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**INSTITUTE CONFIDENTIAL**

**REPORTING, RECEIVING AND HANDLING CONCERNS OF MISTREATMENT OR OTHER NONCOMPLIANCE ISSUES**

**1. Purpose**

The purpose of this policy is to define and provide guidelines for reporting allegations of mistreatment of animals, violation of Institute animal use policies, serious deviations from the Guide for the Care and Use of Laboratory Animals, and noncompliance with federal regulations regarding humane care and use of laboratory animals.

**2. General Information**

Definitions:

- a. **Mistreatment:** Any action, physical or psychological, which results in wrongful or abusive treatment of an animal (e.g., inadequate or improper care or housing of animals).
- b. **Noncompliance:** Violation of Institute procedures or policies, which encompass those of the Public Health Service and the Animal Welfare Act. Examples include unauthorized use of animals for any activity or procedure; failure to have an active IACUC approval for an activity involving animals; continuing an activity past its authorized expiration date, and unauthorized personnel performing procedures on an approved IACUC protocol.
- c. **Subcommittee:** A subcommittee may be formed by the IACUC Chair. The Chair may request that the subcommittee investigate the concern or allegation and report back to the IACUC. The subcommittee may also ask the Principal Investigator (PI) to formulate a corrective action plan. The subcommittee may be asked to make a recommendation to the IACUC.

Reporting concerns or allegations:

It is not always obvious at what level of alleged mistreatment or noncompliance the IACUC should become involved. Frequently the attending veterinarian, animal care personnel and investigators can work together to prevent or resolve a problem. However, serious or repeated problems always require the involvement of the IACUC. The IACUC then must determine whether a report to National Institutes of Health, Office for Laboratory Animal Welfare (OLAW) should be made. If in doubt it is better to submit a report to OLAW, as this may well protect the animals, Institute, the complainant, and the alleged violator(s).

**3. Reporting Procedures:**

Concerns or allegations may be reported verbally (in person or by phone), or by correspondence (letter, fax, e-mail) to any member of the IACUC, the veterinary staff, the Director for Research Compliance, who is the Institutional Official (IO), the Audit Services and Institute Compliance Office, the Human Resources Office, or the Caltech Hotline (see item #6 below). Anyone can report a concern or allegation. Individuals with an animal welfare concern are encouraged to report their concern. This includes researchers, veterinary staff, and IACUC members. Reports may be made anonymously. There will be no threat of reprisals against anyone reporting a perceived mistreatment or noncompliance in good faith, in accordance with the Institute's Whistleblower Policy ([https://hr.caltech.edu/documents/50-citpolicy\\_whistleblower.pdf](https://hr.caltech.edu/documents/50-citpolicy_whistleblower.pdf)).

Any information reported to an IACUC member or the personnel listed above will be promptly relayed to the Chair. All concerns or allegations brought to the attention of the IACUC will be fully documented. A concern or allegation has no substance until proven, and should remain confidential to the extent possible to protect all concerned. If the person raising the concern or allegation has freely identified him/herself, it is appropriate that receipt of the concern or allegation be acknowledged. All animal welfare issues will be immediately addressed. An assessment of the concern or allegation will be made by the IACUC Chair, Research Compliance Officer and a member of the veterinary staff, to determine whether an investigation is warranted. If the concern has sufficient basis, an investigation will proceed.

**4. IACUC Procedures for the Investigation of Concerns or Allegations:**

The Chair may elect to bring the matter as a whole before the IACUC or may appoint a subcommittee to investigate the concern or allegation. The person(s) against whom the concern or allegation has been raised should have an opportunity to respond to the concern or allegation. Necessary documentation will be collected. This may include animal receiving records, housing and health records, billings, protocols, memos and other written materials. It may also be necessary to conduct interviews or to carry out an inspection of the facilities.

The IACUC will consider myriad factors (see attached) in determining whether the concern or allegations is merited, and if so, whether it is reportable to OLAW. The IACUC will also create or approve a definitive corrective plan and schedule.

In the case of reportable events, the IACUC may consider the funding source and whether the sponsor requires reporting.

The results of the investigation and any recommended corrective actions will be presented at the next IACUC meeting. The results of the investigation, and IACUC determination, will be communicated to the IO, who has responsibility for reporting to OLAW when there is a reportable event.

## 5. Institutional Responses:

- a. The Institute's response is governed by the nature of the investigative findings, institutional policy, and legal requirements. If the concern or allegation is verified by the IACUC, the IACUC is empowered to suspend a previously-approved project in accordance with USDA Regulations and PHS Policy. If the activity is supported by PHS funds, the IACUC through the IO must file a full report to OLAW. In cases where there is sufficient evidence of serious noncompliance, it may be prudent for the IACUC to suspend an activity pending the outcome of a full investigation. In these cases, a preliminary report will be provided to OLAW and the USDA (as applicable), through the IO or OLAR Director, on the understanding that a full report will be submitted at a later date.
- b. The IO, in consultation with the IACUC, has the power to impose further sanctions on anyone found to be responsible for mistreatment or noncompliance. Each case will be considered individually when determining the appropriate sanction.

## 6. Complaints may be brought to the attention of the following:

Name	Title / Position	Phone	Mail Code	E-mail
IACUC	Research Compliance Office	395-8448	02-31	<a href="mailto:iacuc@caltech.edu">iacuc@caltech.edu</a>
Caltech Hotline		(626) 395-8787 Toll free (888) 395-8787		<a href="https://hotline.caltech.edu/contact">hotline.caltech.edu/contact</a> (anonymous online form ) <a href="mailto:caltechhotline@caltech.edu">caltechhotline@caltech.edu</a>

To disclose information to an IACUC Member directly, please follow this link to the IACUC Website:

<https://iacuc.caltech.edu/members>

### Factors to Consider Regarding Concerns or Allegations

The IACUC will consider myriad factors in determining whether the concern or allegation is merited, and if so whether it should be reported to OLAW. These factors include, but are not limited to:

- the health and welfare of the affected animals, such as whether:
  - the event jeopardized the health or well-being of the animal
  - the event resulted in pain, distress, or death of an animal
  - animals were not monitored post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures)
  - recovery from a euthanasia procedure occurred
  - veterinary instructions (e.g., treatments) were not carried out
- the researcher's intent, such as:
  - the event was intentional
  - the event was due to carelessness.
  - the research was in accordance with an IACUC-approved protocol
- whether the event is part of a pattern, such as:
  - the event was recurring, either in a particular lab, or by a particular individual
- whether there are any mitigating factors, such as:
  - the individual(s) involved were appropriately qualified and trained, as determined by the IACUC
  - the individual had a reasonable explanation or other response.