

A. PURPOSE

To describe the procedures for the investigation of reportable new information (RNI), and if applicable, the determination of non-compliance that pertains to the care and use of animals at the University of Arizona.

B. DEFINITIONS

Non-Compliance: RNI that do not adhere to the following:

- IACUC approved protocol
- Regulation
- Institutional policy
- Veterinary directive
- Occupational Health and Safety
- Vivarium procedures
- Other administrative processes, including Post-Approval Monitoring (PAM) and inspection findings

Although the circumstances of non-compliance may be quite variable, the IACUC will differentiate these issues into two categories: **Serious and Minor**. Listed below are examples of the sorts of issues that can be included in each of these categories. These lists are provided as a general guideline to help investigators understand the process and are not intended to provide an exhaustive list of non-compliance issues. The significance of each case will be determined case by case, based on the particular facts and circumstances surrounding the issue. To this end, self-reporting and proactive corrections taken by the investigator will be considered by the IACUC when an issue of non-compliance is evaluated.

Serious Non-Compliance: Non-compliance that significantly and directly affects the care and use of animals, regulatory reporting, or impacts the University's accreditation status. Serious non-compliance may result in the cessation of research activity through suspension or termination of portions of a protocol or the entire protocol.

Examples may include, but are not limited to:

- Failure to provide post-procedural pain relief as required on an approved protocol.
- Performing a procedure in such a manner that animals endure distress, pain, or suffering that is not included in the approved protocol.
- Repeated incidents of minor issues of non-compliance.

Minor Non-Compliance

Examples may include, but are not limited to:

- Not submitting an amendment for the addition of personnel.
- Improper animal transportation.
- Minor protocol deviation not resulting in pain, distress, or suffering, such as site of injection, change in time frame, etc.

Continuing Non-Compliance: While IACUC regulations do not define continuing non-compliance, the IACUC may determine that a RNI determined to be non-compliance rises to the level of continuing in nature as defined as:

A pattern of behavior of non-compliance by the Investigator or their research team that indicates a lack of understanding about the regulations or requirements to protect the care and use of animals. The pattern of non-compliance is assessed by repeated incidents occurring during the course of a protocol(s), and whether the same non-compliance action was repeated or many different non-compliance events occurred and collectively indicate a significant concern. If allowed to continue, the non-compliance is likely to increase the harm to the welfare of animals, or to the University's requirements to maintain a sound regulatory and accredited program. Non-compliance that rises to either continuing may result in additional IACUC actions.

A [flowchart](#) outlines the process for review of an RNI.

C. RESPONSIBILITY

Upon receipt of a report of a RNI, the Animal Welfare Program (AWP) is responsible for triaging the request. The AWP ensures the reportable item request is sorted in a timely fashion to the IACUC leadership (Chair and Vice-Chair) and Attending Veterinarian (AV).

The AWP, under the direction of the IACUC, investigates non-compliance with federal or institutional regulations and requirements, or animal welfare issues. This includes concerns about any animal owned and/or used by the University of Arizona for research and teaching, regardless of the location of the animal.

The IACUC is responsible for making determinations and any required changes as a result of the RNI. All RNI are reported to the IACUC and potential non-compliance is brought to a meeting of a quorum of IACUC members

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. The Principal Investigator will be contacted as soon as possible, and the matter will be referred to the IACUC and Institutional Official for further investigation.

D. PROCEDURES

Investigations are conducted by the AWP under the direction of the IACUC. The Institutional Official, however, may convene an ad hoc investigative committee, with members chosen from University of Arizona staff and faculty or outside consultants based on the suitability of their expertise and background. These investigative committees are advisory to the IACUC.

AWP staff initially triage the request. The AWP leadership and Post-Approval Monitor (PAM) Manager, in consultation with the IACUC Chair/Vice-Chair and AV, gathers the necessary information to present a complete summary of the RNI to the IACUC. Immediate actions are considered to reduce any harm to the

animal(s) while the investigation is ongoing. This may include gathering detailed information from Investigator, the Veterinary staff, or other relevant parties. The IACUC or AV may require an in-person site visit or immediate need to stop activity.

At the next available convened meeting of the IACUC the RNI will be reviewed and discussed. A convened meeting of a quorum of the IACUC and with the vote of a majority of the quorum present is required to make a determination on the RNI. The IACUC will determine whether the RNI is in fact non-compliance after initial triage, and whether the RNI rises to the level of Serious or Minor non-compliance, the IACUC may vote to suspend or terminate individuals, certain parts of the protocol, or the entire protocol at their discretion. Additional corrective measures may also be required including added oversight, requiring the Principal Investigator to submit a Corrective and Preventive Action Plan (CAPA) that details how recurrence will be prevented, retraining, etc. The Principal Investigator may be asked to meet with the IACUC to address concerns about the RNI or in order to reinstate the protocol. Similarly, the IACUC may lift a suspension only after it has been determined that the protocol's activities can be accomplished in full compliance with the relevant rules and regulations and that adequate measures have been taken to prevent recurrence of the non-compliant activity.

Following the convened IACUC meeting, the determination of the IACUC will be reported to the investigator in writing.

A determination of the IACUC of serious or minor non-compliance, or suspension or termination of research activity, may not be overturned by any other body.

The AWP will complete the necessary internal documentation to reflect the outcome of the IACUC decision.

E. REPORTING

Results of all investigations are reported as applicable:

- **OLAW**
 - Any serious deviations from the provisions of the Guide
 - Any serious or continuing non-compliance with the PHS policy
 - Any suspension of activity by the IACUC

Prompt reporting:

OLAW should be notified promptly, without delay, through a preliminary report via a phone call as soon as possible. Then a thorough report should follow once the investigation is complete.

- **USDA**
 - Incidents that led to significant injury or illness, unrelieved pain or distress, or death of a regulated animal
 - Reported as part of USDA inspection process

- AAALAC – Reporting of significant adverse events is required to maintain accreditation.

In the AAALAC International Annual Report:

- Protocol violations which *had the potential* to compromise animal welfare
- Animal use not approved by the IACUC

Prompt reporting:

- Inadequate veterinary care
 - Conditions that resulted in unexpected animal harm or deaths
 - Inappropriate euthanasia techniques and/or failure to confirm euthanasia
 - Substantiated complaints or reports regarding animal welfare concerns
 - Internal or external reviews/inspections or other similar reports that document significant adverse events or non-compliance that resulted in animal harm or death; investigations by national oversight bodies; and other serious incidents or concerns that negatively impact animal well-being (e.g., failure to follow the approved protocol which resulted in compromised animal welfare; death during transport)
 - Significant humane health issue directly related to the animal care and use program
- Other funding agencies – Any suspension or termination of IACUC approval will be reported to the funding agency, if applicable, supporting the animal work.
 - Institutional leadership – All serious non-compliance and suspension or termination of animal work are reported to institutional leadership. Minor non-compliance may be reported to leadership to support the IACUC and Attending Veterinarian in any corrective action as applicable.

F. APPEAL PROCESS

A Principal Investigator may present new information to the IACUC for them to consider a reversal of any IACUC determination, including suspension or termination. New information must be relevant and directly applicable to the RNI and IACUC determination. The Investigator may be asked to present the material in writing or in person at an IACUC meeting. If presenting in person, the Investigator will be given a reasonable amount of time to present the information and then will be excused from the meeting so the IACUC may deliberate and vote. New information will be considered by the IACUC, but may not necessarily change the determination of the IACUC.

A determination of the IACUC does not prohibit an investigator from utilizing other processes at the University, such as the grievances process.

G. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- I-IC-GU-115 Reportable New Items
- Flowchart Reportable New Information
- Federal notice NOT-OD-05-034: Guidance on prompt reporting to OLAW under the PHS policy on human and use of laboratory animals