University of Cincinnati
Animal Care and Use Program

Reporting Adverse Events and Protocol Deviations

The IACUC is 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 that result in serious animal welfare issues must be reported to the IACUC. 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.

Reporting is intended to be an interactive process with the PI, the Veterinarian and IACUC. The purpose of reporting is to provide a collaborative means of facilitating research effectiveness and to improve animal care.

IACUC views the failure to report an adverse event by animal research participants as a non-compliance incident, and it will be addressed by the IACUC on a case-by-case basis.

Responsibilities

1. Reporting is the responsibility of the Principal Investigator, all animal users, staff, and technicians.
2. Research staff are expected to seek assistance from veterinary staff and to report the adverse event to the IACUC office within 48 hours. Veterinarian consultation MUST occur when pain or distress is beyond the level anticipated in the protocol or when interventional control (such as analgesics) is not possible.
3. Veterinary staff can assess the situation, assist in seeking solutions, and help with the report.
4. The IACUC office will notify the PI, study contacts and veterinary staff when the report has been received.

Definitions

1. **Unanticipated Adverse Event (UAE):** any unexpected incident that leads to significant injury or illness, unrelieved pain or distress, or death of an animal. UAEs must meet one of the following conditions:
    a. The event is research-related but is not identified in the protocol or is occurring at a rate or severity higher than is indicated in the approved protocol.
    b. The event is not research-related but results from a facility, physical plant, equipment, or personnel failure, malfunction, or mistake.
2. Protocol deviations - departures, omissions or mistakes made by the research team inconsistent with the intent of the approved protocol.

Events that MUST be reported include, but are not limited to the following:

- Unexpected animal death or study related complications associated with approved animal activities in a cohort of animals (e.g., allergic reaction to treatment, broken limbs, complications during or recovering from surgery, anesthetic/analgesic approved in protocol that appears ineffective, sudden death).
- Mortality greater than 10% of that predicted in the IACUC protocol or greater than 10% of the animal subjects in a study group if no mortality is expected.

- Unanticipated phenotypes from genetic manipulation that may negatively affect animal well-being (e.g. unforeseen immunodeficiency).
- Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire, pump failure in an aquatic system) that negatively impact the welfare of an animal.
- Unforeseen events that lead to harm of animal(s) or that cause pain or distress not justified and approved in the protocol.
- A high rate of surgical complications such as anesthetic deaths, infections, or wound dehiscence.
- Protocol deviations (e.g. unclear or missing procedures in protocol, refinements not clearly defined in protocol).

Abnormal Behavior/conditions that require veterinary notification but do not typically require a report to the IACUC:

1. Anticipated clinical signs/possible adverse events described in a protocol or amendment, as they are potentially expected from the research activities.
2. Injury or illness unrelated to study procedures (e.g. fight wounds, barbering, age-related mortality, etc.).
3. Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire, etc.) that do not negatively impact welfare.
4. Surgical complications such as anesthetic deaths, infection, or wound dehiscence that occur rarely. High complication rates will likely require a report to the IACUC.

Examples of situations that are not required to be reported:

1. Injury/illness unrelated to approved procedures and being treated by veterinary staff.
2. Death or morbidity of animals as expected and described in the approved IACUC protocol.
3. Death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate.

IACUC Review of UAEs:

1. Adverse events will be reviewed at the next IACUC meeting by the full committee.
2. The IACUC will review the event and the associated IACUC protocol (if relevant), then vote to determine whether the event meets the definition of a UAE.
3. The IACUC will deliberate and vote upon recommendations for actions that may include:
    a. Retraining on specific procedures.
    b. Pilot studies to refine outcomes.
    c. Protocol amendments to describe and justify newly recognized adverse events secondary to procedures, disease models or newly recognized phenotypes. Amendments must outline monitoring, management of adverse clinical signs and humane endpoints.
4. PIs will receive official communication from the IACUC outlining determinations and recommendations.

Reporting UAEs to outside agencies:

Depending on the circumstances, an animal-related incident may require mandatory reporting to external agencies and institutions (e.g., USDA, OLAW, AAALACi, etc.) in a timely manner. UC IACUC uses criteria detailed in NOT-OD-25-148 and AAALAC International Adverse Events Guidance Statement as guidance in deciding on prompt reporting requirements to AAALAC, OLAW, and/or the USDA for all animal activities.

1. Office of Laboratory Animal Welfare (OLAW)
    a. Reporting is required for PHS-funded animal activities if the UAE includes a protocol noncompliance or suspension. PHS-funded animal activities include those funded through: NIH, NSF, NASA, DOD and VA.
    b. Reporting to OLAW is required for these types of noncompliance:
        i. Serious or Continuing Noncompliance with PHS Policy.
        ii. Serious deviation from The Guide.
        iii. Suspension of an activity by the IACUC.
2. United States Department of Agriculture (USDA)
    a. Reporting is only required if animal activities involve species covered by the Animal Welfare Act (hamster, rabbit, pig, sheep, etc.).
    b. Reporting to USDA is required only if UAEs are associated with:
        i. Suspension of a protocol by the IACUC.
        ii. Failure to adhere to a plan to correct a significant deficiency.
3. AAALAC International
    a. Prompt reporting of UAEs to AAALAC follows the guidance laid out by AAALAC through its Adverse Events Guidance Statement and may include:
        i. Investigations by applicable external oversight bodies
        ii. Public Records requests
        iii. Lawsuits alleging animal care and use program concerns
        iv. Events anticipated to attract external attention
    b. Any report made to OLAW is also reported to AAALAC International

References

1. Animal and Plant Health Inspection Service, USDA. Animal Welfare Act and Animal Welfare Regulations. July 2023. CFR Title 9, Subchapter A - Animal Welfare. U.S. Government Printing Office, Washington DC.
2. National Research Council. Institute for Laboratory Animal Research. 2011. Guide for the Care and Use of Laboratory Animals. Public Health Service, Bethesda, MD.
3. Office of Laboratory Animal Welfare, National Institutes of Health, US Department of Health and Human Services. Public Health Service Policy on Humane Care and Use of Laboratory Animals. 2015. Public Health Service, Bethesda, MD.
4. AAALAC International Guidance Statement Adverse Events (March 2026)
5. NOT-OD-25-148: Notice on Update to Guidance on Prompt Reporting to OLAW Under the PHS Policy on Humane Care and Use of Laboratory Animals. January 20, 2026.