IACUC REVIEW OF ANIMAL WELFARE CONCERNS AND NONCOMPLIANCE

PURPOSE: This guideline establishes procedures for review of concerns reported to Michigan State University regarding animals under the University’s ownership or control; or noncompliance in animal use for teaching, research, and outreach. Noncompliance would include, but not be limited to: conducting animal activities without IACUC approval; failure to adhere to the methods, procedures, and conditions of the approved protocol.

When a concern or an issue of noncompliance becomes known, it should be reported to any of the following: IACUC Chair, IACUC Administrator, Attending Veterinarian, Research Liaison, IACUC member, IACUC staff, Facility Manager, or any animal caretaker who in turn will inform the IACUC office. Preliminary assessment of the situation will be made by the Attending Veterinarian, the IACUC Chair or Vice Chair, and/or the IACUC Administrator with possible consultation with the Animal Care Program Executive Committee. [An exception will be made when the concern involves one of the aforementioned and/or they are not available for consultation.] After careful deliberation, these individuals will determine a course of action deemed to be in the best interest of the welfare of the animals. If necessary, the Assistant Vice President for Regulatory Affairs (AVPRA) will be included in such deliberations if available; otherwise he/she will be apprised of the situation as expeditiously as possible. The Institutional Official (IO) will be kept informed through the AVPRA.

If the issue presents a potential immediate animal health or welfare risk, the Attending Veterinarian or designee will assess the situation and take any action determined to be, in their professional judgment, appropriate to alleviate unnecessary pain and distress in animals.

The University’s Attending Veterinarian or designee, the Institutional Official, or the IACUC Chair may ask an investigator to cease procedures in process if cessation is determined to be in the best interest of the animals. All reasonable attempts to receive input from the above individuals and the principal investigator should be exhausted before such decision is made.

The investigative process may be delegated to a subcommittee of the IACUC or other individuals appropriate to conduct the investigation. In cases of delegation, the IACUC retains responsibility to assure that the investigation is conducted in an appropriate and legal manner. The IACUC will be notified of investigations as soon as possible, but no later than the next regularly scheduled meeting. The IACUC staff will manage the process.
Process for Conducting Investigations:

1) The IACUC Chair or Vice Chair shall:
   a) Consult with the AV to determine if immediate veterinary care is needed.
   b) May appoint a subcommittee to investigate the concern.
   c) Notify the AVPR and IO that an investigation has been initiated.
   d) Notify the subject of the situation that an investigation is in process unless doing so may interfere with the investigation. Notifications shall include a description of the allegation/complaint and a request for information concerning the incident. It may also include an invitation to meet with the subcommittee.

2) The IACUC Administrator shall:
   a) Call meetings and manage the review process.
   b) May instruct administrative staff to collect additional information.
   c) Provide a written report to the IACUC with the subcommittee’s conclusions at a regularly scheduled meeting or a special called meeting if necessary.

3) The IACUC Subcommittee shall:
   a) Use any legal method deemed necessary to obtain information for the investigation which may include but are not limited to:
      i) Unannounced visits to the laboratory or facility;
      ii) Review of lab and/or facility procedures or documents whether written or electronic;
      iii) Interviews or obtain written statements from involved personnel;
      iv) Review records pertaining to the affected animals, projects, or procedures;
      v) Review Animal Use Forms, inspection records, or other pertinent IACUC records as applicable;
      vi) May request external reviewers to assess the situation and provide additional information to aid in the investigation.
      vii) Review history of noncompliance or repeat offences.
   b) Review the written report detailing the committee’s findings, conclusions, and recommendations.
   c) Determine which items, if any, require a written statement from the affected party(s) and a deadline for receipt of the written statement.

4) Upon receipt of the Subcommittee’s preliminary report the IACUC shall:
   a) Deliberate the Subcommittee’s preliminary report and any supplementary material.
   b) Determine, by majority vote, the outcomes of the investigation and any necessary corrective actions.
   c) The Principal Investigator (PI) who holds the approval for the animal activity in question will be given a summary of the investigation and informed of the required corrective actions.

5) Invitation of involved individuals to address the IACUC:
   a) The IACUC may invite individuals involved in the situation to address the full committee if the IACUC deems it appropriate.
   b) Individuals may request to meet with the committee, but it is the decision of the IACUC whether to allow a verbal presentation. Individuals may submit written statements for consideration by the IACUC in their deliberations.
c) If an invitation is extended, it will include the items for discussion, the party(s) invited, the date, time, and time limitations for the meeting.

6) At the conclusion of the IACUC’s deliberations, including any verbal or written statements from the affected individuals, the IACUC will vote on the final recommendation of the Subcommittee.
   a) The IACUC may accept the recommendation in full, require modifications to the recommendation, reject the subcommittee recommendation, or vote to approve an alternate course of action.

7) Following the IACUC final determination of an outcome, the IACUC Chair shall:
   a) Notify the AVPRA and the IO of the IACUC’s decision and corrective actions. If the IACUC recommends to the Institutional Official that a person have their animal use privileges suspended, the IACUC will confer with Legal Counsel and Human Resources to develop the process for which this is to occur.
   b) Notify the affected individual(s) of the Committee’s decision and corrective actions.
   c) Regarding an animal welfare concern, the complainant will be notified of the committee’s decision if not made anonymously.
   d) If the complainant wishes to remain anonymous information on the decision can be requested from the IO’s office.

All investigations and actions shall be conducted in accordance with appropriate federal, state, and university legal and policy standards. If necessary, the IACUC will seek expertise (e.g. Departmental, Human Resources, Legal Services) to assure investigations and actions are properly conducted and follow due-process.

Every attempt will be made to protect the rights of both the complainant and others involved in investigations. Protections to insure confidentiality will include, but are not limited to, allowing reports and complaints to be made anonymously as well as withholding names from written and oral reports.

The appropriate internal and external regulatory entities will be notified as necessary.