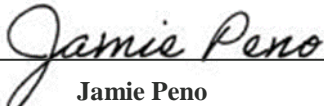
 <div> <div>DIVISION OF RESEARCH & INNOVATION</div> <div>Research Integrity & Compliance</div> </div>		Institutional Animal Care and Use Committee Standard Operating Procedures	
<p align="center">Title: Reporting and Investigating Noncompliance of Care and Use of Animals</p>			
Effective Date:	December 22, 2020	Document Number:	IACUC-SOP-01- 16.00
Approval/Date: <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <hr style="width: 100%;"/> Jamie Peno Director, Research Integrity and Compliance </div> <div style="text-align: center;"> <hr style="width: 100%;"/> 12/22/2020 Date </div> </div>			
REVISION HISTORY			
Date	Section	Author	

PURPOSE

The University of North Texas Institutional Animal Care and Use Committee has been tasked with the primary responsibility to ensure the humane care and use of animals in research at UNT. Complaints concerning the welfare, mistreatment, or misuse of research animals and/ or non-compliance with regulations are taken seriously and should be reported immediately to the UNT IACUC.

SCOPE

Reports of Non-compliance may be reported by anyone to the appropriate units described in this SOP and will be promptly investigated at UNT.

It is the responsibility of the Principle Investigator and their research staff to fully comply with any investigation processes and to conform to any immediate actions requested by the committee.

DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton

IACUC- Institutional Animal Care and Use Committee

SOP/SOP's- Standard Operating Procedure(s)

IO- Institutional Official

PI- Principal Investigator

OLAW- Office of Laboratory Animal Welfare

PROCEDURES

I. Non-compliance Reporting

- A.** All steps possible will be taken to keep complainants anonymous by request. Complainants will not be discriminated against or be subject to any reprisal for reporting concerns.
- B.** All reports will be referred to the IACUC for review and, if warranted, investigation to determine the appropriate corrective action.
- C.** Documentation will be kept on all reports and investigations by the IACUC Administrative Office
- D.** Examples of reportable situations include, but are not limited to the following:
 - 1. Conditions that jeopardize the health or well-being of animals
 - 2. Conduct of animal-related activities without appropriate IACUC review and approval
 - 3. Failure to adhere to IACUC approved protocols
 - 4. Implementation of any significant change to IACUC approved protocols prior to modification or amendment approval
 - 5. Conduct of animal-related activities beyond the expiration date
 - 6. Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained
 - 7. Failure to monitor animals post-operatively as necessary to ensure well-being during recuperation
 - 8. Failure to maintain appropriate animal-related records
 - 9. Failure to ensure death of animals after euthanasia

II. Methods of Reporting a Formal Complaint

- A.** Complaints may be made either verbally or in writing to any of the following (current contact information is provided on the [UNT IACUC website](#)):
 - 1. UNT Attending Veterinarian
 - 2. UNT IACUC Chairperson
 - 3. UNT Research Integrity and Compliance personnel
 - 4. UNT Trust Line (University Compliance and Ethics)
- B.** Complainants should provide as much detailed information as possible, including the following:
 - 1. Complainants name and a method of contact
 - 2. Individual or Unit the complaint is against
 - 3. Description of events with dates of observation and the alleged events
 - 4. Copies of any documentation or evidence that may substantiate the events
 - 5. Names of any voluntary witnesses

III. Processing of a Formal Complaint

- A.** Upon the receipt of a formal complaint, all documentation will be forwarded to the IACUC Administrator and retained in the Office of Research Integrity and Compliance.
- B.** At any time in the investigational process the study or studies involved may be placed on an Administrative Hold if warranted.
 - 1. The PI should be informed of this hold in writing via a memo from the IACUC Chair.
- C.** The Formal Complaint will be presented at the next IACUC meeting, emergency meetings may be scheduled as deemed necessary.
- D.** Should the committee decide that the evidence warrants a formal investigation, a sub-committee, or inquiry team may be formed as necessary.
 - 1. Investigations of studies involving PHS funding must be reported to OLAW promptly by Research Integrity and Compliance personnel via phone or email.
 - a) Must provide, at a minimum, the UNT Assurance number, species involved, title of study or studies involved, name of Principle Investigator(s).

- b) Updates should be provided as requested at time of reporting.
 - c) A final Report must be provided to OLAW outlining the process, findings, and corrective actions at the conclusion of the inquiry.
- 2. The subcommittee or investigation team will perform the investigation and will document all correspondence and findings in a report or memo to be submitted to the full committee and Institutional Official.
- 3. Investigations may be performed before and/or after notification has been given to the associated PI and methods may include, but are not limited to:
 - a) Laboratory Inspections
 - b) Personnel Interviews
 - c) Review of lab, animal, and study records and procedures.
- E.** Upon determination of non-compliance
 - 1. All parties will be informed of the investigation at this time by the IACUC Administrator.
 - 2. The PI and/or personnel investigated should be given an opportunity to respond to allegations.
 - 3. The appropriate course of corrective actions will be discussed and decided on by the Full Committee
 - 4. The decisions will be sent in writing to the Institutional Official via the IACUC Chair
 - 5. A letter of reprimand from the IO will be sent to the parties involved, delineating the corrective actions required. Examples of possible corrective actions include but are not limited to:
 - a) Requiring an amendment be submitted the IACUC to approve of changes needed to the protocol
 - b) Requiring that current lab procedures be revised
 - c) Requiring a study to be re-evaluated by the IACUC
 - d) Suspension of research activities
 - e) Sanctions to the Principle Investigator responsible for the conduct of the study
 - f) Requiring more frequent Post Approval Monitoring to take place for a study of facility (See IACUC Procedure 01.15 Post Approval Monitoring Methods)
- F.** Upon determination a complaint is insufficiently substantiated
 - 1. A letter will be sent to applicable parties stating the investigation has concluded and there will be no further course of action at this time.
 - 2. A Final Report will be created documenting the process, findings, and actions taken.

IV. Informal Complaints

- A.** Individuals who have serious concerns without first-hand knowledge are still encouraged to notify the above. These concerns will be followed up on by IACUC personnel via review of protocols and procedures, discussions with PI's and lab personnel, and/ or unannounced laboratory inspections.
- B.** This process may lead to a Formal Complaint and will then follow the process stated above.

REFERENCES

- 1. <https://research.unt.edu/research-services/research-integrity-and-compliance/animal-subjects-iacuc/reporting-animal-welfare-concerns>
- 2. IACUC Procedure 01.15 Post Approval Monitoring Methods

APENDICES

IACUC Standard Operating Procedures