ADA Forsyth®

Animal Program Policy

Title: **Reporting Adverse Events**
Date Created: 08/01/2023
Date Reviewed: 09/27/2026

This policy addresses significant, unexpected, isolated adverse events that affect animal welfare. Such events could be related to animal husbandry (e.g., deaths due to disease or unknown causes, flooded cages, dystocia, etc.) or related to experimental manipulations (e.g., unanticipated deaths following surgical or other procedures, unanticipated morbidity or mortality associated with tumor development, or any animal harm that was not anticipated in the protocol or is occurring at a higher rate than anticipated). Other specific examples include:

- 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, such as HVAC or power failure, that negatively impact the welfare of an animal(s).
- Forsyth IACUC Disaster Plan and the Forsyth Emergency Response Plan provide guidance on Institute wide adverse events.
- 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.

Any such adverse events should be promptly reported to the Director of Animal Care or other animal facility staff. He/she will then:

1. Decide if any immediate course of action is needed, such as:
    a. Provide treatment or analgesia.
    b. Contact the consulting veterinarian.
    c. Euthanize the affected animal(s).
2. After any required acute care has been provided, the Director of Animal Care will report the event to the IACUC chair. If the report is made in person or by phone, the chair should document and file the report. Discussion should take place regarding any additional actions needed in the short term.
3. A final report of the adverse event and response/resolution will be sent to the IACUC for recommendations.
    a. The IACUC will discuss if any additional actions are needed to prevent the adverse event, and recommend a course of action.
    b. The IACUC will decide if any additional regulatory action is needed.
    c. The IACUC will recommend any external reporting (OLAW or AAALAC) and the time frame for such reports.
    d. The IACUC Chair will prepare and submit any required reports