UNIVERSITY OF TEXAS AT ARLINGTON

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

INVESTIGATION OF CONCERNS INVOLVING THE CARE AND USE OF ANIMALS SOP

I. Regulatory Authority:

Animal and Plant Health Inspection Service, USDA 9 CFR Chapter 1, 1-1-92 Edition
Subchapter A – Animal Welfare (Animal Welfare Act)

Section 2.31 (c)(4) Institutional Animal Care and Use Committee (IACUC) Functions

“Review, and if warranted, investigate concerns involving the care and use of animals at
the research facility resulting from public complaints received and from reports of non-
compliance received from laboratory or research facility personnel or employees.”

II. University of Texas at Arlington IACUC Policy:

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, or IACUC policy), or complaints
regarding the care received by animals housed in University laboratory animal, wild
animal or agricultural facilities.

B. Steps in the process:

1. 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.

2. The concerned individual(s) begins the process of filing a Formal Complaint by
contacting one the following:
   (a) The Attending Veterinarian (Contact Information)
   (b) The University Ethics Hotline, 877-507-7314.
   (c) The Office of Regulatory Services, 817-272-3723.
   (d) The Institutional Official (Vice President for Research), 817-272-6791.
   (e) UTA Campus Police, 817-272-3381.
3. The following information is to be provided for any concern:
   (a) The complainant’s name (voluntary)
   (b) The individual(s) or unit the complaint is against
   (c) Description of the event or charge including the dates of observation of the alleged violation(s)
   (d) Copies of any written, photographic, or taped documentation to substantiate the charges
   (e) Names of any other witnesses to the events/charges being described or made (voluntary)
   (f) Signature of the Complainant (voluntary)

4. The Office of Regulatory Services, IACUC Chair, or IACUC member will assist the complainant in completing the written description and will submit the Complaint to the IACUC.
   (a) Complainants must be the actual individual(s) who have witnessed the violation.
   (b) While hearsay complaints cannot be formally filed, individuals who have serious concerns based on hearsay evidence can call any of the individuals listed under II.B.2.
   (c) The Office of Research Compliance 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.

III. IACUC Review

A. The Formal Complaint will be reviewed by the IACUC Chair and the Office of Regulatory Services to determine if there is enough evidence to warrant an investigation. They will then determine a course of action which may include assignment of the investigation to a sub-committee or individual, or an internal memo to the Pertinent Individual (known hereafter as the PIND).

1. Following the review of the complaint, should the committee find that the complaint is insufficiently substantiated, the Committee shall:
   (a) Document the review findings.
   (b) Provide a confidential written response to the Complainant, if known, explaining the findings of the Committee.
   (c) The Office of Regulatory Services shall place the Complaint Form, IACUC Committee’s report, and all correspondence into a separate IACUC file for formal complaints, by year.
   (d) Provide an opportunity for all IACUC members to review the Complaint and report to provide a minority view, should they so desire.

2. If there is sufficient evidence to warrant an investigation, the Office of Regulatory Services shall:
(a) Document the review findings.
(b) Inform the Complainant, if known, that the IACUC will be performing an investigation of the complaint.
(c) At the discretion of the Committee, inform the PIND (principle investigator, Facility manager, etc.), in writing that a complaint was made. The PIND may receive a summary of the concerns without reference to the individual(s) name(s) who filed the complaint and a copy of the IACUC’s Report.

IV. IACUC Investigation of Alleged Violations of Animal Care and Use Policies.

A. The Office of Regulatory Services and the IACUC Chair will decide whether to assign the investigation to a sub-committee or individual.

B. The Office of Regulatory Services will notify Institutional Official (IO) of the initiation of the Investigation.

C. The IACUC Chair or Office of Regulatory Services will notify the PIND of the IACUC’s intention to carry out the investigation.

D. 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 complaint 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 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.
Reviewers would do such reviews confidentially, with signed confidentiality statements. 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.

E. The PIND may be invited to discuss the issues in an effort to resolve them and work together to find solutions to the issues raised in the investigation. Harsh actions such as 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.

F. After the investigation, a list of recommended corrective actions will be compiled, if deemed necessary. 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. Additional training
   6. Increased monitoring
   7. Suspension of the research activity (Protocol)
   8. Sanction against the PIND
   9. Find that the complaint was unwarranted or unsubstantiated

G. Once the facts have been gathered, the IACUC will reconvene the entire committee to review all the information. A quorum of the Committee must be present. 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.

H. The Committee will review the package and fully discuss all issues. Once discussion is complete, the Committee will review the recommended corrective actions. The committee will vote on whether there was non-compliance and whether it was serious and/or continuing. The committee will also vote on corrective actions. All actions must pass by a majority vote and minority opinions be recorded.

I. The Committee shall complete the investigation by the following documentation and notifications:
   1. The IO shall receive a summary document of the findings of the Committee and the final actions which will be taken.
2. The IACUC, through the IO, will follow the reporting requirements found in PHS Policy F.3. Guidance on reportable situations can be found in NOT-OD-05-034.

3. If suspension is the action being taken and the activity is supported by PHS, the IACUC, through the IO, shall file a full report with OLAW.

4. If suspension is the action being taken and the activity involves USDA-covered species, a report must be filed with APHIS.

5. 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.

6. The Complainant will receive a summary of the actions taken, but any confidential and information concerning the protocols will not be included.

7. 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.

8. 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.

J. 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.

K. The IACUC Chair will provide letters of thanks to all individuals who assisted in the completion of the investigation.

V. Confidentiality of the Complainant

A. 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.”

B. IACUC Policy:

1. 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.

2. The standards of the Animal Welfare Act listed in 3.1 above will be strictly followed by all members of the University community.

3. 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 Texas at Arlington which are applicable to the given case.

VI. Authority of the Attending Veterinarian

A. Regulatory Authority: AWA Section 2.33(a)(2)

“Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.”

B. IACUC Policy

The Attending Veterinarian has the authority to immediately halt inhumane care, use, or treatment of animals.

VII. Suspension of Animal Activities

A. Regulatory Authority: AWA Section 2.31 (d)(xi)(6) and (7)

“The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present; if the IACUC suspends an activity involving animals, the appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity.”

B. IACUC Policy

The IACUC will follow this policy when necessary to ensure compliance with the AWA and PHS Policy.