Guideline #1: Reporting Adverse Events or Unanticipated Outcomes

Approval Date: 08.29.2018

A. Purpose

To standardize the procedures for reporting adverse events or unanticipated outcomes to the IACUC and Office of the Campus Veterinarian.

B. Background

Both the PHS Policy (IV.C.5) and USDA Animal Welfare Regulations [9 CFR 2.31(d)(5)] require continued review of previously approved protocols. The IACUC, as a part of post-approval monitoring, requires investigators and animal care staff to notify the IACUC and OCV of any adverse events or unanticipated outcomes to animals during the course of the project.

C. Guideline

Any happening that is not consistent with routine expected outcomes that results in any unexpected animal welfare issues (death, disease, or distress) or human health risks (zoonotic disease or injuries).

D. Resources

The IACUC expects that everyone involved in the care and use of animals is aware of the need to report and procedure to report adverse events and/or unanticipated outcomes. Reporting must be in a timely manner to identify ongoing trends, to ensure adequate
veterinary care and to minimize the effect on animal welfare. Examples of adverse events and/or unanticipated outcomes include:

- 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 morbidity or mortality
- Surgical complications such as anesthetic deaths, infection or wound dehiscence
- Phenotypes associated with transgenic animals (e.g., tumor development, early death) that negatively impact the welfare of an animal
- Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire) that negatively impact the welfare of an animal

Adverse events and/or unanticipated outcomes do not include those described in a protocol or amendment, as they are potentially expected from the animal activities. In addition, animals removed from study or euthanized under early removal criteria are not considered adverse events and/or unanticipated outcomes, as they are potentially expected from the animal activities.

If there is a question as the need for reporting, OCV veterinarians or Animal Welfare Program staff will be able to provide guidance.

To report an adverse event or unanticipated outcome:

- If immediate veterinary assistance is required, call OCV at 1-509-335-6246 or if after-hours at 1-509-330-1871 to report to the OCV veterinary staff
- Report adverse events or unanticipated outcome directly to Animal Welfare Program staff or OCV veterinary staff. In this case, an Adverse Event/Unanticipated Outcome form will still be completed and submitted to the Animal Welfare Program Office.
- Complete an Adverse Event form & submit to the Animal Welfare Program office. The form is available at the IACUC website. The Animal Welfare Program staff or the Office of the Campus Veterinarian staff will help finalize the report including establishing a corrective action plan when appropriate.

When an Adverse Event/Unanticipated Outcome form is received, the following steps occur:

- The IACUC is notified of the event. A member may request discussion by the full committee, in which case the report will be discussed at a fully convened IACUC meeting.
• The Principal Investigator and OCV veterinarian will be notified, if this has not already occurred.
• Based on veterinary and IACUC review, modifications to the protocol activities or other corrective actions such as additional training or post-approval monitoring may be required. Reporting to external agencies may be necessary depending on the type of event.