IACUC Procedure 001: Managing Noncompliance & Animal Welfare Concerns

Version 2.0, Approved: 11/08/23

1. **Purpose:** The purpose of this procedure is to outline the process for conducting an IACUC investigation of an animal welfare complaint, concern, protocol deviation, or unexpected adverse event. In addition, this procedure describes the requirements for reporting events to the applicable funding, accrediting, or regulatory agencies (where applicable).

2. **Scope:** The scope of this procedure applies to the investigation of concerns raised by staff or employees of Ohio University, individuals in the community, and members of the IACUC as well as the potential outcomes of an IACUC investigation. Concerns are received by a variety of reporting mechanisms: including phone, email, written, LEO Event or Deviation Report, in-person, or EthicsPoint

3. **Timeline for Reporting:**

- For animal welfare concerns or complaints, the individual may call or email The Office of Research Compliance or elect to use EthicsPoint to file an anonymous report, reports should be made within 24 hours of the incident.

- Protocol deviations should be reported to the IACUC via the Deviation Form as soon as discovered.

- All potential unexpected adverse events (UAEs) requiring immediate care for an animal and/or if the incident relates to husbandry or clinical care of animals must be promptly reported to the Attending Veterinarian or their designee. UAE's that encompass multiple areas and/or protocols due to facility events, the Animal Facility Director or Attending Veterinarian will report the event to the IACUC. All other events will be reported by the PI (or designee) via the Event Form, which should be completed and submitted to the IACUC within 24 hours of the event being observed or identified**.**

4. **Procedure:**

4.1. **Subcommittee Review:**

4.1.1. In the event that there is an urgent safety or welfare concern identified prior to the subcommittee review, then the Attending Veterinarian (AV) or designee will expeditiously assess the concern. The Attending Veterinarian has the authority delegated by the Institutional Official (IO) & the IACUC to assess the animal, treat the animal, remove it from the experiment, institute appropriate measures to relieve pain or distress, or perform euthanasia if necessary.

4.1.2. Office of Research Compliance (ORC) staff will consult with the Chair or Vice-Chair, the AV, and as necessary, the LAR Director or university counsel for the

subcommittee review. Any individual with a potential conflict of interest must recuse themselves from the subcommittee review.

4.1.3. The subcommittee will collect preliminary information. The following information (at minimum) should be obtained:

- **WHO**- the name(s) of the associated individual(s), title, role
- **WHAT**-
  - the animals involved
  - a description of the issue
  - associated process/activity
  - equipment/instruments used
- **WHEN**- the date(s) of occurrence
- **WHERE**- the location of the occurrence
- **WHY** (if known)
- **HOW** (if know)

4.1.4. The IACUC Chair will inform the Principal Investigator (PI) and Co-Investigator(s), as applicable, of an allegation of noncompliance or contacted for a response during the subcommittee review, depending on available information and the nature of the alleged noncompliance.

4.1.5. Once the subcommittee has determined that sufficient detail about the incident has been gathered, the subcommittee determines if the incident meets OLAW's criteria of a reportable situation (refer to Table 1. below).

Table 1. Reportable Situations [5]

a.	any serious* or continuing noncompliance* with this PHS Policy IV.F.3;
b.	any serious deviation* from the provisions of the Guide; or
c.	any suspension of an activity by the IACUC.

*For more information, please refer to Section 4. Definitions

4.1.6. In addition to OLAW's criteria of a reportable situation, the subcommittee will determine if incident meets any additional thresholds that warrant reporting to AAALAC International [11]. The following examples are intended to illustrate the types of scenarios to be promptly reported to AAALAC in addition to the Table 1 criteria above:

- Inadequate veterinary care
- Conditions that resulted in unexpected animal harm or deaths

- Accidents or errors
- Equipment failure
- Natural disaster
- Significant animal rights activities (e.g., protests, break-ins, property damage, FOIA and other public records requests that include AAALAC International documents)
- 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 noncompliance 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 human health issue directly related to the animal care and use program

4.1.7. For issues brought to the subcommittee that do not meet the reportable event criteria, the subcommittee will work with ORC staff to archive the documents/materials used to justify the determination The results of the subcommittee review will be reported to IACUC at the next convened meeting.

4.1.8. For issues brought to the subcommittee that do meet the reportable event criteria, the subcommittee will present the information collected to the full committee. See section 3.2

4.2. **Full Committee Review:**

4.2.1. The IACUC will initiate an investigation to determine the cause or the most probable cause of the incident [(2)]. Once the cause of the incident has been identified, the IACUC will use this determination to better inform the corrective action plan. The IACUC may use elect to:

- interview study personnel
- request to review protocol documents
- visit the site

4.2.2. The scope of the investigation may expand to other protocols (where applicable). For example, the IACUC may elect to review or inquire about other protocols involving a particular investigator, species, practice, or procedure. The purpose of

this step is to determine if the concern is an isolated occurrence or if additional action is needed to completely address the issue or eliminate the concern.

4.2.3. The IACUC may elect to work with the responsible party(ies) and process stakeholders to determine the corrective action plan, assign tasks, and determine the implementation timeline. The IACUC will use the elements in the Corrective Action Plan Template (Appendix IV).

- The IACUC may identify the need for both short-term and long-term corrective action. The IACUC is responsible for overseeing the completion of corrective actions and adherence to the implementation timeline.

- Corrective action(s) and or remediation may include, but are not limited to:

    - personnel training or retraining
    - implementation of a new policy or procedure
    - revising or clarifying an existing policy or procedure
    - enhanced IACUC oversight
    - study amendment
    - suspension of animal activities [6]
    - reporting noncompliance or adverse events to the applicable oversight and funding agencies (NIH-OLAW, USDA, etc..) AAALAC and/or funding agencies

4.2.4. Upon completion of the corrective action tasks, the IACUC will evaluate the corrective action plan and assess the effectiveness of the actions taken.

4.3. **Communications:**

4.3.1. The IACUC Chair will notify the PI(s) of the outcome of the IACUC investigation. The Institutional Official (IO), Investigator(s)' Dean, and/or the Department Chair (or equivalent) may also be informed, at the discretion of the IACUC Chair or Vice-Chair.

4.3.2. The IACUC Chair will work collaboratively with the IACUC, the IO, and the ORC to develop communications with regulatory agencies (if applicable). Written reports to regulatory agencies will be submitted through the IO. Refer to Appendices II & III below for the information needed for reporting.

4.4. **Appeals Process:**

4.4.1. The PI will have 14 days to appeal the IACUC decision. The appeal must be submitted in writing and must be signed and dated by the PI and sent to compliance@ohio.edu and carbon copy (CC) the IACUC Chair.

4.4.2. The appeal must state the reason or reasons for appeal and include any information that the PI would like the IACUC to consider. If an initial investigation was conducted, information that was reasonably available during the initial investigation and not submitted to the IACUC in the initial investigation will not be considered on appeal.

4.4.3. The appeal will be considered during the next convened IACUC meeting, and the PI may be invited to attend, or may request to speak. The PI will be notified within 5 business days of the final decision of the IACUC.

4.4.4. The sanctions imposed by the committee will remain in place until modified by a majority vote at a convened meeting.

5. Definitions:

- **Deviation-** any change, divergence, or departure from the study design or procedures defined in the protocol or associated attachments (i.e., experimental design, permits, etc..).
- **Ethics Point**- EthicsPoint is a comprehensive and anonymous telephone-based reporting tool that assists university faculty and staff in working together to address fraud, waste, and abuse of university resources while helping to cultivate a positive work environment.
- **LEO**- Ohio University's protocol submission software
- **Noncompliance** – the failure or refusal to comply with a regulation or to deviate from protocol procedures approved by the IACUC
- **Continuing Noncompliance**- Is typically defined as a situation that meets any of the following criteria:
    - The investigator(s) has committed the same or similar instance of non-compliance repeatedly after having been notified of this type of noncompliance by the IACUC
    - The investigator has failed to respond within a reasonable timeframe to a request from the IACUC to resolve an instance of noncompliance;
    - A pattern of frequent instances of documented noncompliance across one or more of an investigator's protocols
- **Serious Noncompliance-** cases where the noncompliance is a failure or refusal to comply with a regulation, the IACUC approved protocol, continuing noncompliance, and/ or conditions that jeopardize the health or well-being of animals. (refer to Appendix I below).

- **Unexpected Incidents/Outcomes**- An unexpected outcome is an unanticipated result of approved IACUC protocol activities that may or may not directly impact animal welfare.[10] Examples of reportable unexpected outcomes include, but are not limited to:
    - Animal morbidity or mortality rate inconsistent with or occurring at a higher frequency than the expected outcomes of the protocol activity (surgery, disease model, etc.) listed on the approved protocol.
    - Unanticipated life threatening or debilitating birth defects discovered after creating or breeding genetically modified animals.
- **Adverse Event-** unexpected incidents that lead to harm, or endanger the well-being of animals and humans at a research facility.[10]

6. References & Resources:

1) Institutional Animal Care and Use Committee Guidebook 2nd Edition (Pages 11 & 178)
2) Guide for the Care and Use of Laboratory Animals 8th Edition (Pages 23-24)- https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf
3) The Institutional Animal Care and Use Committee- https://olaw.nih.gov/resources/tutorial/iacuc.htm
4) Reporting Noncompliance- https://olaw.nih.gov/guidance/reporting-noncompliance.htm
5) Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals Notice Number: NOT-OD-05-034 - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html
6) PHS Policy- PHS Policy on Humane Care and Use of Laboratory Animals | OLAW (nih.gov)
7) The Code of Federal Regulations- 9 CFR, Part 2, Subpart C 2.32(c) (4)
8) Departures from the Guide- https://olaw.nih.gov/policies-laws/21st-century-cures-act/Departures
9) Administrative Non- Compliance- https://olaw.nih.gov/sites/default/files/laban51_05_0522.pdf
10) Adverse Events at Research Facilities- https://olaw.nih.gov/sites/default/files/laban46_06_0617.pdf
11) Managing and Reporting Adverse Events- https://www.aaalac.org/accreditation-program/faqs/#H2

7. Appendices:

- **Appendix I-** Examples of Reportable Situations [5]

- conduct of animal-related activities beyond the expiration date established by the IACUC;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- failure to maintain appropriate animal-related records (e.g., identification, medical, surgical, husbandry);
- conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC-approved protocols;
- failure to report unanticipated adverse events to IACUC or OCV;
- participation in animal-related activities by individuals who are not listed on the approved protocol and have not been determined by the IACUC to be appropriately qualified and trained;
- failure to monitor animals post-procedurally as necessary to ensure well-being;
- failure to ensure death of animals after euthanasia procedures;
- failure of animal care and use personnel to carry out veterinary treatments;
- IACUC suspension that results in the temporary or permanent interruption of an activity due to noncompliance;
- Conditions that jeopardize the health or well-being of animals.

- **Appendix II-** Investigation Preliminary Report Template [4]

Please include each of the items below:

- Name and contact information of person reporting
- Name of institution
- Assurance number
- Funding component and if contacted (for situations related to PHS-supported activities)
- Brief description of incident
    - ***(e.g., species, category of personnel involved, dates, times, animal deaths)***
- Plan and schedule for correction and prevention (if known)
- Timeframe for final report from the Institutional Official

- **Appendix III-** Investigation Final Report Template [4]

Please ensure that the final report contains each of the items below:

- Preliminary report
- Explanation of incident: Explain in detail what happened, when and where, the species of animals(s) involved, and the category (but not the names) of the individuals involved.
- Corrective actions
- Grant/contract number: Include the relevant grant or contract number (for situations related to PHS-supported activities).
- Impact on PHS-supported activities:
- Compliance with terms and conditions: If the incident involved PHS-supported activities and was not compliant with the terms and conditions of grant award, confirm that the situation was reported to the funding component and that all unauthorized costs initially paid from the grant have been removed and covered by other sources (see also NOT-OD-10-081). Or, certify that no unallowable costs were charged during the noncompliant period.

- **Appendix IV-** Corrective Action Plan Template [(4)]

The corrective action plan must include the following elements:

- A description of both short term and long-term corrective actions
- Clear assignment of corrective action tasks to a responsible party or individual
- A timeline for the completion of each task
- Once, the corrective action tasks are completed, the committee must review the plan and determine effectiveness

8. Change History:

Version Number:	Details of Change:	Approval Date:
1.0	New IACUC Procedure	04/13/2023
2.0	Removed "prohibiting the use of data collected during an approval lapse or process deviation." from the list of potential corrective actions/remediation.	11/08/2023