Reporting Unexpected Outcomes/Adverse Events

Federal laws, regulations and policies require continued institutional oversight of animal use activities after IACUC approval. Researchers participate centrally in this oversight by reporting unanticipated research outcomes to the IACUC. The Principal Investigator (PI) or their designee must contact the University Veterinarian (Attending Veterinarian) and/or IACUC as soon as an adverse outcome is identified or suspected. Reporting will allow the University Veterinarian and the IACUC to work with the researcher to assess the situation and develop a plan for revising the protocol and/or experimental protocol (e.g., anesthesia, procedural method, monitoring interval, humane endpoints) as needed to ensure the well-being of the animals by circumventing or alleviating the impact of the unexpected outcome.

An unexpected outcome/adverse event is an occurrence of an unforeseen event that negatively affects the welfare of animals; that is, an event that involves pain, distress, and/or death of the animal. These are events that are not identified as a possible risk or outcome in the IACUC approved protocol.

Examples of unexpected outcomes which must be reported include, but are not limited to, the following:

- The phenotype of a genetically modified or mutant animal is discovered to include an unexpected condition that negatively affects animal well-being (e.g., malocclusion, impaired immunity, unexpectedly high mortality of offspring).
- Physical restraint of an animal results in lesions, illness, or behavioral changes.
- A surgical procedure causes unexpected complications, which may include recurring unexpected anesthetic deaths.
- A higher-than-expected morbidity or mortality rate occurs due to the experiment or other unanticipated events (e.g., husbandry problem, infection, tumor metastasis, elevated levels of induced disease).
- Unforeseen events such as equipment failure or natural disaster that leads to the harm of animals, or that cause obvious distress not scientifically justified and approved in the protocol.

Examples of unexpected outcomes that do not require reporting:

- Death or morbidity of animals described as expected in the approved IACUC protocol.
- Mortality resulting from surgical complications anticipated in the approved protocol at or below the rate anticipated in the approved protocol.
- Injury/illness unrelated to approved procedures and being treated by a veterinarian.
- Since the chance of mortality increases as a function of age in all animals, the death of aged animals due to natural causes.

Timeline for Reporting

The first priority is to protect animal health and welfare. The PI or designee should immediately contact the University Veterinarian, IACUC Chair, or the Office of Research Compliance.

All unexpected outcomes/adverse events are to be reported within 72 hours following the initial event/incident. In the event of a major disaster or emergency that precludes prompt communication, the reporting requirements may be extended. In these situations, reporting should occur as soon as circumstances allow.

Methods for Reporting

Unexpected outcomes/adverse events can be reported via the online Animal Unexpected Outcome Report found on the ORC/IACAC website.

Information to include within the report:

- Principal Investigator (PI)
- Protocol Number (PRN)
- Animal information (e.g., species, breed, age, sex)
- Number of animals involved.
- Location
- The nature and severity of the event (describe what occurred)
- Any identified or potential contributing factors or additional details that may be pertinent to assessing the event.
- Any treatment(s) that were initiated.
- Suggestions or steps taken to address and prevent future occurrences.

Reporting Requirements (External Agencies)

At any point during the evaluation of adverse events or unexpected outcomes, the IACUC through the Chair may report or may be required to and will report the event to relevant university offices, regulatory oversight agencies (OLAW and/or USDA), and/or funding sources.