Purpose
This policy defines the procedures used by the IACUC of TTUHSC El Paso to investigate potential animal mistreatment and potential IACUC protocol violations, and the subsequent actions that will be taken. Federal animal welfare regulations (under the Animal Welfare Act) state that all employees or concerned parties must have the means to report deficiencies in animal care and treatment. Federal animal welfare regulations state that no facility employee, committee member or laboratory personnel shall be discriminated against or be subjected to any reprisal for reporting violations of any regulation or standards under the Animal Welfare Act.

1. Definitions
Mistreatment - Any action that results in wrongful or abusive treatment of an animal.
Noncompliance - Violation of University policy or noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the USDA Animal Welfare Act Regulations (USDA AWAR), and other applicable federal, state, and local laws or regulations governing animal care and use.

2. Who may report
Any person, including any University employee, student, volunteer, or member of the general public, may report concerns involving the care and use of animals at TTUHSC El Paso. Such concerns may be reported anonymously. If the complainant identifies him/herself, protection of his/her identity will be maintained to the extent possible within the legitimate needs of law and the investigation.

3. When and what to report
Based on federal requirements, the IACUC has identified several kinds of reportable incidents that may serve as examples to guide individuals in making their determinations. These incidents include, but are not limited to, the following: a condition that is or may be a threat to the health or safety of animals, the conduct of animal-related activities or protocol modifications without prior IACUC review and approval, continuing activities past the protocol expiration date, the conduct of activities by uncertified and/or unlisted personnel, or continuing noncompliance.

4. How to report
A. Reports are encouraged to be made in writing so as to assure a clear understanding of the issues raised, but may be made verbally. Such reports should contain as much specific, factual information as possible to allow for a full investigation and proper assessment of the nature, extent, and urgency of the concern. Information should include, but need not be limited to, the nature, date, time, and location of the occurrence; the person(s) against whom the allegation is being made; and any supporting documentation.

B. A complaint may be reported either orally or in writing, to any member of the IACUC. Complaints may also be sent by email to larcelp@ttuhsc.edu or anonymously by visiting www.ethicspoint.com or calling 866.294.9352.

C. If the complaint is against the IACUC Chair, then it should be reported directly to the Institutional Official D. (IO). All other complaints should be reported to the IACUC Chair.

5. Reporting and processing of complaints
A. If the Institutional Veterinarian (IVet) is the subject of the complaint, the IO will appoint an individual to
conduct the initial investigation.

B. If the complaint includes issues regarding animal welfare, then the IACUC Chair will inform the iVet and both will be involved in further investigation of the complaint.

C. The IACUC Chair will inform in writing the person who is the subject of the complaint (and also the PI, if the PI isn't the direct subject of the complaint) that a complaint has been received and provide a summary of the complaint.

D. The IACUC Chair will also notify the Complainant (in writing) that the complaint has been received, unless the Complainant chooses to remain anonymous or does not provide sufficient contact information.

E. All records of the complaint (including all results and communications) shall be documented and maintained in IACUC files for a minimum of three years.

6. Evaluation of complaints and immediate action steps
   Upon receipt of a reported concern, the IACUC Chair, in consultation with the IVet, will evaluate the complaint to determine whether there is sufficient information to investigate further. As much information as is reasonably needed will be collected, which may entail review of documents, inspection of the facilities, and/or discussions with pertinent individuals.

   A. If no violations are found, then no further action after investigation of the concern will take place, other than to inform (in writing) both the Complainant and the subject of the complaint of the finding and the recommendation that no further action will be required. If the Complainant disagrees with the response from the IACUC Chair, then the complaint will be further processed as a "Disputed Violation" and handled as described below in Section 7.B.

   B. If mistreatment of animals is found, the Chair and IVet shall take immediate steps to ameliorate the problem and protect the animals. Depending on the situation, such ameliorative steps may include veterinary medical intervention, confiscation of the animals, and/or pause of specified activities. In some cases, involvement by the IO, legal counsel, and other University officials (e.g., Department Chair) may be required at the outset of the investigation.

   C. If animal activities should be paused, the IVet will notify the person who is the subject of the complaint (and also the PI, if the PI is not the direct subject of the complaint) in writing and in a timely manner.

7. Further actions to be taken after a violation has been found
   A. Minor Violation(s)
      If, following the initial investigation, it is determined that a minor violation (consisting of one instance of policy noncompliance but no inhumane treatment of animals) has occurred, then all of the following will occur.

      1) The IACUC Chair will inform in writing the person who is the subject of the complaint and his/her Department Chair or supervisor of the findings and recommendations and of any required remediation, including a time frame in which corrections are to be completed.

      2) The IACUC Chair is responsible to report the complaint, the findings and recommendations, and any remedial action to the IACUC.
3) The IACUC Chair and/or IVet will be responsible to verify that the remediations have been completed in a timely manner.

4) If either the Complainant or the person who is the subject of the complaint disagree with findings, or if the person who is the subject of the complaint disputes or refuses the remedial actions, the complaint will be further processed as a “Disputed Violation” as described below in Subsection B, below.

B. Major Violation(s) and/or Disputed Violations

If, after the initial investigation, it is determined that a major violation has occurred (consisting of either two or more instances of noncompliance or the inhumane treatment of animals) or the initial findings are disputed (as discussed in sections VI.A and VII.A.4), then all of the following will occur.

1) The IACUC Chair will schedule a meeting of the IACUC Protocol Violations Subcommittee (Subcommittee) within 10 business days from receipt of IVet's findings and recommendations. The Subcommittee is a standing committee with members appointed by the IACUC Chair. All Subcommittee members will be expected to attend this meeting. If essential duties require absences, a majority of the standing subcommittee members must be present.

2) The Subcommittee will review the complaint and the initial findings and recommendations of the IACUC Chair and the IVet and obtain additional information as needed.

   a) The Complainant may be requested to meet with the Subcommittee. If the Complainant is unwilling or unable to make a personal appearance, the Complainant may submit a written statement to the IACUC Chair prior to the meeting. The IACUC Chair shall provide a copy of the statement to the person who is the subject of the complaint.

   b) The person who is the subject of the complaint will be given an opportunity to meet with the Subcommittee to respond to the complaint and ask questions of the Complainant and any other witnesses. At least three (3) business days prior to the meeting, the person who is the subject of the complaint will be provided a copy of any written complaint or other written documentation pertaining to the complaint. If the person who is the subject of the complaint is not the Principal Investigator (PI), the complaint may be forwarded, at the discretion of the IACUC Chair or Vice Chair, to the PI or other supervisor directly responsible for the animal(s) subject to the complaint. If a verbal complaint is made, the person who is the subject of the complaint will be informed of the substance of the complaint at least three (3) business days prior to the meeting.

   c) The Complainant and the person who is the subject of the complaint may have an advisor at the meeting with Subcommittee, provided that written notice is given to the IACUC Chair at least two (2) business days in advance of the meeting with the Subcommittee. Advisors are present in an advisory capacity only and are not permitted to speak or present information directly to the Subcommittee.

   d) If the Complainant and/or the person who is the subject of the complaint elects not to meet with the Subcommittee, the complaint will be reviewed on the basis of information available, and a recommendation will be made by the Subcommittee. No inference may be drawn against the Complainant and/or the person who is the subject of the complaint for failure to appear before the Subcommittee.

   e) At the meeting, the Subcommittee may call the IVet or any other witnesses as it deems necessary.

   f) When the Subcommittee concludes that all pertinent information has been received, anyone who is not a voting member of the Subcommittee shall be excused, and the Subcommittee shall discuss, deliberate and prepare its findings and recommendations. By majority vote of those present, the Subcommittee will determine whether or not mistreatment of animals or policy noncompliance has occurred (findings) and make recommendations. If the findings and
recommendations are not unanimous, opinion(s) may be written and attached by those who differ with the majority’s findings and recommendations.

3) The Subcommittee will present its findings and recommendations to the IACUC at the next scheduled meeting, including any differing opinion(s) and any plans for corrective actions. The IACUC will then determine final action(s) to be taken. IACUC action(s) may include, but is not limited to:
   a) Finding of no violation and/or the complaint was not substantiated, and filing this written notification in the PI's IACUC protocol file. If the person who is the subject of the complaint is not a PI, the written notification will be filed in the IACUC file;
   b) Reprimand to the person who is the subject of the complaint, which may include notice to the PI that if the same or similar circumstances which were the basis of the complaint are found to continue, this could result in suspension or complete revocation of approval of all protocols relevant to the complaint under which animal(s) were obtained;
   c) Suspension of the protocol for a stated period of time, or immediate revocation of the protocol approval; or,
   d) Recommendation to the IACUC IO to remove LARC access of the person who is the subject of the complaint for a stated period of time, or to take other action as the IO deems appropriate.

4) For IACUC protocols that have been formally suspended, the protocol can only be reinstated upon a vote of the full IACUC committee with a quorum present. A majority vote is needed to reinstate the protocol.

5) The IACUC Chair will report in writing, as appropriate, to the following individuals:
   a) The Complainant (if contact information is known);
   b) The person who is the subject of the complaint;
   c) The Departmental Chair or supervisor of the person who is the subject of the complaint; and,
   d) The IO.

6) The IO will report the findings and actions taken to all appropriate external organizations and/or governmental agencies.

Related policies

Investigators must comply with all other institutional policies at TTUHSC El Paso and Federal Guidelines. This list includes, but is not limited to, the following:

IACUC Policy #0: Introduction to IACUC Policies and Procedures
IACUC Policy #2: Veterinary Care
IACUC Policy #13: Protocol Approval, Implementation, Review and Amendment Processes
IACUC Policy #19: Humane Endpoints Regarding Severe or Chronic Pain or Distress

REFERENCE

1. The IACUC Handbook by Jerald Silverman (Editor); Mark A. Suckow (Editor); Sreekant Murthy (Editor). 3rd edition. Boca Raton : CRC Press. 2014