

<b>Institutional Animal Care &amp; Use Program - UTEP</b>	
<b>Title:</b> Adverse Events	
<b>Policy#:</b> 027	<b>Date in Effect:</b> 16 December 2024
<b>Version #:</b> A	<b>Rev Date:</b>
<b>In Effect</b> <input checked="" type="checkbox"/> <b>Rescinded</b>	<b>Date Rescinded:</b>

## 1. RESPONSIBILITIES

It is the responsibility of all personnel using animals at The University of Texas at El Paso (UTEP) to abide by this policy. Exceptions to this policy must be approved by the Institutional Animal Care and Use Committee (IACUC) before implementation.

## 2. APPLICATION

This policy applies to all faculty animal users engaged in research and teaching at UTEP.

## 3. INTRODUCTION

Manipulation of animals in research or teaching may occasionally result in unanticipated or adverse clinical consequences. Unexpected or unanticipated events unrelated to the protocol may also adversely impact animals. Prompt and 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 and is required by *The Guide for the Care and Use of Laboratory Animals*. In addition, documentation of adverse events that occur with novel procedures or experimental compounds can provide insight for future studies and support scientific rigor and reproducibility.

## 4. POLICY

To assist the Institutional Animal Care and Use Program (IACUP) in fulfilling this requirement, unanticipated study-related adverse events and non-study related adverse events (e.g., pump failure in an aquatic system) that result in animal welfare issues must be promptly reported. This allows the Institutional Animal Care and Use Committee (IACUC), Principal Investigator (PI), facility managers and Attending Veterinarian (AV) to work together to evaluate the cause and, when possible, identify changes that can be implemented to help prevent re-occurrences. Reporting is not intended as a punitive action against investigators, but an effort to facilitate research effectiveness,

communication and improve overall research and animal welfare. Some adverse events and incidents may require reporting to regulatory, funding and/or accrediting organizations, so timely notifications are essential.

The IACUC expects that everyone involved in the care and use of animals be aware of the need to promptly report issues and be trained on the procedures to report unanticipated adverse events, abnormal conditions and/or incidents. Prompt reporting to Laboratory Animal Resource Center (LARC) or the Attending Veterinarian (AV) is crucial to ensure adequate veterinary care, minimize the effect on animal welfare and identify ongoing trends.

Adverse events and incidents should be reported through IACUCs approved electronic platform using the Report function. A reporting function is also available on the IACUC website. Examples of unanticipated adverse events and incidents requiring notification to the Attending Veterinarian and the IACUC include but are not limited to:

- Unexpected clinical signs potentially related to a protocol procedure that are not currently described in the protocol
- Expected clinical signs related to a protocol procedure that are occurring at an increased severity or rate than stated in the protocol.
- A significant increase in morbidity or mortality related to protocol procedures (e.g., 20% death during a procedure is expected, but 40% death is occurring).
- Phenotypes associated with transgenic animals (e.g., tumor development, neurological conditions, fertility issues, skin conditions, early death) that negatively impact the welfare of an animal, but are not stated in the protocol
- Accidents, unrelated to the research protocol, that negatively impact animal welfare.
- Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire) that negatively impact the welfare of an animal(s).
- A high rate of surgical complications such as anesthetic deaths, infections, or wound dehiscence.
- Frequent incidents of drowning of rodents as a result of issues with water source.