ANIMAL EYE CONSULTANTS OF IOWA

Animal Eye Consultants of Iowa	
Institutional Animal Care and Use Committee	
Policy #27	**"Procedure for Reviewing Animal Care Concerns and Potential Non-Compliance with IACUC Policies or Procedures"**
Approval Date: 5/2/2023 (Replacing Version 9/25/2019)	

A. Background

The IACUC is charged with reviewing and, if warranted, investigating animal welfare concerns and potential non-compliance. Non-compliance, whether accidental or intentional, occurs when procedures not approved by the IACUC are applied to animals in research or teaching, when there are deviations from the IACUC approved Animal Subjects Approval Form (ASAF), or when there is a departure from IACUC approved policies. Non-compliance violations can range from minor protocol deviations (e.g., failure to notify IACUC of new personnel, minor changes in drug administration or sampling frequency, etc.) to significant. A significant deviation is defined as one that is or may be a threat to animal health, welfare, or safety (e.g., unapproved animal procedures that result in animal death, injury, or disease, failure to provide post-operative analgesics, failure to follow safety procedures, etc.) or is a substantial departure from IACUC policy (e.g., research or teaching involving animals occurring without IACUC approval). The IACUC is responsible for identifying non-compliance issues and ensuring appropriate corrective actions are implemented to prevent reoccurrences.

B. Applicability

This policy applies to situations under the IACUC's purview where a suspected non-compliance with federal regulation, AEC animal use policies or an animal welfare concern is reported. Anyone can submit a report or identify a potential non-compliance or animal welfare concern (See IACUC Guideline #2 for Reporting Animal Care Concern). Principal Investigators (PIs) are responsible for the actions of those who work under their supervision. The IACUC?s purview includes any activity associated with the AEC Animal Care and Use Program.

C. Procedure

Following the report, a preliminary inquiry will be initiated by the Office of Research Assurances (ORA), Animal Welfare Program (AWP), AEC Veterinary Staff (AEC), and/or the IACUC. The inquiry may include a routine animal facility inspection, interviews of the PI, students, or staff, and identification of funding sources or other resources appropriate to the problem.

In the event that an urgent safety or welfare concern is identified in the preliminary inquiry, the Attending Veterinarian (AV) or the AV's designee will expeditiously assess the concern. The AV has the authority delegated by the Institutional Official (IO) and the IACUC to assess the animal, treat the animal, remove it from the experiment, institute appropriate measures to relieve pain or distress, or perform euthanasia if necessary (AEC BPPM 45.42).

The findings of the preliminary inquiry will be discussed with the PI, and their response will be considered. The results of the preliminary inquiry and the response by the PI or relevant party will be reported to the IACUC chair, ORA Director, AWP Assistant Director and AV.

D. Actions

Follow up on reports:

1) Representatives of the IACUC, AEC, and ORA/AWP will review the results of preliminary inquiry and determine if there is a non-compliance issue or welfare issue. The PI will be notified whether non-compliance was established or not.
    a) If non-compliance issues were not identified, the inquiry will be closed. Any welfare issues not related to non-compliance will be addressed.
    b) If non-compliance occurred, a plan to correct the non-compliance will be developed and implemented if not already done so.

2) If significant non-compliance is identified, a letter of non-compliance will be sent from the IACUC Chair, ORA Director, or AWP Assistant Director to the PI. The letter should explain the basis of the non-compliance finding and the required corrective actions. Depending on the circumstances, the Departmental Chair or Director, the Associate Dean of Research (or equivalent), Dean, Vice Chancellor of Research, and

the Institutional Official (IO) may also be included. Corrective actions for minor deviations will be communicated via email or in a post-approval review form.

3) Required corrective actions may include any or all of the following:
    a) Mandating training aimed at preventing future incidents
    b) Amending animal care and use protocols or standard operating procedures for IACUC review and approval
    c) Enhanced monitoring of procedures and records by the IACUC or AEC, including requiring procedural observations, which may incur a service cost
    d) Requiring the PI to provide a written response addressing the non-compliance to the satisfaction of the IACUC and/or to appear before the IACUC
    e) Increased frequency of post-approval monitoring with updates provided to the IACUC at monthly meetings
    f) Increased frequency of de novo protocol review (e.g. annually instead of every 3 years)
    g) Protocol knowledge assessment (e.g. written or verbal test) of applicable personnel
    h) Other actions such as those in response to animal welfare

If the non-compliance requires reporting to federal agencies (OLAW and/or USDA) or other funding sources, a report of the details including circumstances and correction of the non-compliance will be written by the Attending Veterinarian, IACUC Chair, ORA Director, or AWP Assistant Director. Written reports to federal agencies and/or funding sources will be sent by the IO and copied to the PI. Depending on circumstances, the Department Chair, Dean, Associate Dean of Research (or equivalent) and/or Vice-Chancellor for Research may also be copied.

Based on Office of Laboratory Animal Welfare (OLAW) guidance and information, examples of reportable situations include, but are not limited to:

- Conduct of animal-related activities beyond the expiration date established by the IACUC;
- Failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- Failure to maintain appropriate animal-related records (e.g., identification, medical, surgical, husbandry);

- Conduct of animal-related activities without appropriate IACUC review and approval;
- Failure to adhere to IACUC-approved protocols;
- Failure to report unanticipated adverse events to IACUC or AEC;
- Participation in animal-related activities by individuals who are not listed on the approved protocol and have not been determined by the IACUC to be appropriately qualified and trained;
- Failure to monitor animals post-procedurally as necessary to ensure well-being;
- Failure to ensure death of animals after euthanasia;
- Failure of animal care and use personnel to carry out veterinary treatments;
- IACUC suspension that results in the temporary or permanent interruption of an activity due to non-compliance;

4) Results of the inquiry, subsequent reviews and required corrections will be communicated to the IACUC during convened meetings. The IACUC may choose to proceed with further review and further actions.
5) Repeated non-compliance is reviewed as described above and handled on a case-by-case basis. Repeated non-compliance may result in additional corrective actions and further actions, thereby jeopardizing ongoing animal activities.

When animal welfare incidents fall outside of the scope of this policy, then the review, determination and corrective actions fall to the discretion of the University Administration. The University Administration (generally the IO) may require further review, corrective actions, sanctions, or suspensions. In accordance with EP-6, the Vice President for Research has the authority to temporarily halt research activities if there is an emergency need for immediate action.

E. Further Actions

1) In the event that further actions are required, the IACUC will decide on additional action at a convened meeting. This may involve requesting a more formal investigation.
   a) If no formal investigation is requested, the IACUC may proceed with corrective actions/sanctions as described in section D2 above or section F below.

b) If a formal investigation is requested, in accordance with USDA Animal Welfare Act Regulations §2.31, (c), (4), a subcommittee of IACUC members and experts will be appointed to conduct the review.
   i) IACUC members and experts (e.g., ORA Director, AWP Assistant Director, etc.) appointed by the IACUC Chair can participate in the investigation.
   ii) The investigating team will report the results of the investigation to the IACUC.
   iii) IACUC will determine a response appropriate to the non-compliance, which may include items listed in section D2 above or section F below.

F. Post-Investigation

At the completion of the IACUC investigation, results will be reported to the PI and the Vice President for Research (the AEC IO). In addition, the IACUC may choose to report the results to the PI's Department Chair, School Director, Associate Dean of Research (or equivalent), Vice Chancellor of Research and/or College Dean.

Sanctions may be proposed by the IACUC following investigation of alleged non-compliance or following semi-annual site visits or any other observations of serious non-compliance. Sanction recommendations must be supported by a majority vote of a properly convened meeting of the IACUC prior to forwarding to the IO or the PI's supervisor. Sanctions may include any, or more, of the following:

- Counseling
- Issuing additional letters of reprimand
- Suspending an animal care and use protocol or standard operating procedure
- Temporary or permanent revocation of privileges to work with animals
- Temporary or permanent suspension of activities using animals
- Other actions such as those in response to animal welfare
- IO and Provost can impose sanctions (such as employment-related sanctions) beyond the IACUC's authority.

IACUC decisions can be appealed in writing or in person at a convened meeting. The sanctions will remain in place until modified by a majority vote and a properly convened meeting.