



Reporting Unexpected Outcomes and Adverse Events

The new Guide of the Care and Use of Laboratory Animals (Guide) acknowledges that “fundamental to scientific inquiry is the investigation of novel experimental variables,” but includes additional emphasis on responding to unexpected outcomes and adverse events. A primary example is the use of genetically modified animals (GMAs), in which unexpected phenotypes are often manifested. While individual animal welfare could be impacted, even an unexpected reduction in fertility may result in Principal Investigators’ need for additional animals than originally approved by the IACUC. The Guide also states that examples “of effective monitoring strategies include... regular review of adverse or unexpected experimental outcomes affecting the animals...”

Monitoring for such outcomes has and will always depend on careful observation by research staff, augmented by daily care provided by the RRF. Historically, adverse events have been resolved by the laboratory in consultation with RRF veterinary staff. While such a routine is entirely appropriate, the Guide suggests that the IACUC should also be made aware of such events.

The new institution-wide compliance database currently in review and implementation will include a web-based mechanism for laboratory and RRF staff to alert the IACUC to unexpected outcomes and adverse events. Furthermore, an animal health database currently being implemented in the RRF will also be used to summarize adverse events within the vivarium (*e.g.*, colony mortality levels). Until these systems are operational, however, the IACUC requests that you provide a report (IACUC@louisville.edu) summarizing unexpected outcomes and/or adverse events. *Please note: as always, animal health-related issues should be reported to RRF veterinary care staff immediately.*

Examples of circumstances that should be reported include (but are not limited to):

- Unexpected phenotypes affecting the health and well-being of animals, which may require additional monitoring or intervention (*e.g.*, immunodeficiency, diabetes mellitus, muscle wasting).
- Unexpected morbidity or mortality (*e.g.*, surgical complications, reactions to test articles, tumor metastasis, elevated levels of induced disease)
- Illness or injury from temporary or prolonged physical restraint
- Accidents leading to significant morbidity or mortality (*e.g.*, water system malfunction, impeded access to food, drug overdose)

These reports should ensure “veterinary consultation when pain or distress is beyond the level anticipated in the protocol description or when interventional control is not possible.”
