TITLE: Adverse Event or Unanticipated Outcome Reporting

PURPOSE: To standardize the procedures for reporting unexpected outcomes or adverse events.

REVIEW/REVISIONS: The IACUC will review and revise this SOP as needed.

PROCEDURES:

The IACUC expects that everyone involved in the care and use of animals is aware of the need 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 moribundity or mortality
- Failure to recover from anesthesia
- Surgical complications such as infection or wound dehiscence (wound opens up)
- Phenotypes associated with transgenic animals (e.g., tumor development, early death) 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, UAC veterinarians or IACUC Office staff will be able to provide guidance.

There are several reporting mechanisms:

- The preferred method is the Adverse Event/Unanticipated Outcome form, which is available at: http://orcr.arizona.edu/iacuc/adverseevent. The form is submitted to the IACUC Office.
- Adverse events and/or unanticipated outcomes can be reported to a UAC veterinarian, UAC clinical staff or the IACUC. In this case, an Adverse Event/Unanticipated Outcome form must still be completed and submitted to the IACUC Office.
- Adverse events and/or unanticipated outcomes can be described on the Annual Status Report. In this case, the information will be transferred to an Adverse Event/Unanticipated Outcome form. This method is not preferred as it results in less timely reporting.

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 a UAC 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.