

**PROMPT REPORTING OF UNANTICIPATED OUTCOMES, PROTOCOL DEVIATIONS,
AND ADVERSE EVENTS**

Unanticipated Outcomes, Protocol Deviations, and Adverse Events must be reported to the IACUC to assist Principal investigators (PI), animal care staff and the Attending Veterinarian to find the cause and to prevent recurrence. Reporting also helps the IACUC meet its federal requirement to monitor animal activities. Reporting is intended to be an interactive process with the PI and IACUC. It is not intended as a punitive action against investigators, but an effort to facilitate research effectiveness and improve animal care.

Definition of an unanticipated outcomes, protocol deviations, or adverse event: Any event not consistent with routine expected outcomes that results in unexpected animal welfare issues (death, disease, distress).

Examples of events that MUST be reported include, but are not limited to the following:

- Animal death or illness from spontaneous disease not related to activities approved in the protocol.
- Unexpected animal death or injuries related to approved animal activities (i.e., allergic reactions, broken limbs, complications during or recovering from surgery, sudden death). Unexpected death includes an increased number of deaths over what was stated in the approved protocol.
- Death due to equipment failure (e.g., HVAC failure, loss of electrical power) or natural disaster.
- Conduct of animal-related activities without appropriate IACUC review and approval (e.g., protocol deviation)

Reporting

PIs and/or animal facility staff should report to the IACUC as soon as they become aware of an event that may impact animal welfare. **An email or phone call is required for a preliminary report as soon as possible after the event.** The Adverse Event form should be completed and submitted to the IACUC **within seventy-two (72) hours** of observing the event.

It is appropriate to seek assistance from the Attending Veterinarian as they can assist in assessing the situation, seeking resolutions, and helping with the report. Attending Veterinarian consultation MUST occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control (such as analgesics) is not possible.

- The form is available on the IACUC website at <http://www.uri.edu/research/tro/about/IACUC/forms.html>.
- Email a copy of the report to: compliance@ds.uri.edu
- Contact information for Attending Veterinarian, David Serra, VMD
 - Ph: (401) 742-2855
 - Email: dserra@ds.uri.edu

Questions regarding the use of this form should be directed to the URI Office of Research Integrity at 873-4328 or compliance@ds.uri.edu

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