



## Procedure for Investigating Concerns Involving Animal Care and Use

### Overview/Purpose

This SOP describes the process for the reporting, investigating and review of allegations of mistreatment of animals or noncompliance of IACUC-approved activities.

### Definitions

Noncompliance is defined as the failure or refusal to comply with a regulation or to deviate from protocol procedures approved by the IACUC.

### Handling Allegations and Findings of Noncompliance

All allegations of noncompliance or mistreatment of animals will be forwarded to the Office of Responsible Research Practices (ORRP). ORRP will process all allegations and findings of noncompliance, whether these reports arise internally (e.g., from Ohio State faculty, staff, ORRP, the IACUC, or investigator self-reports) or from outside the University (e.g. regulators, anonymous reports). The procedures for handling these allegations will be as follows:

### Initial Inquiry

1. ORRP staff will consult with the Chair or Vice-Chair of the IACUC and University Attending Veterinarian (AV) and, as necessary, University counsel on all allegations or findings of noncompliance. Any individual with a potential conflict of interest may not participate in the inquiry. Additional information will be gathered as needed by ORRP staff in order to help determine next steps.
2. The Principal Investigator (PI) and Co-Investigator(s), as applicable, will be informed of an allegation of noncompliance or contacted for a response during the initial inquiry, depending on available information and the nature of the alleged noncompliance. If the Investigator(s) is contacted for a response during the initial inquiry, a written response will be requested by a specified date.
3. The IACUC Chair and AV will determine the options to be taken based on information provided and include:
  - Dismissal of the allegation (i.e., unsubstantiated)
  - Referral to other appropriate University process (e.g., misconduct review)
  - No further action required
  - Corrective action(s) recommended
  - Review by convened IACUC required
  - Further investigation required by the Compliance Subcommittee
4. When further investigation or convened IACUC review is not warranted (e.g., dismissal of the allegation or referred to other University process), the incident will be considered resolved. The IACUC will be informed of all allegations and outcomes of the inquiry at the next convened meeting and information will be provided in a spreadsheet maintained by ORRP.

5. All reasonable efforts will be made to notify the investigator(s) of the outcome of the inquiry in writing within 14 days of being considered resolved. 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. Notification will be sent to the person(s) originating the report of noncompliance within 30 days, as applicable.
6. All reasonable efforts will be made to complete initial inquiries within 30 days of receipt of the allegation or the finding of noncompliance. The entire IACUC will be informed of all allegations of non-compliance.

### **Investigation and Compliance Subcommittee**

1. The Compliance Subcommittee of the IACUC will investigate allegations or reports of noncompliance at the discretion of the IACUC Chair and AV. Any individual with a potential conflict of interest may not participate in the investigation. Additional members may be appointed to deal with specific cases. These additional members may consist of IACUC members with expertise appropriate for review of the alleged noncompliance, clinical veterinarians, ORRP staff or others with expertise relative to the situation. The subcommittee will be facilitated by ORRP staff and advised by University counsel, as needed. The Compliance Subcommittee will meet as necessary to ensure timely review of pending allegations.
2. The investigation by the Compliance Subcommittee may include interviews with or requests for written responses from witnesses of noncompliance and/or the PI whose personnel have been observed in noncompliance. Audits of research records or medical records may be done.
3. In all cases, the PI will have the opportunity to respond to the allegations. Unless circumstances require additional time, a written response or meeting with the investigator and lab staff will be requested within 14 days of notification, to facilitate review and conclusion of the investigation.
4. The Compliance Subcommittee will consider materials and recommendation from the initial inquiry, the Investigator(s)' response, and other information relevant to the investigation (e.g., interviews, audit reports, literature searches, etc.). A summary report that includes the allegation, information considered by the Compliance Subcommittee, and its conclusions and recommendations will be prepared for the IACUC for discussion at the next convened IACUC meeting.

### **Convened IACUC Review**

1. Information regarding all allegations of noncompliance will be presented to the committee at the next convened meeting. Information from the initial inquiry or summary report from the Compliance Subcommittee, the Investigator(s)' response (if any), and any other relevant materials (e.g., research protocol, medical or facility records, occurrence of previous noncompliance, etc.) will be distributed to all members in advance of the meeting.
2. IACUC will review the information provided and determine if additional information is required or if the incident requires corrective actions. The IACUC will also determine if the noncompliance is considered serious and/or continuing as defined by OLAW in their policy on non-compliance (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>). Corrective action(s) will be based on the nature of the noncompliance, extent to which animals were placed at risk, occurrence of previous noncompliance, etc. The range of possible corrective actions that the Chair, Vice-Chair, Compliance Subcommittee, or IACUC may consider includes, but is not limited to:
  - Modification(s) of the animal use protocol through amendments initiated by the PI
  - Monitoring of animal use activity (including audits or assessments of technical abilities)
  - Education or training for the Principal Investigator and/or research staff
  - Confirmation of receipt of required materials (e.g., drugs or equipment)
  - Additional reporting (e.g., more frequent review)

- Limitations on research activities, use of research facilities, or use of research data
  - Restriction of PI involved to co-investigator status
  - Suspension or termination of IACUC approval for one or more of the Investigator(s)' protocols
  - Suspension of personnel from working with animals
3. All reasonable efforts will be made to notify the Investigator(s) in writing within 5 business days of the decision of the IACUC. Notification will also be sent to the person(s) originating the report of noncompliance, as applicable.
  4. The PI will have 14 days to appeal the IACUC decision in writing. The appeal will be considered during the next scheduled IACUC meeting, and the PI may be invited to attend, or may request to speak. The investigator(s) will be notified within 5 business days of the FINAL decision of the IACUC. Written notice of process and findings will be sent to the person who submitted the original complaint within 30 days.
  5. When approval of animal use activities is suspended, the reason(s) will be communicated to the investigator(s) and their department heads, along with any corrective actions required to ensure future compliance with the regulations. Other University committees, such as Institutional Biosafety or Radiation Safety committees, responsible for oversight of the investigator(s)' research will also be notified, if applicable.
  6. If not previously reported to regulatory agencies, any suspension or termination of IACUC approval or noncompliance that is determined to be serious or continuing will be verbally reported by ORRP followed by a written report from the IO if required.
  7. The convened IACUC or designee (e.g., Chair or Vice-Chair of the IACUC), will review the Investigator(s)' response to corrective actions. If the PI and Co-Investigator(s), as applicable, do not comply with the required corrective action(s) within the time specified in the corrective action plan, additional action(s) may be taken, including suspension of IACUC approval(s) for ongoing animal use activities. The Investigator(s) and the convened IACUC will be notified of resolution of corrective actions or the need for additional action(s). Consideration for reinstatement of approval for activities will be based on whether there are remaining concerns about:
    - Potential pain or distress to animals
    - Investigator or research staff noncompliance
    - Other issues that were related to or resulted in suspension (e.g., drug availability or facility issues)
  8. ORRP will prepare drafts of any letters to investigators or regulatory agencies. Letters to investigators will be signed by the IACUC Chair. Written reports to regulatory agencies will be submitted through the IO.

## History of Revisions

**302-00** - new SOP 05/16/14

**302-01** – minor revisions in wording and changes in definitions, approved 05/19/2017