Department of Veterans Affairs
VA Pittsburgh Healthcare System
Research and Development Office

Guidelines for Reporting an Unanticipated Event at VA Pittsburgh Healthcare System

I. Purpose:

Unanticipated event reporting is performed at the VA Pittsburgh Healthcare System (VAPHS) to proactively identify unanticipated welfare complications associated with animal research and to facilitate the correction or adjustments for such problems.

These guidelines apply to all research personnel working with animals described on an approved Institutional Animal Care and Use Committee (IACUC) protocol at the VAPHS.

II. Introduction:

Continuing IACUC oversight of animal activities is mandated by federal laws, regulations and policies. The Guide for the Care and Use of Laboratory Animals, 8th Edition requires monitoring of research activities by a variety of means, including regular review of unexpected experimental outcomes affecting the animals.

Definition of an Unanticipated Event: An unexpected and unfavorable clinical outcome to research manipulation resulting in either:

a) Levels of mortality that are 15% or greater than anticipated in the approved protocol* (including either spontaneous death or animals being euthanized due to study-specified or other humane end-points).

b) Significant mortality due to complications unanticipated in the protocol (determined in conjunction with dialogue that includes the Animal Research Facility (ARF) Staff and/or veterinary personnel).

c) High levels of cluster mortality (a grouping of animal deaths occurring closely together significantly above anticipated study loss levels).

** Early mortality in studies may be higher than that experienced later in the project as a consequence of a "learning/experience curve" effect. Unanticipated event reporting is not required until animal loss in absolute terms exceeds by >15% that predicted in the protocol, although it is considered advantageous to discuss high early mortality rates with ARF Staff and veterinary personnel such that any preemptive action necessary can be considered.*

Unanticipated events in the context of these guidelines are generally associated with mortality. However; investigators should also report unexpected animal morbidity occurring either at a frequency or severity significantly beyond that anticipated in the approved protocol. In particular, morbidity complications leading to significant animal discomfort (especially those creating difficult to manage levels of pain or distress, or those creating uncontrollable pain or distress) should be reported.

III. Guidelines

The unanticipated event form in Appendix A is to be completed by the Principal Investigator (PI) after consultation and interaction with the ARF Staff and/or veterinary personnel when unanticipated research outcomes rising to the level discussed in Section II occur. After signoff of the Corrective Action Plan (CAP) provided by the ARF Supervisor or Consulting Veterinarian, such occurrences will be reported to the IACUC at the next convened meeting for Committee awareness and discussion of any further action necessary.

If the Veterinarian deems that an unanticipated loss of life is significant or out of the range of expected outcomes, such events will be reported to the IACUC within five (5) business days of becoming aware of the situation. The unanticipated event form will be filled out by the PI and the Veterinarian. The Veterinarian will then send the form to the IACUC Program Assistant for notification to the IACUC.

Appendix A

IACUC Protocol No.: **Click or tap here to enter text.**
Protocol Title: **Click or tap here to enter text.**
Principal Investigator: **Click or tap here to enter text.**
Date: **Click or tap to enter a date.**

UNANTICIPATED PROBLEM DESCRIPTION

Classification(s) of unanticipated event:

☐ Levels of mortality experienced are ≥ 15% that anticipated in the approved protocol

☐ Mortality due to complications unanticipated in the approved protocol

☐ High "cluster" mortality (Cluster mortality is defined as a grouping of animal deaths occurring closely together, significantly above anticipated study loss levels)

☐ Morbidity/non-fatal complications significantly beyond that anticipated in the approved protocol, especially those creating difficult to manage levels of pain and distress

☐ Other (list): **Click or tap here to enter text.**

Summarize the excessive or unanticipated mortality or morbidity being reported including:

a) Species involved: **Click or tap here to enter text.**

b) Number of animals impacted: **Click or tap here to enter text.**

c) Animal identification number(s) – if applicable: **Click or tap here to enter text.**

d) Date or date range of incident(s): **Click or tap here to enter text.**

e) A short narrative describing the unanticipated events occurring (please list and compare with the anticipated nature and frequency of morbidity or mortality listed in the currently approved protocol):
Click or tap here to enter text.

f) Preliminary considerations as to the pathogenesis of the adverse event(s):
Click or tap here to enter text.

g) Any existing or pending diagnostics or other data that may help to explain the cause of the unanticipated event:
Click or tap here to enter text.

h) Any additional information, review of circumstances or other details that may be helpful in reviewing the matter:
Click or tap here to enter text.

Has there been prior communication or consultation with the ARF Staff and/or Veterinarian concerning this/these event(s)? If yes, please summarize.
Click or tap here to enter text.

In the space below, describe the Corrective Action Plan (CAP) to reduce or prevent future morbidity or mortality:
Click or tap here to enter text.

**Please note the following in conjunction with unanticipated event filing:*

a) Events listed in this form should be summarized and included in the next Annual Renewal Application for the protocol.

b) If levels of morbidity or mortality experienced cannot be maintained at levels specified in the protocol, a modification must be filed requesting adjustment to the new levels or complications being experienced.

c) All unanticipated event reports filed are reviewed by the full IACUC and the Committee maintains the right to grant final approval of the CAP. Additional stipulations may also be required by the Committee.

_____ Date: **Click or tap to enter a date.**
Signature of Principal Investigator

_____ Date: **Click or tap to enter a date.**
Signature of ARF Supervisor or Veterinarian consulted