To ensure the humane care and treatment of animals used in research, teaching, and testing, the Institutional Animal Care and Use Committee (IACUC) must “...review and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees” (AWR§2.31(c)(4)). Such concerns may include incidents that involve actual or potential harm to animal health and well-being, including accidents, and protocol non-compliance.

In order to allow for timely resolution of reported concerns, the Institutional Official (IO) and IACUC Chair have designated a subcommittee of the IACUC, the Compliance Subcommittee (CSC), with the authority to investigate and implement corrective action, with the exception of protocol suspensions, on the behalf of the full committee. The CSC will meet as often as necessary to address reported incidents.

This policy discusses the following key topics:

- Responsibility
- Incident reports
- Investigation and IACUC review
- Suspensions
- Reporting to external agencies

**RESPONSIBILITY**

Any researcher, animal care staff, veterinary staff, IACUC member or OAW personnel who witnesses and/or suspects threats to animal welfare have occurred has the ethical responsibility to report this incident to the IACUC.

- Principal Investigators and research staff should self-report non-compliant activities that happen within their laboratory. This includes deviation from IACUC approved protocols, even if the situation does not result in a direct threat to animal welfare.
- ULAR staff should self-report serious lapses in programmatic practices (relevant ULAR SOPs) and animal health or welfare concerns in the facilities.
- IACUC members and OAW staff should self-report lapses in programmatic practices (IACUC and relevant OAW SOPs) that are counter to the regulations and guidance.

**INCIDENT REPORTS**

Identification of animal welfare concern
1. Direct and/or ongoing threats to animal health must be reported to the ULAR veterinarian immediately.
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2. Program personnel may intervene to provide immediate relief and/or remove the animal from the painful/distressful situation, based upon their skills or level of training, if necessary prior to arrival of the veterinarian. Personnel should not put themselves at risk of injury or other hazards.

3. For incidents that result in animal death or unexpected euthanasia, a post-mortem analysis may be necessary. Necropsy requests should be submitted to the ULAR veterinarian as soon as possible to ensure that tissues are still viable and allow for appropriate and complete analysis.

Notifying the IACUC of incident
1. Reports should be communicated as soon as possible by email, phone, or in person to the IACUC or the Office of Animal Welfare (OAW). All reports made directly to the IACUC or OAW are confidential. More information, including contact information, can be found in the Reporting Animal Welfare Concerns Policy.

2. Completely anonymous reports may be filed through the Office of Institutional Compliance by calling P-COMPLY from any University phone. Reports should be as detailed as possible to facilitate the resulting investigation.

3. Following a routine post-approval monitoring visit (PAM), animal welfare concerns or protocol non-compliance may be identified. The CL will notify the IACUC Chair, CSC Chair, and/or Director of Animal Welfare of these findings which may result in further investigation by the CSC. The CL will make every effort to identify which items may result in further investigation, and notify laboratory members during the exit briefing and the PI via email. Please see the PAM Policy for more information.

Receipt of incident report
1. The IACUC or OAW member receiving the incident report will attempt to gather all pertinent information from the reporting individual. At a minimum, the following information may be collected:
   a. Principal Investigator
   b. Protocol number
   c. Location of incident
   d. Species and number of animals involved
   e. Cage card numbers
   f. Personnel involved
   g. Date and time (if known) of incident
   h. Summary of incident
   i. Any adverse impact to animal health or well-being
   j. Immediate actions taken by the laboratory
   k. Whether the veterinary staff has been contacted, and if so, which veterinarian and any what veterinary care they provided
2. The receiving individual will then notify the IACUC Chair, CSC Chair, and/or Director of Animal Welfare who will determine how to proceed with the investigation. The ULAR veterinarian will be notified as necessary.

INVESTIGATION AND IACUC REVIEW

Initial investigation
1. An initial investigation will be conducted in order to gather as much information as possible. The investigation may be conducted by the CSC and/or CLs. The initial investigation may include, but is not limited to:
   a. Visiting the facility and/or laboratory
   b. Meeting with the PI and/or personnel involved in the incident
   c. Meeting with ULAR animal care and/or veterinary staff
   d. Review of protocols and animal use records
2. CLs may assist the PI and/or other responsible parties in the development of a resolution plan. The purpose of the resolution plan is to resolve the current issue of concern and ensure that repeat incidents do not occur. Note that upon IACUC review, additional actions may be requested. However, proactive resolution plans are indicative of good-faith efforts to ensure animal welfare and are strongly encouraged.
3. Notification to the PI and/or other responsible parties subject to the report will be made, in writing, as soon as possible. Notification may be delayed if necessary to facilitate the investigation.

Review of incident by CSC
1. Following the initial investigation, a verbal report will be provided to the CSC by the CL or CSC member, including:
   a. Summary of the incident, including the PI, species, and funding source
   b. Immediate actions taken to resolve the issue
   c. Proposed resolution plan
   d. Previous compliance history
2. The CSC will determine whether the initial investigation and proposed resolution plan is sufficient. Further action may be requested, e.g., submission of a protocol amendment, completion of (re)training, or temporary cessation of animal use activity until the issue is resolved. The CSC may request a meeting with the PI and/or responsible party to obtain more information.
3. The CSC will determine if the issue is an animal welfare concern. The CSC will take into account whether the issue caused actual or potential harm to the animal. Clinical histories and necropsy findings will be reviewed when available.
4. If the issue is deemed to be an animal welfare concern, the CSC will determine if the issue is reportable to external agencies. The CSC will use rational judgment in making this determination.
5. If at any time the CSC cannot come to a unanimous decision, the issue will be elevated to the full committee for further discussion.

**Review of incident by full committee**

1. Incidents will be included on the full committee agenda for discussion for the following reasons:
   a. The CSC has determined that an incident is reportable to an external agency based upon published guidance documents
   b. The CSC could not reach a unanimous decision on how to proceed with an incident report
   c. At the request of any IACUC member

**Notification to responsible party**

1. If it is determined that the incident is an animal welfare concern and/or reportable to outside agencies, the PI and/or responsible party will be notified of the decision in writing via a letter from the IACUC or CSC Chair. The letter will include a summary of the incident, citation of the relevant regulations, policies, or guidelines, and required action items.
   a. The ULAR veterinarian will receive a copy of any letter regarding animal welfare concerns
   b. The IO will receive a copy of any letter regarding reportable incidents
2. If it has been determined that the incident is not an animal welfare concern and/or not reportable to outside agencies, the PI and/or responsible party will be notified via email by the CL or CSC member. The email will include a summary of the discussion and any necessary action items.
3. If further information is requested, the CL or CSC member will communicate with the PI and/or responsible party via email.

**SUSPENSIONS**

The PI may voluntarily suspend performance of animal work, specific procedures, or specific individuals from performing animal work while the details of the events are being collected and reviewed, and corrective action plans are being completed.

Formal suspension of approved IACUC activity may occur only after the review of the matter at a convened meeting of a quorum of the IACUC, with a vote for suspension from a majority of the quorum present. The CSC cannot vote to suspend an approved protocol, but can recommend this action to the full committee.

1. At the time of suspension, the IACUC vote may include the terms of reactivation of the protocol depending upon the scope and severity of the issue. A protocol cannot be reactivated until all corrective actions have been completed.
2. The IACUC should decide at the time of suspension whether reactivation must be approved by the full committee or CSC.

3. The PI will be notified of the decision in writing via a letter from the IACUC or CSC Chair. The letter will include a summary of the incident, citation of the relevant regulations, required action items, and terms for reactivation of the protocol if they have been determined.
   a. The IO will receive a copy of any letter regarding suspensions.

REPORTING TO EXTERNAL AGENCIES (OLAW, AAALACi, USDA, and Funding Agencies)

Consultation with the IO
The IACUC or CSC Chair will promptly notify the IO of the IACUC’s decision to report an incident to an external agency.

Criteria for reporting to OLAW (NIH) or AAALACi
Incidents that involve animals under PHS-funded activity and/or that occur in accredited facilities (e.g., PSOM) may be reported to OLAW and/or AAALAC, respectively.

PHS Policy IV.F.3
“The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
   a. any serious or continuing noncompliance with this Policy;
   b. any serious deviation from the provisions of the Guide; or
   c. any suspension of an activity by the IACUC.”

OLAW NOT-OD-05-034 “Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals” will be used to identify situations that meet the above criteria.

Criteria for reporting to USDA-APHIS
IACUC suspension of activities involving USDA-covered species must be reported to USDA-APHIS, Animal Care, division in accordance with the Animal Welfare Act and Regulations. Self-suspension of personnel or activities by the PI during an investigation will not be reported to USDA-APHIS.

AWR§2.31(d)(7)
“If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any federal agency funding that activity.”
The animal program is also required to report to the USDA-APHIS, Animal Care division, any significant deficiency (a deficiency that may be a threat to the health and safety of animals) that is not corrected according to the plan and schedule for correction. This applies to any significant deficiencies identified by the USDA during a visit as well as any identified by the IACUC during semi-annual site visits. It is imperative to contact OAW prior to the due date for correction if the corrective action plan and date need to be modified, to allow for revision of the plan and date of correction and preventing a scenario that must be reported to the USDA-APHIS.

AWR§2.31(c)(3)
“Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity.”

Process for Reporting to Funding Agencies
NIH has published specific guidelines for use of funds supporting non-compliant activities that are reported to OLAW as determined by the above detailed criteria. Other funding agencies may include similar criteria within their terms and conditions for funding with Penn.

1. NOT-OD-10-081 Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals
2. NOT-OD-07-044 NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld

When non-compliance fits the Criteria for reporting to OLAW (NIH) or AAALACi, OAW will notify the Associate Vice President/Associate Vice Provost, Office of Research Services (ORS) of the details of the event. ORS will contact the PI and BA to review the terms and conditions for each funding source regarding reportability to the funding source, provide guidance in determining the amount of funds that have been charged (typically all animal costs associated with the non-compliance from the point of animal purchase or birth, if bred onsite, until euthanasia), and assist the PI and BA in coordinating communications with the NIH grant manager or appropriate party for non-NIH funded projects.

Potential outcomes of the discussion with the funding agency may include the following:

1. No grant funds would be required to be reimbursed or reallocated.
2. Grant funds may need to be reallocated to an internal account.
3. Grant funds may need to be reimbursed to the funding agency.