Title: **Unanticipated Adverse Events**
Effective Date: **August 17, 2010** Revision # **02**
Standard Operation Procedure Number: **IACUC-RVW-026** **Last Committee Review: August 8, 2017**

Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to outline the IACUC's procedure regarding the reporting and follow-up evaluation of adverse events. This procedure (i.e., the reporting of adverse events, review of circumstances surrounding them, and subsequent determinations as to whether procedural changes are necessary to prevent additional problems) is intended to be an interactive process with the Principal Investigator and IACUC. It is not intended as a punitive action against investigators, but an effort to facilitate research effectiveness and improve animal care.

Materials

Adverse Event Reporting Form

Background

The Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act require as part of adequate veterinary care: (1) effective programs for the management of protocol-associated disease, disability, or other sequelae and (2) the timely and accurate communication of information on problems of animal health, behavior and well-being. In spite of the measures taken in protocol design and review and the ongoing care provided by animal care personnel, the experimental manipulation of animals in research, teaching or testing activities occasionally results in serious unanticipated consequences.

Definitions

Adverse events – unexpected or excessive, unfavorable outcomes resulting in any one of the following:

a) levels of mortality that are 10% or greater than anticipated in the approved protocol including both spontaneous animal deaths and animals being euthanized due to reaching study-specified or other humane end-points; or
b) mortality due to complications unanticipated in the approved protocol; or
c) groupings of animal deaths occurring closely together that are above anticipated study loss levels; or
d) morbid complications leading to unanticipated animal discomfort, especially those creating difficult to manage levels of pain and distress or situations of uncontrollable pain or distress; or
e) mortality or morbidity not research-related, but is unanticipated or due to a facility, physical plant, equipment, or personnel failure, malfunction, or mistake; or
f) any animal that escapes its designated holding facility.

Policy/Procedure

The Principal Investigator (PI) is responsible for reporting an adverse event to the IACUC Chair within three (3) days of discovering the event. This initial report may be made by phone, email or in-person. The IACUC Chair will advise the PI whether an Adverse Event Reporting form must be completed and may require immediate action by the PI. In the event an Adverse Event Reporting Form submission is required, the convened IACUC will review the form at the next regularly scheduled meeting or at a special meeting to be determined by the Chair. The IACUC maintains the final right of approval of any initial actions required by the Chair and any proposed corrective plans or may require further action(s) if deemed necessary. Further actions may include but are not limited to:

a) Additional follow-up reporting

b) Specific modifications to the protocol

Any actions taken or requirements from the IACUC will be reported to the Principal Investigator by the Chair. The PI may appeal any IACUC decisions to the IACUC.

All documentation relating to the adverse event will be maintained in the IACUC protocol file as well as in an Adverse Event file in the Office of Research Compliance. If the adverse event is required to be reported, the procedures outlined in IACUC-RPT-004 will be followed.

Examples of Reportable Unanticipated Adverse Events

- an animal having an allergic reaction to a treatment
- an anesthetic approved for the study that doesn't adequately work
- animal develops unanticipated infection following surgery or other approved procedure
- animal death due to anesthetic overdose
- life threatening birth defects discovered after creating or breeding genetically modified animals
- unanticipated animal morbidity or mortality in excess of expected morbidity or mortality commensurate with approved activity/protocol
- unforeseen events such as equipment failure or natural disaster that lead to the harm of animal(s) or that cause obvious distress not justified and approved in the protocol
- unintentional or negligent misuse or accident that results in animal morbidity or mortality or negatively impacts animal welfare

Examples of Events Not Reportable

- death of animals that have reached the end of their natural life spans
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters were in accordance with LARAC SOPs.
- animal death or illness when appropriate quarantine, preventative medical, surveillance, diagnostic, or therapeutic procedures were in place and followed
- animal death or injuries related to manipulations that fall within the parameters described in the IACUC-approved protocol
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause is water valves jammed with bedding (frequent problems of this nature, however, must be reported along with corrective action plans and schedules)

Reviewed:

IACUC Chairperson Date

Research Compliance Director Date