

SOP# 105.1	TITLE: Mistreatment or Non-Compliance	Date Effective: 9/20/19 Last Revision Date: 3/26/24
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## I. Purpose

This procedure sets forth the definition of non-compliance and the IACUC process for assessing non-compliance and issuing corrective actions. Please note: for incidents involving adverse events, please see SOP # 106.1.

## II. Definitions

action is needed, further inquiry is necessary, or the issue should be presented to the convened IACUC.

3. If the allegation is determined not to involve non-compliance, no further action will be taken.
4. If the allegation is substantiated but only involves minor or administrative issues, the research compliance office will contact the investigator to resolve the concern. The ORA Director and research compliance office will notify the IACUC chair of the report. They may decide that no additional action is needed, further inquiry is necessary, or the issue should be presented to the convened IACUC.
5. If the allegation is substantiated and may involve serious or continuing non-compliance the IACUC chair will be notified, and an inquiry may proceed. If the allegation involves an increased risk of or actual harm to the welfare of the animal, then the Attending Veterinarian will be consulted, and the chair may immediately suspend the project until the inquiry is complete (as in SOP 104.1 - Suspension and Termination).
6. At the completion of the assessment, and when it is appropriate, the research compliance office will communicate the IACUC chair's decision to the complainant through the complainant's chosen mode of communication.

#### Inquiry into Non-Compliance

1. The ORA Director, research compliance office, and IACUC chair determine that an inquiry is necessary based on the nature and seriousness of the complaint.
2. An inquiry may also be initiated by the IACUC chair in response to reports by investigators in situations where multiple reports involving immediate risks to animals have been submitted to the IACUC, or at the Chair's discretion.
3. The IACUC Chair notifies the Principal Investigator of the inquiry in writing and conveys the nature of the complaint.
4. The IACUC chair designates a sub-committee of at least three individuals, consisting of the Research Compliance Officer, IACUC members, and non-members as appropriate to constitute the appropriate expertise to assess the complaint.
5. The sub-committee may take any of the following actions during the course of the inquiry:
  - a. Review protocol(s) specific to the complaint.
  - b. Review any sponsor audits, if available.
  - c. Review relevant study records and documents.
  - d. Conduct facility inspections.
  - e. Conduct interviews with research personnel.
6. If the PI requests or is requested to be present at a sub-committee meeting to be interviewed about the alleged non-compliance, they may be accompanied by a faculty representative, legal counsel, or another member of their department. The role of the individual is to provide support to the PI, they may not engage in the discussion.

8. The results of the inquiry are reviewed at a convened IACUC meeting where all IACUC members will have access to relevant protocol documents and the inquiry report. The sub-committee may provide a report at the convened meeting.
9. If the inquiry suspects research misconduct, the findings are shared with the Research Integrity Officer and further investigation will follow University Policy #56: Ethics in Research.
10. If the inquiry substantiates a finding of serious and/or continuing non-compliance, the IACUC votes to