REPORTING NONCOMPLIANCE

Scope

One of the basic functions of the IACUC, as specified in the USDA Regulations, 9 CFR Part 2, Subpart C, Section 2.31 (c)(4), is to "review and, if warranted, investigate concerns involving the care and use of animals at the facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees". Also required under 9 CFR Part 2, Subpart C, is training of personnel in the "methods whereby deficiencies in animal care and treatment are reported including deficiencies in animal care and treatment reported by any employee of the facility." The institution should have established procedures for reporting, receiving and handling allegations of animal mistreatment or other noncompliance. This SOP establishes the IACUC procedures to receive, investigate, and make determinations of corrective actions/sanctions with respect to allegations of noncompliance with federal regulations, the Guide for the Care and Use of Laboratory Animals, or any approved protocol, policy, procedure or directive of the IACUC.

Procedure

a) Reporting Concerns

The Animal Care and Use Committee (IACUC) at the University of Pittsburgh investigates all concerns regarding the care, treatment, and use of animals for research or teaching at the university. To report a concern, please contact any or all of the following:

Dr. Frank Jenkins, Chair, IACUC	**fjenkins@pitt.edu**	**412-623-3233**
Dr. Denise Capozzi, Director, IACUC	**dcapozzi@pitt.edu**	**412-383-2009**
Dr. David Schabdach, Senior Executive Director, DLAR and Attending Veterinarian		
	dschab@pitt.edu	**412-648-8166**
DLAR Emergency On-Call Veterinarian		**412-917-2340**
University of Pittsburgh Confidential AlertLine		**1-866-858-4456**

Anonymous reports are acceptable, and all are investigated. The identity of anyone making an anonymous report will be held in confidence to the extent possible. The University AlertLine permits complete anonymity in reporting. In addition, federal laws prohibit discrimination or reprisal for reporting violations of standards and regulations promulgated under the Animal Welfare Act.

b) Receiving and Handling Allegations

Reports of concerns involving the care and use of animals submitted to one of the above listed individuals will be sent to the IACUC Office and immediately distributed to the IACUC Chair, University Veterinarian, IACUC Director, and the Compliance Officer. The University Veterinarian, a designee, or the Compliance Officer will investigate the allegation as soon as possible to ensure that the health and well-being of the involved animals are not compromised. The IACUC Director will refer allegations related to biological, chemical, or radiological safety of University personnel to the appropriate University office.

The University Veterinarian, or designee, or Compliance Officer shall remedy immediately any identified problems that negatively impact the health or welfare of animals. Deficiencies compromising the immediate health and well-being of humans involved in the incident will be remedied immediately by the appropriate University official.

Based on a report of noncompliance, the Institutional Official may suspend a protocol immediately if the circumstances so warrant. This action will be reviewed at the next convened meeting of the IACUC at which a quorum is present.

The University Veterinarian, the Institutional Official, and, as designated by the Institutional Official, the Compliance Officer, are authorized to suspend further conduct of all or any portion of animal subject research upon the identification of significant animal welfare concerns and/or significant noncompliance with the respective IACUC-approved protocol or institutional policies. This suspension shall remain in effect until such time that the convened IACUC has formally addressed the matter.

Following resolution of any immediate animal welfare concerns, the Compliance Officer will thoroughly investigate all aspects of the allegation and prepare a written incident report. A copy of the incident report will be sent to the involved principal investigator (PI) with the request that the PI submit his/her response regarding the identified problems to the IACUC. The IACUC Executive Committee will review the report at its next regularly scheduled meeting and will ascertain the completeness of the investigation and will develop recommendations for corrective actions and, if warranted, sanctions for subsequent presentation at the next convened meeting of the IACUC.

At its convened meeting, the IACUC shall:

- Review the incident report and discuss the allegations with the investigator(s) involved.
- Substantiate the validity of the allegation by a majority opinion of the IACUC.
- Record a listing of noncompliance issues.
- Decide on the response to the originator of the allegation.
- Decide on reporting the noncompliance issues to relevant regulatory agencies.
- Determine appropriate sanctions and/or additional corrective actions for the investigator.

The minutes of the IACUC meeting will record these actions.

The IACUC Chair will send a letter to the Institutional Official (IO) delineating the noncompliance issues and the recommended corrective actions/sanctions. The Institutional Official, in consultation with the IACUC, may impose further corrective actions/sanctions for the investigator or support the IACUC's recommended corrective actions/sanctions.

The IACUC Chair will send a letter to the investigator describing the noncompliance issues and the required corrective actions/sanctions, with related deadlines, prescribed by the IACUC. The letter will also inform the investigator of his/her option to appeal the decision by writing the IACUC Chair,

within 10 days of receipt of this letter, detailing the basis of the appeal and requesting a second meeting with the IACUC.

The IACUC Chair will also inform the originator of the allegation of the IACUC's disposition of the allegation.

c) Determination of Corrective Actions/Sanctions

All issues reported to the University of Pittsburgh IACUC involving known or suspected noncompliance with federal regulations and /or IACUC requirements or determinations governing animal research is submitted for review by the IACUC as described above. If the IACUC, by majority vote, finds the allegations have merit and represent noncompliance the following guidelines will be used to determine corrective actions/sanctions:

For Serious or Continuous Noncompliance Issues
Acts of noncompliance are deemed serious if they impact, or have the potential to impact, the health, safety or well-being of animals or personnel. If the IACUC determines that the reported problem represents serious or continuing noncompliance with federal regulations and/or IACUC requirements or determinations it may institute one or more of the following sanctions:

- Termination of the IACUC approval of the respective research protocol.
- Suspension of the IACUC approval of the respective research protocol.
- Suspension of an animal research-related activity.
- Suspension of further animal orders for the research study.
- Suspension of animal-use privileges of the investigator or any listed co-investigator for a duration and under conditions determined by the IACUC.
- Institution of an IACUC-mandated corrective action plan.
- Levy a monetary fine.
- Take such other action as the IACUC deems appropriate.

Termination and Suspension
Serious or repeat noncompliances may result in the termination of the applicable protocol or the suspension of the protocol or an animal research-related activity described in the protocol. A previously-approved research **protocol** may be Terminated or Suspended by:

- a vote by a quorum of voting IACUC members;
- the Institutional Official, in consultation with the IACUC.

Animal research-related activities may be suspended if the activity if found to produce harm or potential harm to animals or research personnel, if the activity may result in pain or distress, or if the activity otherwise threatens the welfare of research animals. Any **animal research-related activity** described in an investigator's IACUC protocol may be suspended by:

- a vote by a quorum of voting IACUC members;
- the Institutional Official;
- The IACUC Chair, in consultation with the Institutional Official;

- The University Veterinarian, in consultation with the Institutional Official and the IACUC Chair;
- The Compliance Officer, in consultation with the Institutional Official and the IACUC Chair.

Upon the termination or suspension of a protocol, all animal-based research described in the protocol must cease immediately, and the animals may not be accessed or manipulated except by animal facility personnel for the purpose of providing food, water, and standard enrichment for the species. If an animal research-related activity is suspended, only the suspended activity must immediately cease. Failure to comply with a termination or suspension constitutes work not approved by the IACUC and will be considered a further instance of noncompliance.

More serious noncompliance circumstances may necessitate revoking an investigator's animal-use privileges at the University. This action may be taken against a single investigator or an entire research group, at the IACUC's discretion. This requires a vote by a quorum of voting IACUC members. The length of suspension may be a set length of time or until a set of conditions is met, also at the IACUC's discretion, as the circumstances dictate.

Terminated protocols may not be resumed. Suspended protocols or research-related activities may be re-activated only via a vote by a quorum of voting IACUC members, though the IACUC may stipulate the conditions under which the suspension will be lifted during the initial vote to suspend.

The decision to terminate or suspend a research protocol or animal research-related activity and the reason(s) for the decision will be reported, within one week of the decision, to the Institutional Official, the NIH/OLAW and, if applicable the USDA Animal and Plant Health Inspection Service and any Federal agency funding the study.

Reporting Noncompliance to PHS/OLAW

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.F, paragraph 3, identifies three areas that require prompt reporting to the Office of Laboratory Animal Welfare (OLAW):

- any serious or continuing noncompliance with the PHS Policy;
- any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*; and
- any suspension of an activity by the IACUC. The determination that a problem falls within the meaning of either a) or b) requires a degree of judgment by the IACUC.

The language used in the Policy was chosen purposely to permit the judicious application of professional judgment by the IACUC in determining what incidents should be considered serious and reportable to OLAW. In an effort to assist IACUCs in making such judgments, OLAW offers the following examples of occurrences that they have determined meet these reporting criteria:

a) Serious or continuing noncompliance with the PHS Policy, such as:
    - Failure to correct situations identified in previous semiannual evaluations as significant deficiencies.

- Conducting animal-related activities without appropriate IACUC review and approval.
- Failure of animal care and use personnel to adhere to IACUC-reviewed and approved institutional policies and procedures.

b) Serious deviation from the provisions of the *Guide*, such as:
   - Conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals.
   - Shortcomings in programs of veterinary care, occupational health or training, identified during semiannual program review and not corrected within institutionally determined time frame.

c) Suspension of an activity by the IACUC, the Institutional Official, IACUC Chair, or University Veterinarian:
   - Any IACUC intervention that results in the temporary or permanent interruption of an activity involving animals.

NOTE: SERIOUS NONCOMPLIANCE WITH THE PHS POLICY AND DEVIATIONS FROM THE GUIDE MUST BE REPORTED TO OLAW, EVEN IF IDENTIFIED INITIALLY BY OTHER AGENCIES, SITE VISITORS OR CONSULTANTS.

Reporting Noncompliance to USDA/APHIS

The Animal Welfare Act Regulations (AWAR) requires prompt reporting to APHIS when the IACUC suspends (or terminates) all or part of an investigator's protocol, even if the suspension is temporary (2.31,d,7). This regulation is applicable to all AWAR-covered species, which are warm-blooded vertebrate animals. Purpose bred mice and rats and wild-caught birds used for research purposes are exempted from this requirement, as the use of these animals is not regulated by the AWAR.

The IACUC will also report to the USDA any noncompliance involving AWAR-covered species that is also reported to PHS/OLAW.

Minor Noncompliance Issues

Acts of noncompliance are deemed minor if they do not affect the health, safety or well-being of animals or personnel and they do not represent a serious disregard of laws, regulations and policies applicable to animal research. If the IACUC determines that the reported problem represents a minor noncompliance with federal regulations and /or IACUC requirements or determinations it may, in consideration of the nature of the research study and the reported problem take one or more of the following actions:

- Elect to make corrective actions only.

- Provide a verbal and/or written listing of the issue of noncompliance to the investigator and require a corrective action plan at a regular meeting of the IACUC and recording this incident in the IACUC minutes.
- Provide a written listing of the issue of noncompliance to the investigator and requiring a corrective action plan within a specified time period. The letter may or may not be copied to the investigator's department chair depending on the IACUC's decision on the sanction.

d) Requests for Reconsideration

A principal investigator may request that the IACUC reconsider its findings and any sanctions if there is evidence that was not was not considered during the committee's deliberation. The procedure for request for reconsideration of any IACUC decision is as follows:

- The investigator must submit an appeal in writing to the IACUC Office. The appeal must include the details and rationale of the request and must be submitted within ten (10) days of being notified of the IACUC's decision.
- A representative from the IACUC Office will acknowledge receipt of the appeal and forward a copy to the IACUC Chair and the IACUC Director.
- The IACUC Chair will decide if the issue requires full committee review or if it can be addressed by a subcommittee.
- The investigator will be informed of the decision and may be asked to appear before either the full committee or the subcommittee to discuss the request.
- Following any discussion of concerns with the investigator, the IACUC or subcommittee will reconsider the issue.
- A written record of the discussion and reconsideration will be made.
- A summary of the written record along with the IACUC's reconsideration decision will be sent to the investigator and the Institutional Official.
- If the investigator is dissatisfied with the result, further reconsideration of the matter may be requested by appealing to the Institutional Official in writing. Such written requests must be filed with the IACUC Office within ten (10) days of the IACUC reconsideration decision being rendered.
- The Institutional Official will meet with the IACUC or subcommittee for further discussion, if warranted.
- A written record will be made of the meeting between the IACUC and the Institutional Official and a summary provided to the investigator along with the final decision on the issue.

APPROVAL

The University of Pittsburgh's Institutional Animal Care and Use Committee has reviewed and approved this Policy as attested by the signature of the Committee Chairperson.

Frank J. Jenkins, PhD _____
IACUC Chairperson **Date**