THE UNIVERSITY OF TOLEDO
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

SUBJECT: Reporting Adverse Events, Unexpected Outcomes, or Incidents

DATE: August 21, 2024

Reporting Adverse Events, Unexpected Outcomes, or Incidents

Manipulation of animals in research or teaching may occasionally result in serious, unanticipated, or adverse clinical consequences. Unexpected 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, unexpected outcomes, or other adverse events and is required by *The Guide for the Care and Use of Laboratory Animals*.

The IACUC is also required to monitor ongoing research and teaching activities related to animal use. To assist the IACUC in fulfilling this requirement, unanticipated study-related adverse events or non-study related adverse events (e.g. pump failure in an aquatic system) that result in serious animal welfare issues must be reported to the IACUC as soon as possible, as well as an accompanying xForm submitted within the IRB Manager system. This allows the IACUC, PI, facility managers and Attending Veterinarian 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 animal care. **Certain adverse events and incidents require reporting to regulatory, funding and/or accrediting organizations, so timely notifications are essential.** After the initial report, the investigator must work closely with the IACUC and respond to IACUC inquiries within 5 business days. If the inquiry is not responded to and/or the xForm is not completed promptly, the protocol may be suspended.

The IACUC expects that everyone involved in the care and use of animals is aware of the need to promptly report issues and is trained on the procedures to report unanticipated adverse events, unexpected outcomes, and/or incidents. Reporting to the proper clinical veterinarian must be in a timely manner to ensure adequate veterinary care, minimize the effect on animal welfare and identify ongoing trends.

Examples of unanticipated adverse events and incidents requiring notification to the Attending Veterinarian and the IACUC include:

- Unexpected clinical signs potentially related to a protocol procedure not currently described in the protocol or occurring at increased severity or rate.
- A significant increase in morbidity or mortality related to protocol procedures.
- 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
- Protocol deviations, departures or mistakes made by the research team inconsistent with the approved protocol.
- Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire) that negatively impact the welfare of an animal.
- A high rate of surgical complications such as anesthetic deaths, infections, or wound dehiscence.