GUIDING PRINCIPLE

The IACUC is under federal mandate to provide continual monitoring and oversight of all research activities related to animal use. To assist the IACUC in fulfilling this requirement, all adverse events or protocol deviations must be reported to the IACUC.

Timely reporting allows the institution to provide the highest quality animal care by engaging all available resources.

Definitions

- **Unanticipated Adverse Events** are outcomes that:
  - adversely affect the health or well-being of animals used in research teaching, or testing,
  - are a result of activities that were approved by the IACUC but were not anticipated in the IACUC’s review of the protocol OR
  - any occurrence of an unforeseen event that negatively impacts the welfare of animals, usually involving pain, distress or death of an animal.

- **Protocol Deviation**—any departure from methods approved in an IACUC protocol or the conduct of animal related activities without appropriate IACUC review and approval.

REQUIREMENTS

**Animal Welfare Act** in accordance with, (9 CFR Ch. 1), Part 2 – Subpart C, 2.31(d)(5), The IACUC shall conduct continuing review of activities covered by this subchapter at intervals as determined by the IACUC but not less than annually.

**The Public Health Service (PHS) Policy** in accordance with IV.C.5-The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.

**The Guide Eighth Edition, page 28**, “Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more
frequent monitoring of animals may be required.”

The Guide for the Care and Use of Agricultural Animals in Research and Teaching, Third Edition, page 2, investigate concerns, complaints, or reports of noncompliance, involving agricultural animals at the facility.

PROCEDURE

1. Principal Investigator/Animal Care Staff Responsibilities
   1.1. The first priority is to protect the health and welfare of staff or animals that are or may be affected.
   1.2. Within 72 hours of learning of the unanticipated adverse event or protocol deviation, the PI and/or animal care staff must report the event to the IACUC Office using the [Unanticipated Adverse Event/Protocol Deviation Reporting Form].
   1.3. If IACUC review suggests that modifications in the protocol are required to prevent further instances, the PI shall file a change in protocol request.

2. Institutional Responsibilities
   2.1. The IACUC is responsible for ensuring that PIs are aware of their responsibilities to report adverse events and protocol deviations.
   2.2. Upon receipt of an unanticipated adverse event or protocol deviation the IACUC Office will forward the report to the IACUC Chair, Attending Veterinarian and if necessary, the Institutional Official.
   2.2.1. If the event requires immediate response to protect the health of animals, the Attending Veterinarian will follow the appropriate procedures.
   2.3. The Research Compliance Administrator and Attending Veterinarian will review the Adverse Event/Protocol Deviation Report, gather additional information, and develop a summary report for the IACUC.
   2.3.1. The reports will be provided to the IACUC at regularly convened meetings. The IACUC will review the report and determine whether any further action is required.
   2.4. The IACUC Office will inform the PI of any decisions, corrective actions, or amendments required by the IACUC.

Examples of unanticipated adverse events:

- Unexpected clinical signs, either related or unrelated to a protocol procedure
- Unexpected euthanasia that is not part of the approved animal activities
- Increased or unexpected moribundity or mortality.
- Failure to recover from anesthesia.
- Surgical complications such as infection or wound dehiscense (wound opens up)
- Phenotypes associated with transgenic animals that negatively impact the welfare of the animal.
- Facility or equipment failure that has a negative impact on animal welfare.

**Examples of protocol deviations:**

- Any intentional or unintentional use of animals that was not described in the approved IACUC protocol;
- Failure to adhere to procedures within an IACUC approved protocol;
- Implementing protocol amendments prior to obtaining IACUC approval.

**Examples of situations that DO NOT need to be reported:**

- Injury/Illness unrelated to approved procedures and being treated by a clinical veterinarian.
- Death or morbidity of animals as expected and described in approved IACUC protocol.
- Death of animals that have reached the end of their natural life spans