Version: 1.0 Effective Date: 10/09/2023	REPORTING ADVERSE OR UNEXPECTED EVENTS AFFECTING ANIMAL WELFARE	Supercedes Document Dated: N/A

I. Background

The use of animals in research and teaching may occasionally result in unexpected outcomes, unintentional events or complications that negatively affect the health and welfare of animals. ACUC has developed this policy to meet the obligations of our Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), our registration with the United States Department of Agriculture (USDA), and our AAALAC International continuing accreditation requirements.

ACUC expects these events to be reported to OLAC veterinarians and subsequently to ACUC. ACUC views the failure to report these events, complications or unexpected outcomes affecting animal welfare by the PI and/or lab members as a potential non-compliance and such unreported occurrences will be addressed by the ACUC on a case-by-case basis.

II. Policy

All occurrences of situations in research and teaching that could be considered unexpected outcomes, unintentional events or complications that negatively affect the health and welfare of animals or pose an imminent risk to animal welfare must be reported promptly to OLAC veterinary staff. Telephone reports or in-person conversations with veterinary staff should be followed by the submission of a preliminary written summary from the person reporting said event, within 72 hours of discovery. This preliminary report must be submitted preferably by the principal investigator for the protocol that covers the affected animal(s) and sent to the Attending Veterinarian (AV) and ACUC. The report should include the nature of the event, how the event and animal welfare were monitored or addressed, and what immediate and long-term steps are being taken or considered to prevent reoccurrence of the event.

All unexpected outcomes, unintentional events or complications that negatively affect the health and welfare of animals are shared with the ACUC Chair and OACU Director by the Attending Veterinarian, for their information and assessment to determine what - if any - ACUC review and action is needed in addition to any immediate action/s taken by the AV (or OLAC Veterinarians). All serious occurrences are brought to the committee for review and discussion. If ACUC members are satisfied that the event has been appropriately addressed, the report will be so noted in the minutes with no further action taken; the principal investigator (PI) will be notified of the committee's decision by the ACUC Chair (or designee). If ACUC members have concerns regarding the resolution to the event, the ACUC/OACU will initiate communications with the PI. Labs experiencing occurrences with events subject to this policy will potentially be subject to increased post approval monitoring (PAM).

III. Definitions

A. Adverse Event - an event that is health-related, resulting in unexpected pain, distress, morbidity and/or death of an animal, often requiring notification or intervention of OLAC veterinary staff. Examples of causes of these events include, but are not limited to:

- Human accidents or errors
- Inappropriate euthanasia techniques and/or failure to confirm euthanasia.
- Equipment failure or malfunctioning
- A high rate of surgical complications such as anesthetic deaths, infections, or wound dehiscence
- Previously unknown phenotypes associated with transgenic animals (e.g., tumor development, early death) that negatively impact animal welfare.
- Natural disasters (e.g., fire, earthquake, tsunami, etc.)
- Other emergencies (e.g., power outages, water supply, disruption of light/dark cycle or HVAC, etc.)
- Environmental Hazards (e.g., animal disease outbreaks; infestations of mold, insects, etc.)

B. Unexpected Outcomes or Complications: This is an unanticipated result of approved IACUC protocol activities that may or may not directly impact animal welfare. In some cases, there may not be a clear cause and effect relationship of the outcome with the activity. Unexpected outcomes or complications may necessitate the need to adjust procedures, requiring an amendment to the IACUC protocol. If animal health and/or welfare is affected, the OLAC veterinarians must be contacted, and a report subsequently filed with the ACUC.

Examples of reportable unexpected outcomes or complications include, but are not limited to:

1. Unexpected clinical signs, potentially related to a protocol procedure and/or animal morbidity or mortality rate inconsistent with or occurring at a higher frequency than the expected outcomes of the protocol activity (surgery, disease model, etc.) listed on the approved protocol.

2. Unanticipated life threatening or debilitating birth defects discovered after creating or breeding genetically modified animals.

3. Unexpected reaction/side effect to an experimental agent.

Adverse consequences that can be expected as part of the research model, as described in the ACUC approved animal use protocol, do *not* need to be reported. Examples of non-reportable adverse events include, but are not limited to:

- Animal death or injuries related to manipulation that fall within parameters described in the ACUC approved protocol.
- Animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and adhered to by individuals responsible for the care of the animals.
- Death of animals that have reached their natural life spans.

IV. Responsibilities

A. Principal Investigator (PI) – The PI is responsible for ensuring that all laboratory personnel working on their AUP understand the AUP, the standards described in it (e.g., euthanasia criteria) and abide by this policy. The PI (or designee) will submit a preliminary report of all unintentional, unexpected, outcomes, adverse events or complications to the AV within 72 hours of discovery. An email report is acceptable.

B. Office of Laboratory Animal Care (OLAC) – OLAC Veterinarians communicate unexpected outcomes, adverse unintentional events or complications that negatively affect the health and welfare of animals to the ACUC and OACU staff; and participate as may be needed in observation, training, and PAMs.

C. Animal Care and Use Committee (ACUC) – review reports of unexpected outcomes, adverse unintentional events or complications that negatively affect the health and welfare of animals to ensure compliance with protocol and/or require amendments as may be necessary for animal welfare, and ensures compliance with approved policies and procedures.

D. Office for Animal Care and Use (OACU) – administratively manage reporting, OACU reviews and conduct PAMs as needed and/or directed by ACUC.

V. References

A. Guide for the Care and Use of Laboratory Animals 8th Edition

B. Animal Welfare Act and Animal Welfare Regulations, United States Department of Agriculture, 2018. § 2143 (4)(A)(iii)

C. AAALAC International Reporting Requirements

D. ACUC Guideline on Reporting Suspected Deficiencies in Animal Care or Treatment