Title: Reporting Adverse Events
Issued Date: August 2023
Revised Date: N/A
Authority: IACUC

## I. Purpose

This Standard Operating Procedure (SOP) outlines the procedures for reporting adverse events that occur during the use of animals in research, testing, and teaching. Federal regulations and professional standards mandate that adverse events are promptly reported to the veterinary staff and IACUC. IACUC is subsequently responsible for determining what must be reported to regulatory agencies, if protocol revisions should be pursued, or if additional actions (e.g., training, veterinary consults) are necessary. An adverse event is an unexpected incident with an animal related or unrelated to its use in a teaching, testing or research IACUC approved protocol. Expected clinical occurrences described in a protocol should be noted/recorded but are not adverse events unless the frequency or severity is greater than described in the IACUC protocol.

## II. Procedures

When an adverse event occurs, the project personnel or animal care staff must follow the procedures outlined below. Failure to report an adverse event by animal research participants is a non-compliance incident and can result, in extreme cases, in protocol suspension.

1. Provide immediate care for the animal. Any clinical issue, regardless of severity, must be reported to the responsible veterinarian as defined in the protocol, the Attending Veterinarian (AV) and the PI within 48 hours.
2. In the case of euthanasia, it is the PIs responsibility to ensure that autopsies and sampling happen immediately after an animal's death to ensure that proper testing can be done to understand the cause of death.
3. The reporting personnel will work with the PI and AV to report the incident to the IACUC. The report should include:
    a. Protocol Number
    b. Species and number of animals involved
    c. Event description

d. If possible, steps that have been, or will be, taken to prevent future occurrence

4. Depending on the severity of the issue, the AV may share the report at a regular convened meeting of the IACUC or require the PI to submit formal written documentation.

5. Regardless of the means of documentation and reporting to IACUC, the adverse event will be linked with the protocol electronically.

6. Following a discussion by the IACUC, a determination will be made whether the event is significant or serious enough to be reportable to outside agencies or institutions. Notification to the appropriate agencies will occur promptly.

**III. Review**

This SOP is subject to annual review.

**SOP Approval:**

Jennifer K Ketzis _____ 11 Aug 23 _____