UNIVERSITY OF TEXAS AT ARLINGTON

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

REPORTING AND PROCESSING ANIMAL CARE AND USE CONCERNS AND INCIDENTS SOP

I. Regulatory Authority and Responsibility

In accordance with University of Texas at Arlington's (UT Arlington's) federal Animal Welfare Assurance:

A. The Institutional Animal Care and Use Committee (IACUC) has the authority and responsibility to review and/or investigate any potential non-compliance or concern relating to animal care and use brought to the attention of the IACUC. This includes 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, Public Health Service [PHS] Policy, or IACUC policy), complaints regarding the care received by animals, concerns brought forth by the Attending Veterinarian, issues self-reported by the Principal Investigator or other protocol personnel, or issues found during inspections, audits, or reviews.

B. The IACUC has the authority to suspend an activity which it previously approved if it determines that the activity is not being conducted in accordance with the applicable provisions of the Animal Welfare Act, the *Guide for the Care and Use of Laboratory Animals* (*The Guide*), the institution's Assurance, or IV.C.1.a.-g. of PHS Policy. 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.

C. The Attending Veterinarian has the individual authority to halt any animal care or use procedure that is considered by the veterinarian to jeopardize the health or well-being of the animal, or that is not in compliance with the PHS Policy on Humane Care and Use of Laboratory Animals, *The Guide*, or institutional policies/procedures.

II. Definitions

A. Concerns and Incidents (CI): A report regarding regulatory compliance, safety issues, or any actual or perceived suboptimal well-being of a research animal being used at UT Arlington that may be communicated in a variety of methods such as phone call, electronic communication, or the university Ethics Hotline. (See Section III.A.)

B. Serious non-compliance is defined as any deviation from the approved protocol, institutional policies and procedures, federal regulations, or provisions of *The Guide* **that jeopardizes the health or well-being of animals**.

C. Continuing non-compliance is defined as multiple similar violations over time, either on the same protocol or for the same investigator across multiple protocols.

D. Pertinent Individual (PIND) is the Principal Investigator, staff member, student, etc. for which the CI pertains to, and/or the person who can address the CI.

E. CI Review Team refers to the group designated by the IACUC to perform review of CIs that are potentially serious/continuing or impact animal welfare to determine actions for resolution. The CI Review Team is comprised of the IACUC Chair (or Vice Chair), a representative from the Animal Care Unit which includes the Attending Veterinarian (or Back-Up Veterinarian) and Animal Care Facility (ACF) Manager, and a representative from the Office of Regulatory Services (ORS).

III. Reporting Concerns and Incidents

A. CI should first be addressed to the individual(s) or unit whom/which the issue concerns. If the issue is not adequately addressed, a report should be made to one of the following:

1. The Attending Veterinarian (Contact Information)
2. The Office of Regulatory Services, 817-272-3723, regulatoryservices@uta.edu
3. The IACUC Chair, iacuchair@uta.edu
4. The Institutional Official (Vice President for Research), 817-272-6791
5. UT Arlington Campus Police, 817-272-3381
6. The University Ethics Hotline, 877-507-7314 (report can be anonymous)

B. CI may include:

1. Adverse events or unanticipated outcomes during a research study, depending on the outcome's impact on the animal and/or compliance.
2. Potential non-compliance to research (IACUC protocol), IACUC policy, ACF policy, federal regulations, or other institutional requirement.
3. Accident or mishap resulting in animal harm or death.
4. Concerns or complaints made by a non-UTA researcher, including a member of the public.

C. Concerns do not have to be associated with any specific IACUC protocol.

D. Individuals receiving the concerns or notification of an incident must promptly notify the Attending Veterinarian (AV) if immediate veterinary care is needed.

E. Concerns may also come from IACUC Semi-Annual Facility Inspections (especially significant deficiencies) or Post-Approval Monitoring (PAM) visits.

IV. Office of Regulatory Services (ORS) Initial Assessment of CI

A. Reports of CI shall be submitted to ORS.

B. ORS will conduct fact-finding which may involve discussions with the PIND, review of protocols or evidence submitted, discussions with other employees, and unannounced laboratory inspections. Information gathered may include:

1. The Complainant's name (voluntary)
2. The name of the PIND and other individuals involved
3. Description of the CI including the dates of observation
4. Copies of any written, photographic, or taped documentation to substantiate the CI
5. Names of any other witnesses to the CI
6. Veterinary care and medical records
7. Funding source
8. Personnel training records
9. Corrective actions already initiated

C. Following review of initial evidence and information gathered, ORS will determine if the CI constitutes potential non-compliance, an animal welfare concern, or both. If the CI constitutes non-compliance, ORS will determine if it is potentially serious and/or continuing. ORS will then facilitate full review and resolution of the CI according to Section V.

V. Review and Resolution of CI

A. For CIs that constitute **minor/non-continuing non-compliance and do not impact animal welfare**, ORS will (as the IACUC's designee) facilitate resolution of the CI through the following actions:

1. Document review findings to support the determination that the non-compliance is not serious and not continuing.
2. Determine corrective actions.
3. Inform the PIND of the review of the CI, the findings, and the corrective actions for resolution, if applicable. The PIND may receive a summary of the CI without reference to the individual(s) name(s) who filed it.
4. At its discretion, provide a confidential written response to the Complainant, if known, explaining the findings of the review.
5. Submit a report of the non-compliance and corrective actions to the IACUC at the next convened meeting.

B. For CIs that constitute **potentially serious or continuing non-compliance and/or impact animal welfare**, the following actions will be taken:

1. ORS will notify the Institutional Official (IO) of the initiation of the review.
2. The CI will be reviewed and evaluated by the CI Review Team utilizing the initial facts and information gathered by ORS. In the event of a conflict of interest or unavailability of the IACUC Chair or AV, the IACUC Vice-Chair or Back-Up Veterinarian may be called upon to participate in the review.
3. The CI Review Team will determine if a CI requires further investigation by the IACUC.

    a. **CIs that require further investigation** will be reviewed in accordance with Section VI. CIs received from the public will automatically proceed to an investigation.
    b. For **CIs that do not require further investigation**, the CI Review Team will facilitate resolution of the CI through the following actions:

        i. Determine whether the CI constitutes non-compliance that is either serious and/or continuing.
        ii. Develop corrective actions. Corrective actions deemed to be immediately necessary to protect or improve animal welfare will be immediately communicated to the PIND and/or ACF Manager to be implemented.
        iii. Submit a report to the IACUC via email describing the CI, the findings, and the recommended corrective actions (including any already implemented). The IACUC will be given 5 business days to respond with additional input, recommendations, or a request for further investigation under Section VI.
        iv. Following review of the CI report by the IACUC (via the email report *or* at a convened meeting), the CI Review Team will finalize and document the review and findings and any details that support the determination of an animal welfare concern and/or serious or continuing non-compliance.
        v. Inform the PIND of the review of the CI, the findings, and the corrective actions for resolution, if applicable. The PIND may receive a summary of the CI without reference to the individual(s) name(s) who filed it.
        vi. At its discretion, provide a confidential written response to the Complainant, if known, explaining the findings of the review.
        vii. Summarize CI reviews and findings at the next convened IACUC meeting for recording in the meeting minutes.

VI. IACUC Investigations

A. When a CI requires further investigation, it will be conducted by a designated Subcommittee of the IACUC.

B. ORS will assign the Subcommittee members which will include, at minimum, a representative from the Animal Care Unit and at least one voting member that is faculty.

C. ORS will notify the IACUC and the Institutional Official (IO) of the initiation of the investigation.

D. The Subcommittee will review the initial facts and information compiled by ORS and/or the CI Review Team.

E. Additional information may be collected by the Subcommittee using a variety of methods. These may include, but are not limited to:

1. Unannounced visits to the laboratory or area of the ACF in question to review procedures, lab/facility documents, or talk with personnel.
2. Submission of documentation from the PIND, co-workers or employees, ACF Manager, or AV. 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 that provide information which may assist in the investigation.
3. Documentation supporting the CI reported by the Complainant.
4. If the Office of Regulatory Services determines to notify the PIND, the PIND will be invited to provide a written response to the CI. (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 IACUC protocols, IACUC inspection reports, Reports of Programmatic Reviews, USDA inspection reports, or any other pertinent IACUC records.
6. Letters of outside evaluation of protocols, programs, or documentation related to the CI performed by external reviewers chosen by the IACUC or ORS. Reviewers would do such reviews confidentially, with signed confidentiality statements. The PIND may be asked to assist in selection of reviewers.
7. Invited site visits by external reviewer(s) to critique facilities or programs.
8. Interviews with the PIND, Complainant or other individuals who can provide

information for the investigation.

F. The Subcommittee will review all evidence and information gathered and take the following actions:

1. Determine whether the CI constitutes non-compliance that is either serious and/or continuing.
2. Develop corrective actions. Corrective actions deemed to be immediately necessary to protect or improve animal welfare will be immediately communicated to the PIND and/or ACF Manager to be implemented.
3. The Subcommittee may elect to either have the full IACUC review and discuss its CI investigation findings during a convened meeting (for example, when significant committee input may be needed), or to finalize its findings and recommendations and submit those in a report to the full IACUC via email. When an emailed report is utilized, it will describe the CI, the findings, and the recommended corrective actions (including any already implemented). The IACUC will be given 5 business days to respond with additional input, recommendations, or a request for review of the CI by the full committee at a convened meeting.
4. Following review of the CI investigation by the IACUC (via the email report *or* at a convened meeting), the Subcommittee will finalize and document the review and findings and any details that support the determination of an animal welfare concern and/or serious or continuing non-compliance.
5. Inform the PIND of the review of the CI, the findings, and the corrective actions for resolution, if applicable. The PIND may receive a summary of the CI without reference to the individual(s) name(s) who filed it.
6. At its discretion, provide a confidential written response to the Complainant, if known, explaining the findings of the review.
7. Summarize CI reviews and findings at the next convened IACUC meeting for recording in the meeting minutes.

VII. Corrective Actions

A. When corrective actions result from the review of a CI, they may 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 ACF
3. Requiring a re-submission of a currently approved IACUC protocol
4. Conducting announced or unannounced laboratory inspections to observe procedures, conditions, and/or review programs
5. Requiring the PIND to provide a written plan that defines how the incident will be prevented from reoccurring

6. Training which may include “hands-on” training, online training, conferences/webinars/workshops, or other targeted training
7. Increased monitoring
8. Suspension or termination of the IACUC protocol or animal research activity in accordance with UTA IACUC Authority SOP.

VIII. Documentation and Notifications

Upon completion of a CI review and/or investigation by the IACUC, ORS shall carry out the following documentation and communication:

A. CIs found to be incorrect or insufficiently substantiated during any part of the review/investigation process will be reported to the IACUC at the next convened meeting.
B. Required notifications to the PIND. If a finding of non-compliance is determined to be serious and/or continuing, the Chair or supervisor of the PIND and the IO shall receive a notification of the conclusion and findings of the review/investigation, a description of violations (if any), and the required corrective actions (if any).
C. Required notifications to the Complainant.
D. Required notifications and prompt reporting to PHS, USDA, AAALAC International, and sponsoring agencies, as applicable.

IX. Appeal Opportunity

The PIND can appeal the findings of a CI review. The appeal must be submitted to the IACUC Chair according to the IACUC Appeal of an IACUC Decision SOP.

X. 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 any regulation 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 Office of Regulatory Services, ACF, or members of the IACUC which would identify the Complainant shall be redacted.
2. The standards of the Animal Welfare Act listed in X.A above will be strictly followed by all members of the UT Arlington community.