

## IACUC Policy for Handling Issues of Non-compliance

### Introduction:

The IACUC must review and address any animal-related concerns raised by the public or institutional employees, in a timely manner and when necessary take prompt appropriate corrective actions. This mandate is required by PHS Policy, the Guide, and Animal Welfare Act. No employee, committee member, or lab personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation.

### Procedure:

1. Non-compliance is reported.
2. IACUC administrator is notified by the recipient of the report.
3. IACUC administrator notifies IACUC Chair (or the Associate Chair in the absence of the Chair).
4. IACUC Chair convenes a meeting of a quorum of the IACUC to perform an evaluation and merit of complaint.
5. Best efforts are made to hold a meeting with a quorum of the IACUC committee within 5 business days of report.
6. The committee should determine if the complaint requires A) further investigation and immediate action, B) further investigation but no immediate action or C) no action.
  - a. Examples of major infractions include pain and harm caused to experimental animals, repeat offenses, altering anesthetics/analgesics/surgical procedures without approval. Minor infractions include delay/failure to submit reports, use of expired chemicals, minor alterations in protocol (those that do not cause pain/suffering/death) without approval.
7. When an issue of noncompliance is reported, a representative of the LAF or IACUC will notify the responsible PI that an issue of noncompliance is under investigation as soon as is possible. In cases where the director of the LAF and/or chair of the IACUC determine that informing the PI about a report of noncompliance may result in reprisal (i.e., a whistle blower scenario) informing the PI can be delayed at their discretion until deemed appropriate.
8. Once this decision is made the IACUC should determine which individuals or other UB offices may require notification. Depending on the nature of the concern, the IO, legal counsel, and the person who submitted the complaint maybe invited to participate.
9. A preliminary report is filed with OLAW indicating an ongoing investigation.
10. If animals are reported to be in immediate, actual or perceived jeopardy, the veterinarian is authorized to halt procedures until the IACUC can be convened, and provide medical intervention. If human welfare is (or maybe) compromised, the IACUC should notify appropriate safety, occupational health, or law enforcement officials.
11. Should the IACUC determine that further investigation is required, the Chair, (or subcommittee appointed by the Chair) should conduct an investigation and report back to the IACUC of the findings. This committee is required to gather information and be given a specified completion date.

12. Information that can be gathered includes: interviewing the complainant, interviewing the person(s) who the allegations are directed, and pertinent UB officials. Can also include observing the animals and their environment, and reviewing records.
  - a. Composing a letter to the PI whose protocol is in question, indicating the initial finding and requesting an explanation.
  - b. The PI is expected to respond within 5 business days
13. A report from the subcommittee to the IACUC should include: the concern, the interview results, the condition of the animals, the results of the record/documents reviewed, conclusions regarding the substance of the concerns in relation to the Guide, PHS Policy, and AWA, and UB Policies, and recommended actions.
14. The report is discussed at the convened IACUC meeting with a quorum. Upon receipt of the report, the IACUC may request further investigation or reports, or find that: there was no evidence to support the claim, the complaint was not sustained (but related aspects of the animal care and use program requires further review), or the concern was valid.
15. The committee decides on general direction of action. This could involve all or some of the actions below:
  - a. No further action.
  - b. Suspension of PI's privileges to continue animal research.
  - c. Suspension of the protocol or a specific procedure for a definite or indefinite period.
  - d. A probationary period (6 months or longer) during which IACUC may arrange for unannounced visits to PI's laboratory or require supervision during performance of procedures.
  - e. Re-training of the PI and his /her personnel. These could include completing on-line course work (UB IACUC and/or CITI) and attending LAF animal handling/surgery etc. training.
  - f. Request for a plan detailing how the PI will prevent re-occurrence of the specific non-compliance issue.
16. Suspensions must be reviewed with the IO and appropriate corrective action taken is reported to OLAW, USAD (APHIS), and any Federal agency funding the activity, and the Chair of the PI's Department.
17. The PI is notified in writing of the final determination and remediation required.