IACUC Policy # 110: Managing reported concerns related to the use of animals in research and teaching

The IACUC must review and resolve any reported concerns related to the use of animals in research, teaching and demonstration to help ensure that animals are used appropriately and receive humane care and treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research. This policy outlines the process for managing such concerns.

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1) Policy

The following policies document the principles for addressing concerns related to the humane use of animals in research, teaching and demonstration at Cornell University.

Cornell Policy 1.4 Care and Use of Animals in Research and Teaching

IACUC Policy #100: Cornell University Whistle Blower Policy

Concerns about animal care and use, or the reporting of instances of suspected non-compliance with laws, rules, regulations and policies can be reported to the IACUC office directly and anonymously through the following written or verbal mechanisms:

1. report form: https://www.iacuc.cornell.edu/documents/Unanticipated Adverse Event or Deviation from Protocol Form.docx
2. telephone: 607-255-5398 or toll free at 1-866-293-3077
3. Cornell University Hotline: www.ethicspoint.com

The Whistleblower policy and contact information are posted in all animal facilities at Cornell University (CU). Cornell University prohibits unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

2) Procedures

A. Reporting Criteria, methods and procedures:

1. Examples of reportable situations and activities include:
   - Situations where animals may be in immediate, actual or perceived jeopardy.
   - Situations involving alleged violations of the Animal Welfare Act and Animal Welfare Regulations ("AW Regulations"), the Office of Laboratory Animal Welfare (OLAW) – approved Cornell University Animal Welfare Assurance (Assurance), the Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) or Cornell Policy 1.4., and departures from the Guide for the Care and Use of Laboratory Animals (the Guide), also including instances when there is no apparent danger to animals.
• Situations involving procedural violations or protocol non-compliance such as performing unauthorized surgery or other procedures not listed on a protocol, allowing unauthorized persons (i.e., not approved on protocols) to participate in a research project, or administering drugs or other substances that the IACUC has not approved.

2. An actual or suspected concern related to animal welfare can be reported to the IACUC office directly, in writing using a report form, by phone (607-255-5398), or anonymously via the Cornell University Hotline at www.ethicspoint.com or toll free at 1-866-293-3077. If a verbal concern is reported, the individual who receives the phone call will document the circumstances fully to ensure that the issues are clear, to prevent any potential misunderstandings. The report will be shared with the IACUC chair and ORIA Director for further action.

3. Information relating to an open inquiry or investigation will be shared only with others at the University (or at a University-affiliated organization whose animal program is covered by the IACUC) who have a need to know, those who are involved in or necessary to the investigative process, and with federal agencies, as required.

B. Initial evaluation and actions by the IACUC:

1. Upon review of the reported concern, the Director of ORIA, IACUC Chair, or the Attending Veterinarian will determine if immediate action is required or if routine investigative procedures will be followed.

2. If the reported concern falls into any of the categories listed below, immediate action is required and must be initiated by the IACUC Chair or designee to mitigate safety, security or health concerns:
   • Conditions that jeopardize the health or well-being of animals will be evaluated and acted upon immediately. In such cases, the Attending Veterinarian is authorized to halt procedures that, in his/her judgment, do not comply with institutional policies, until the IACUC can be convened to review the matter.
   • Situations that may involve potential criminal activity, human safety or security of Cornell property are evaluated immediately by the institution's compliance or occupational health and safety officials, or law enforcement authorities, as appropriate.

3. Allegations of other ongoing policy or procedural matters, or other situations that do not involve apparent immediate danger to animals, may not require immediate attention, but nonetheless will be investigated promptly.

4. In all cases, the Institutional Official (IO), the IACUC Chair or designee will promptly submit a preliminary report to the Office of Laboratory Animal Welfare (OLAW) when required by Public Health Service (PHS) Policy (referenced below).

5. After an initial action, a report must be submitted to the IACUC for review of issues related to animal care and use. Emergency meetings of the IACUC may be called as necessary.
   • Upon receipt of the reported concern, the Director of ORIA, IACUC Chair, Attending Veterinarian or designee will lead the investigation, working with IACUC staff to gather detailed information to inform the IACUC. The IACUC Chair may appoint a subcommittee of IACUC members to collect and review the information. This process may include:
     (a) Consultations and/or interviews with: the complainants (if known), any persons against whom allegations were directed, the PI and research team, members of the Veterinary staff, animal care personnel, the PI’s department chair, program officials, and any other individuals who may have information pertinent to the incident. Observing the animals and their environment;
(b) Reviewing all pertinent records, (e.g., animal health records, protocols, and other documents); and
(c) Consulting with appropriate experts.

- The PI responsible for the protocol ordinarily will be provided with notice of the investigation, and an opportunity to provide relevant information to the IACUC. Generally, the investigation will result in a report detailing findings and recommendations, which will be provided to the IACUC Chair and other institutional officials, as appropriate, and reviewed at the next convened IACUC meeting for further determination of actions. The report will typically include:
  (a) A description of the concern(s);
  (b) A summary of interviews that were conducted;
  (c) The condition of the animals and their environment;
  (d) The results of document reviews;
  (e) Copies of all supporting documentation including correspondences, reports, animal records, and any other pertinent materials; and
  (f) Conclusions regarding the substance of the concerns vis-à-vis requirements of the AWRs, the PHS Policy, the Guide, institutional policies and procedures, and recommended actions, if appropriate.

6. The Chair of the IACUC and the Director of ORIA will review the report that will be sent to a convened meeting of the IACUC. The IACUC will determine subsequent actions that are required, including notifications or reporting (either internal or external). The following categories of actions are possible:

- No credible concern related to noncompliance or animal welfare
  (a) Close the report with No action: If the IACUC determines that no further action such as reporting or follow up is required, the discussion is documented in the minutes of the IACUC meeting. No further action is taken.

- Confirmed case of non-compliance and/or animal welfare
  (a) No further investigation required: If the IACUC determines that the incident constitutes serious non-compliance or an unresolved animal welfare concern, and that no further investigation is needed to determine causes and corrective actions, it may make a decision based on the information provided in the report. Please refer to the section “Outcomes and final actions” (Section C below) for possible courses of action that the IACUC may take.

- Incomplete or insufficient information to make a determination
  (a) Further investigation required: If deemed necessary by the IACUC, the Chair, a subcommittee or an individual appointed by the Chair will conduct a further investigation of the facts and circumstances related to the incident and report back to the IACUC by an assigned completion date. Special care will be taken to avoid actual or perceived conflicts of interest during this process.

C. Outcomes and final actions

1. The IACUC shall review all reports from the investigation or initial report (in cases where further investigation was not required) and any information provided by the PI before reaching a decision. After evaluating these materials, the IACUC may request additional information and/or take action with respect to the investigation, including but not limited to the following:

- Dismissal of the complaint/concern;
• Requirement of submission and approval of a protocol amendment, or placement of specific additional conditions or stipulations on the protocol;
• Imposition of specific remedial education and training for the PI and/or other personnel listed under the protocol;
• Monitoring research, testing, or training that involves animals;
• Temporary revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;
• Issuing letters of reprimand;
• Restricting research practices, such as limiting the PI to conduct studies with certain procedures, or conduct of research under supervision;
• Suspension of approval for one or more of the PI’s studies and establishment of conditions for reinstatement;
• Termination of approval for one or more of the PI’s studies;
• Permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals; and
• Recommendation to the Institutional Official that institutional sanctions (e.g., reassignment, suspension or termination of employment) be imposed.

2. The IACUC will notify the PI in writing of any action taken by the IACUC and the reasons for that action. In addition, the IACUC will notify, as it deems appropriate:
• Other investigators or collaborating organizations involved in the animal care and use activities that were the subject of the investigation;
• The PI’s department head (and any additional department heads where the PI holds multiple professional appointments);
• Any additional departments involved in the project;
• The Institutional Official (who will contact any additional institutional authorities) and other pertinent program officials as required (such as appropriate supervisory and management staff, the public affairs office, the compliance office, the office of the general counsel);
• Any funding, regulatory or accreditation agencies, as required.

3. The PI may elect to provide a written response to the final report to the Chair of the IACUC if he/she chooses to appeal the IACUC decision or present further information related to the incident.

D. Suspension of Protocol
1. As indicated above, the IACUC is empowered to suspend a protocol if it finds violations of the PHS Policy or Assurance, the Guide, or Animal Welfare Act or Regulations. Suspension may occur only after review of the matter at a convened IACUC meeting with quorum, and with a vote for suspension from a majority of the quorum present. In addition, the PI may (and in appropriate cases will be encouraged to) agree to voluntarily suspend his/her protocol pending review by the IACUC. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW, funding agencies, collaborating organizations, and/or the USDA APHIS, as required. At the time of suspension of a protocol, the IACUC will vote on terms for reactivation of the protocol. The IACUC may vote for the IACUC Chair to be empowered to reactivate the protocol at his/her discretion or it can vote that the Committee itself must approve reactivation. Protocols will be reactivated only after violations have been corrected.
E. Reporting noncompliance, deviations from the Guide and suspensions
1. Circumstances that must be reported to OLAW by the Institutional Official, are:
   - serious or continuing noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals ("the PHS Policy");
   - serious deviations from the NRC-ILAR’s Guide for the Care and Use of Laboratory Animals ("the Guide"); and
   - suspensions of protocols by the IACUC.

F. Allowable charges to NIH grants during periods of non-compliance
1. “The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. ([https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html))” Therefore, if the incident relates to conduct of non-approved procedures on a protocol that is supported with NIH funding, charges to the grant related to the animal activities involving the incident will require removal. The PI and facility staff will determine the dollar amount that will be credited to the funding allocation. The IACUC office will work with Sponsored Financial Services (SFS) and the PI to process the financial transaction and will submit a report to NIH, as required.

3) Regulatory Mandates and Guidelines

A. Federal Requirements Regarding the Reporting of Animal Care and Use Concerns: USDA – Animal Welfare (9 CFR Ch.1)
1. Part 2 - Subpart C 2.31 (c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility shall:
   - (4) 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 noncompliance received from laboratory or research facility personnel or employees;
2. 2.31 (d)
   - (6) The IACUC may suspend an activity that it previously approved if it determines that an 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;
   - (7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any federal agency funding that activity.
3. 2.32 Training and Instruction of personnel must include
   - (4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care are treatment reported by any employee of the facility. No facility employee, Committee members, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations or standards under the Act.
4. 2.33
   - (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. (USDA provides the authority and responsibility to the attending veterinarian to temporarily suspend an activity involving animals.)

B. Public Health Service (Implementation of Public Law 99-158)
   1. B. Functions of the IACUC
      - 4. Review concerns involving the care and use of animals at the Institution;
   2. C. IACUC Review of PHS-conducted or Supported Research Projects
      - 6. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a-g of this Policy. The IACUC may suspend an activity only after a 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.
      - 7. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW
   3. F. Reporting Requirements
      - 3. The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this Policy; b. any serious deviation from the provisions of the Guide; c. any suspension of an activity by the IACUC.

C. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals
   2. Examples of reportable situations:
      - conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
      - conduct of animal-related activities without appropriate IACUC review and approval;
      - failure to adhere to IACUC-approved protocols;
      - implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
      - conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
      - conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
      - conduct of official IACUC business during a period of time that the Committee is improperly constituted;
      - failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
      - chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;
participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;

- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);

- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);

- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO2);

- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or

- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.

3. OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the Guide. OLAW offers the following examples of situations which may not meet the threshold for reporting, based on consideration of the circumstances by the IACUC. Examples of situations not normally required to be reported:

- death of animals that have reached the end of their natural life spans;

- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;

- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;

- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or

- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).