or permanent   interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance |

**External Reporting to AAAALAC International**: Similarly, the AAALAC International Rules of Accreditation3

require prompt reporting of significant adverse events related to the animal care and use program. IACUC Manager

handles reporting to AAALAC International.

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| **AAALAC International Prompt Reporting Examples3,4** |
| * Inadequate veterinary care * Conditions that resulted in unexpected animal harm or deaths (e.g., accidents or errors, equipment   failures, natural disasters)   * Significant animal rights activities (e.g., protests, property damage) * Inappropriate euthanasia techniques or failure to confirm euthanasia * Substantiated complaints or reports regarding animal welfare concerns |

**External Reporting to USDA**: Similarly, the USDA6 requires prompt reporting of significant adverse events related to the animal care and use program. IACUC Manager handles reporting to the USDA.

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| **USDA Prompt Reporting Examples6** |
| * Inadequate veterinary care * Conditions that resulted in unexpected animal harm or deaths (e.g., accidents or errors, equipment   failures, natural disasters)   * Significant animal rights activities (e.g., protests, property damage) * Inappropriate euthanasia techniques or failure to confirm euthanasia * Substantiated complaints or reports regarding animal welfare concerns |

References:

1. [PHS Policy on Humane Care and Use of Laboratory Animals](https://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf)

2. OLAW NOT-OD-05-034 – [Guidance on Prompt Reporting to OLAW under the PHS Policy on](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html)

[Humane Care and Use of Laboratory Animals](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html)

3. AAALAC International – [Rules of Accreditation](https://www.aaalac.org/accreditation-program/rules-of-accreditation/)

4. AAALAC International FAQ – [Managing and reporting adverse events](https://www.aaalac.org/accreditation-program/faqs/#H2)

5. [UM AE Policy](https://www.umt.edu/research/compliance/iacuc/policies/default.php)

6. USDA- Animal welfare Act 2143(b)(4)(C), Animal Welfare Regulations 2.31(c)(7), Animal Welfare Regulations 2.31(d)(7)