



A. PURPOSE

The IACUC is required to ensure humane care and use of vertebrate animals used for research, instruction, and testing and to adhere to the applicable federal and state regulations and institutional policies affecting such use. This guidance describes the procedures for the submission of reportable new information (RNI) related to the care and use of animals at the University of Arizona.

B. DEFINITIONS

Reportable New Information: Any outcome that is not described or expected in the approved IACUC protocol, including welfare concerns. A RNI may include, but is not limited to:

- Higher than expected mortality
- 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
- Non-adherence to an approved IACUC protocol
- Animal welfare reports from internal, external, and/or anonymous sources
- Accident or escape resulting in harm or distress

Animals removed from study or euthanized under early removal criteria are not considered adverse events and/or unanticipated outcomes, as they are expected from the animal activities.

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

C. RESPONSIBILITY

It is the responsibility of all University personnel to report any incident that may impact the care and use of animals in a timely manner. This includes the investigator, laboratory staff, vivarium staff and veterinarians, IACUC members, and Animal Welfare Program (AWP) staff, employees, students, volunteers, and/or members of the public.

All RNI reported to the Animal Welfare Program (AWP) are distributed to IACUC leadership, Chair and Vice-Chair, and Attending Veterinarian, along with the Animal Welfare Program leadership for review. Under the direction of the IACUC Chair/Vice-Chair, the AWP will initiate an investigation of the RNI (Per I-IC-SOP-112).

D. PROCEDURES

Mechanisms for reporting

There are several mechanisms for reporting concerns, which can be in person, by phone or in writing:



- To the AWP via an online form
- To any member of the AWP
- Through University Animal Care
- To the independently operated University Ethics and Compliance Hotline

In cases where an animal's immediate health or welfare is threatened, University Animal Care veterinarians have the authority to act on behalf of the animal's welfare, up to and including immediate euthanasia.

RNI are triaged by the AWP and IACUC Chair/Vice-Chair and Attending Veterinarian. Not all RNI rise to the level of non-compliance. The significance of each case will be determined case by case, based on the particular facts and circumstances surrounding the issue. The IACUC Chair/Vice-Chair may request another IACUC member review the RNI to assist in the determination of whether the RNI should be determined to be non-compliance. To this end, self-reporting and proactive corrections taken by the investigator will be considered when an issue is evaluated. The attached [flowchart](#) outlines the process for review of a RNI.

Confidentiality

Reports can be made anonymously. The confidentiality of any complainant will be maintained to the fullest extent possible by all individuals involved in the review and/or investigation of alleged RNI.

A University of Arizona employee who discloses and subsequently suffers an adverse personnel action as a result, is subject to the protection of ABOR Policy 6-914 Protection of Employees from Reprisal for Whistleblowing.

E. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- Reportable New Information form: <https://research.arizona.edu/compliance/IACUC/iacuc-awp-forms-signs-labels>
- I-IC-SOP-112 Investigation of Reportable New Information and Determination of Non-Compliance