

Institutional Animal Care and Use Committee		UNTHSC
Title: Reporting and Investigation of Concerns Involving the Care and Use of Animals		
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A. BACKGROUND INFORMATION

- a. This procedure outlines the steps which will be followed to handle complaints concerning mistreatment of animals and noncompliance with applicable polices, including, but not limited to UNTHSC IACUC policies and federal and state laws and regulations. Any person may file a complaint about the treatment and conditions of animals at UNTHSC. Complaints shall be taken seriously and reviewed in accordance with this policy.

B. RESPONSIBILITIES

- a. It is the responsibility of faculty, staff and students to report to the IACUC any concerns of animal care and welfare or non-compliance.
- b. It is the responsibility of the IACUC to investigate reports of animal abuse, animal welfare concerns or non-compliance according to this procedure.

C. PROCEDURES

- a. The IACUC will review and/or investigate any concern relating to animal care and use brought to the attention of the Committee. This includes claims by the public concerning any aspect of the animal care and use program or by employees or students who report alleged instances of animal abuse, violation of approved protocols, use of animals not covered by approved protocols, violation of any animal-related regulation or standard (such as the Animal Welfare Act, PHS Policy, AAALAC accreditation standards, or IACUC policy), or complaints regarding the care received by animals housed in University laboratory animal, wild animal or agricultural facilities.
- b. STEPS IN PROCESS
 - i. Concerns should first be addressed to the individual(s) or unit at whom/which the complaint is directed. If the concern is not adequately addressed, the individual has the option to take the concern to the next level.
 - ii. The concerned individual(s) begins the process of filing a Formal Complaint by contacting one the following:
 - 1. Director, Department of Laboratory Animal Medicine at 817-735-2017
 - 2. A member of the IACUC (found on the Committees website or call the IACUC Administrator Office at 817-735-2533).
 - 3. The Ethics-line: 1-877-606-9187
 - 4. UNTHSC Campus Police at 817-735-2210
 - iii. The following information is to be provided for any concern:
 - 1. The complainant’s name (voluntary)
 - 2. The individual(s) or unit the complaint is against

3. Description of the event or charge including the dates of observation of the alleged Violation(s)
 4. Copies of any written, photographic, or taped documentation to substantiate the charges
 5. Names of any other witnesses to the events/charges being described or made (voluntary)
 6. Signature of the Complainant (voluntary)
- iv. The Director, IACUC Chair, or IACUC member will assist the complainant in completing the written description and will submit the Complaint on to the IACUC Administrator.
 - v. Complainants must be the actual individual(s) who have witnessed the violation.
 - vi. While hearsay complaints cannot be formally filed, individuals who have serious concerns based on hearsay evidence can call any of the individuals listed under (2) The Director of DLAM or an IACUC representative will follow up on concerns by means other than the formal complaint process (such as review of protocols, discussions with other employees, or unannounced laboratory inspections). This process may lead to the filing of a Formal Complaint.

c. IACUC REVIEW OF COMPLAINT

- i. The Formal Complaint will be presented to the next regularly scheduled meeting following receipt by the IACUC Office. An emergency meeting may be called if appropriate. The Sub-committee will review the complaint and talk with Director or IACUC member who has brought the complaint forward. If evidence warrants a formal investigation, the sub-committee members will so recommend by a majority vote of those present. The Sub-committee and Administrator will:
 1. The IACUC Administrator shall document the review findings of the Sub-committee and schedule a meeting of the full Committee at the earliest possible date.
 2. Inform the Complainant, if known, that the IACUC will be performing and investigation of the Complaint.
- ii. Should the Sub-committee, following the review of the complaint, find that the complaint is insufficiently substantiated, the Subcommittee will:
 1. Document the review findings of the Sub-committee.
 2. Provide a confidential written response to the Complainant, if known, explaining the findings of the Sub-committee.
 3. The IACUC Administrator shall place the Complaint Form, sub-committee's report, and all correspondence into a separate IACUC file for formal complaints, by year.
 4. Provide an opportunity for all IACUC members to review the Complaint and Sub-committee report to provide a minority view, should they so desire.
- iii. At the discretion of the Sub-Committee, inform the Pertinent Individual (principle investigator, Facility director, etc.), in writing that a complaint was made. The investigator will then receive a summary of the concerns without

reference to the individual(s) name(s) who filed the complaint and a copy of the Sub-committee's Report.

d. IACUC INVESTIGATION OF ALLEDGED VIOLATIONS

- i. When the Sub-Committee has voted to initiate an investigation, the IACUC Administrator will Schedule a meeting of the full committee at the earliest possible date.
- ii. The Committee as a whole will review the documentation and determine a course of action, which may include assignment of the investigation to a sub-committee or individual.
- iii. The Chair will notify the Institutional Official of the initiation of the Investigation.
- iv. The Chair will notify the Principal Investigator, animal facility administrator, or other Pertinent Individual (known hereafter as the PIND) of the IACUC's intention to carry out the investigation. This notification will include:
 1. Citation of the section of the federal regulations which allow for investigations of concerns related to animal care and use.
 2. Description of the complaint and the sub-committee's review report.
 3. An invitation to meet with the IACUC, IACUC Chair or sub-committee to personally discuss the allegations.
- v. The IACUC may use a variety of methods to obtain information to assist the investigation. These will include, but are not limited to the following:
 1. Unannounced visits to the laboratory or animal facility in question to review procedures, lab/facility documents, or talk with personnel prior to formal notification of the PIND.
 2. Submission of documentation from the PIND, co-workers or employees, or from the animal facility where animals were housed. Such documentation could include: research records relating to animal experimentation, surgical records, animal health records, purchase orders, standard operating procedures, diagnostic laboratory reports, quality assurance reports, or others which will provide information which will assist in the investigation.
 3. Documentation supporting the allegations provided by the Complainant.
 4. The PIND will be invited to provide a written response to the Complainant and any additional documentation provided by the Complainant. (Names, addresses, or other information which could result in breach of the Complainant's confidentiality will be deleted from materials provided to the PIND).
 5. Review of Animal Care and Use Protocols, IACUC inspection reports, Reports of Programmatic Reviews, USDA, or AAALAC inspection reports, or any other pertinent IACUC record.
 6. Letter of documentation solicited from other University employees who can provide insight into the investigation. For example: letters from animal facility veterinarians, managers, or other facility personnel; letters

from other committees, such as the Institutional Biosafety Committee; or other individuals.

7. Letters of outside evaluation of protocols, programs, or documentation related to the complaint performed by external reviewers chosen by the Committee. Such reviews would be done confidentially, with signed confidentiality statements by reviewers. The PIND may be asked to assist the IACUC in selection of reviewers.
 8. Invited site visits by external reviewer(s) to critique facilities or programs.
 9. IACUC interviews with the PIND, Complainant or other individuals who can provide information for the investigation.
- vi. Once the IACUC has completed its fact gathering period, the IACUC will reconvene the entire committee to review all the information. A quorum of the Committee must be present and at least one community member and one veterinarian at the meeting. Because of the great amount of documentation that may be collected, it is recommended that several individual members of the IACUC be selected to review and summarize information which will be presented to the IACUC. Individual members will have access to all documentation, should they wish to review the entire package.
- vii. The Committee will review the package and fully discuss all issues. Once discussion is complete, the Committee will form recommendations for action. Recommendations will be individually voted on all actions must pass by a majority vote. Such actions could include, but are not limited to:
1. Requiring an amendment to the IACUC approved protocol
 2. Requiring a change in procedures previously approved in an IACUC protocol or requiring a change in procedures or program of the animal facility in question.
 3. Requiring a re-submission of a currently approved IACUC protocol.
 4. Conducting additional unannounced laboratory inspections to observe procedures or unannounced facility visits to observe conditions, procedures, and/or review programs. In either case, the end result of the inspection(s) may include any of the actions outlined in this section.
 5. Suspension of the research activity (Protocol).
 6. Sanction against the PIND.
 7. Find that the complaint was unwarranted or unsubstantiated.
- viii. With the Investigation complete and actions contemplated, the IACUC will invite the PIND to meet with the Committee to review the Committee's findings. This meeting will provide an opportunity for the PIND and Committee to resolve issues and work together to find solutions to the issues raised in the investigation. Harsh actions such a suspension or sanction can hopefully be avoided by this process and result in the mutual agreement and satisfaction of the Committee and the PIND.

- ix. After the PIND has met with the Committee, the Committee will formulate its final actions and Vote on these individually. All actions must pass by a majority of quorum vote and minority opinions be recorded.
 - x. The Committee shall complete the investigation by the following documentation and notifications:
 - 1. The Institutional Official shall receive a summary document of the findings of the Committee and the final actions which will be taken.
 - 2. If suspension is the action being taken and the activity is supported by PHS, the IACUC, through the Institutional Official, shall file a full report with Office for Protection from Risks (OPRR). A full report, for suspensions involving covered species, must be filled with APHIS.
 - 3. If sanction of the animal care program is to occur, the letter will be directed to the Administrator to immediately halt inhumane care, use, or treatment of animals.
 - 4. The Complainant will receive a summary of the actions taken, but any confidential and information concerning the protocols will not be included.
 - 5. The PIND will be informed, in writing, of the final conclusions/actions of the Committee and of any response that is required from the PIND.
 - 6. If the Complaint was found to be unwarranted or unsubstantiated, a strong letter of support will be provided to the PIND from the Committee for the research, animal care facility, or other program, as appropriate.
 - xi. The Committee will complete a final report and close the file, keeping all documentation for the complaint, review, investigation, and all other information in the Formal Complaint file, by year.
 - xii. The IACUC Chair will provide letters of thanks to all individuals who assisted in the completion of the investigation.
- e. CONFIDENTIALITY OF COMPLAINANT
- i. Regulatory Authority: Animal Welfare Act Section 2.32(c)(4): “No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of the regulations or standards under the Act.”
 - ii. IACUC Policy: The confidentiality of any complainant will be maintained by all individuals involved in the review and/or investigation of alleged violations of animal care and use regulations and standards. Information on any documentation which is provided to individuals other than the Director, Department of Lab Animal Medicine or members of the IACUC which would identify the complainant shall be removed by cross out, white out, black out or other method.
 - iii. Should charges be brought that are false and in malicious manner by the Complainant to purposely harm the University or any of its departments, divisions, or units, the IACUC, or any individual, then such will be handled according to pertinent classified staff, academic professional, or faculty policies

of the University of North Texas Health Science Center which are applicable to the given case.