

IACUC MANUAL

Revised 10/2025

IACUC Office 412-383-2008

e-mail: iacuc@pitt.edu www.iacuc.pitt.edu

Dr. Deborah L. Chapman

Chair, Institutional Animal Care and Use Committee dlc7@pitt.edu
(412) 624-0774

Mr. Jeremy S. DeRicco

Director, Division of Animal Research Protection
Animal Care Compliance Officer jsd71@pitt.edu
(412) 383-2009

Mr. Michael C. Kessler

Director of Regulatory Affairs
Division of Animal Research Protection
mckessle@pitt.edu
(412) 383-2018

Dr. Amy Cassano

Attending Veterinarian cassano@pitt.edu
(412) 648-8166

Table of Contents

About this Handbook	3
Institutional Animal Care and Use Committee	3
The University of Pittsburgh IACUC	4-8
Subcommittees	
IACUC Reporting Structure	
IACUC Roles and Responsibilities	
Division of Animal Research Protection (ARP)	
Meetings	
Program Evaluation	9-10
Facilities Inspection	
Animal Welfare Concerns	11-16
Receiving and Handling Allegations	
Determination of Corrective Actions and Sanctions	
Requests for Reconsideration	
Protocol Review and Approval	17-23
Protocol Application Process	
Full Committee Review	
Committee Decisions	
Other Committees	
Protocol Modifications	
Post-Approval Monitoring	
Approval of Work Performed Outside the University	24-27
Collaborations with Other Institutions	
Animal Work Contracted with a Company	
Appropriate Modification of Protocol	
Requests for Exemption	
Personnel Training	27
External Program Review	28-31
NIH	
USDA	
AAALAC International	

About this Handbook

Maintaining humane animal care in research and teaching is a dynamic endeavor and requires conscientious interpretation of animal welfare regulations. This Handbook explains the regulations, guidelines and processes involved when performing animal-based research at the University of Pittsburgh. While this Handbook addresses a wide range of matters that warrant the concern, attention, and thoughtful interpretation by the research community, it claims neither to be exhaustive nor definitive, nor can it possibly address the inevitable variations among actual cases that will arise.

If you have a question or concern that is not addressed in this handbook, please contact one of the officers named on the handbook's cover.

Institutional Animal Care and Use Committee

Institutional Animal Care and Use Committees (IACUCs) are self-regulating entities that, according to U.S. federal law, must be established by institutions that use laboratory animals for research or instructional purposes. Such committees are mandated by law to oversee and evaluate all aspects of an institution's animal care and use program.

Two agencies of the US Government require the appointment of an IACUC: The United State Department of Agriculture (USDA) requires an IACUC at any institution that uses animals covered under the Animal Welfare Act, and the Public Health Service (PHS) requires an IACUC at any institution that conducts PHS-supported research involving live vertebrate animals.

Section IV.A.3.b. of the PHS Policy addresses the compositional requirements of an IACUC. The Policy states that the committee must consist of not less than five members, and include at least:

- one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution
- one practicing scientist experienced in research involving animals
- one member whose primary concerns are in a non-scientific area (for example, ethicist, lawyer, member of the clergy) and
- one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution

No more than three regular, voting members may represent the same department or administrative unit.

The University of Pittsburgh IACUC

The University of Pittsburgh has established an IACUC, which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and policies. The Institutional Official (IO), the Vice Chancellor for Research Protections, has been designated by the Chancellor to appoint its membership and endorse its authority.

The IACUC consists of voting members and ad-hoc non-voting members (consultants), representing many university departments. Ad-hoc non-voting members provide consultation expertise to the committee, particularly in the areas of veterinary medicine and occupational health and safety. Faculty members have volunteered their time to serve on the committee. University of Pittsburgh personnel interested in being members of the IACUC should contact the Animal Research Protection (ARP) office.

Subcommittees

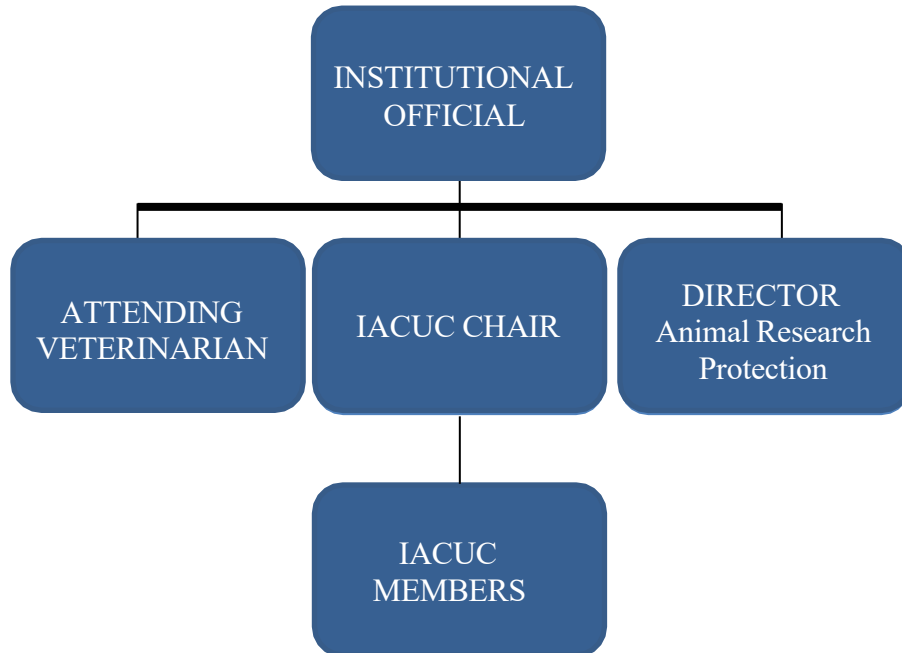
For the purpose of protocol review, the IACUC is divided into four subcommittees: three for the review of rodent and aquatics protocols, and one for the review of large animals and nonhuman primates. The large volume of rodent work at the university necessitates three rodent-specific subcommittees. Each subcommittee consists of several faculty members and veterinarians that are assigned to the subcommittee by the IACUC Chair.

An Executive Committee exists for the purpose of reviewing IACUC issues, such as incidents of noncompliance, and for making recommendation to the IACUC on how to respond to such incidents. The Executive Committee is composed of the IACUC Chair, Vice-Chairs, the Attending Veterinarian, the ARP Director and Compliance Officer, the Director of Regulatory Affairs of the ARP office, and other ad-hoc members.

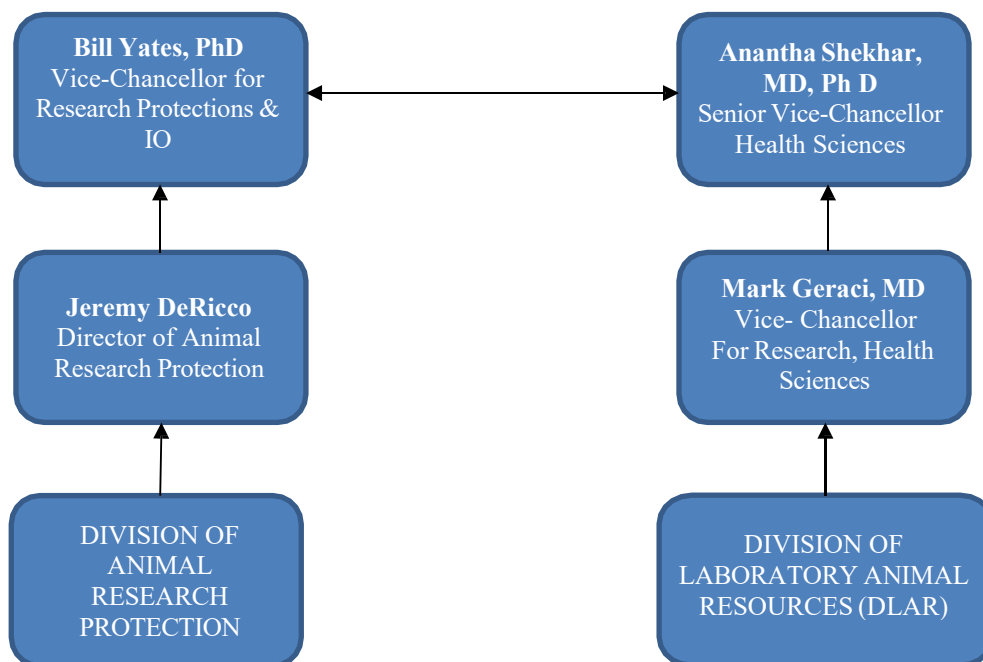
Specialty subcommittees are formed by the IACUC when the need arises.

IACUC Reporting Structure

Functionally, the IACUC Chair/IACUC (through the Chair), Attending Veterinarian and the Director of ARP office report directly to the IO, Dr. Bill Yates, Vice- Chancellor for Research Protections, by the following scheme:



Administratively, as the following scheme illustrates, the Division of ARP office staff report to the Vice Chancellor for Research Protections via the ARP Director. The veterinary/animal care staff of the Division of Laboratory Animal Resources (DLAR) report to the Sr. Vice Chancellor, Health Sciences, via the Associate Vice-Chancellor, Health Sciences.



IACUC ROLES AND RESPONSIBILITIES

The IACUC, as an agent of the University of Pittsburgh, is charged with several responsibilities that this handbook explains in the pages that follow. In brief, they are:

- **Program Evaluation.** The review of the University's animal program every six months, using the current *Guide for the Care and Use of Laboratory Animals* as a basis for evaluation.
- **Facilities Inspection.** The inspection of the University's animal facilities (including satellite facilities and investigator-managed housing facilities and use sites) every six months, using the *Guide* as a basis for evaluation.
- **Animal Welfare Concerns.** The review of concerns involving the care and use of animals at the university.
- **Program Improvement.** The formulation of recommendations to the IO regarding the university's animal program, facilities, or personnel.
- **Protocol Review and Approval.** The review and approval of activities related to the care and use of animals and proposed significant changes to ongoing approved activities at the University. Likewise, the IACUC is authorized to require modifications to proposed activities and, in consultation with the IO, to suspend ongoing activities involving animals and report the action to the NIH Office of Laboratory Animal Welfare (OLAW).
- **Personnel Training.** The IACUC ensures that all personnel involved with animal care, treatment or use are provided with training on applicable University policies concerning research integrity, occupational health and safety, IACUC function, species-specific animal use, humane practices and the concept, availability and use of research, teaching or testing methods that replace, reduce, or refine the use of animals or animal distress.
- **Reporting.** The submission of reports of IACUC activities to the IO, OLAW and accreditation agencies.

Division of Animal Research Protection (ARP)

The main function of the Division of Animal Research Protections Office is to facilitate the interaction between the IACUC and the research community at the University, to maintain accurate records of research protocols, and to verify compliance with applicable animal welfare regulations. In addition, the office personnel are a resource to faculty seeking advice on regulatory and animal welfare issues. They are available to assist investigators in maintaining compliance with federal, granting agency, and University animal welfare regulations.

The ARP is responsible for maintaining the following records:

- OLAW Assurance documentation
- Minutes of IACUC meetings
- Records of IACUC activities and deliberations

- Minority IACUC views
- Documentation of protocols reviewed by the IACUC, and proposed significant changes to protocols
- IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction
- Accrediting body and USDA determinations.

All records are kept for a minimum of three years, apart from records that relate directly to protocols which must be kept for the duration of the activity and for an additional three years after completion of the activity. Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the *Guide* and with commonly accepted professional standards.

Meetings

The IACUC meets on the third Monday of each month unless precluded by a holiday. IACUC business may only proceed with the attendance of a quorum, which consists of one more than half of the number of voting members. The meeting is divided into two segments. The first segment is the IACUC protocol review meeting where issues concerning protocols being considered for full committee review (see Protocol Review Process below) are discussed. The second segment is the General IACUC meeting where issues relating to animal care and use at the University are discussed. This is a closed meeting with attendance limited to only members of the IACUC, and, if invited by the IACUC chair, investigators whose protocols are being reviewed or other persons.

The Executive IACUC meets monthly on the first Monday of the month unless precluded by a holiday. This is a closed meeting.

Minutes of the IACUC Full Committee meetings are kept by the ARP Office and are made available for review to the pertinent regulatory agencies, as required.

Program Evaluation

PHS Policy and USDA Regulations require that the IACUC conduct semi-annual evaluations of the animal care and use program. Key aspects of this evaluation include IACUC functions and procedures, protocol review practices, provisions for dealing with reports of non-compliance or other concerns regarding animal care and use, and the procedures employed to meet reporting requirements. In addition, the institution's occupational health program, veterinary care procedures and personnel qualification review process are evaluated.

Program evaluation deals principally with administrative aspects of the animal care and use program. Ongoing review of established practices allows the opportunity for the IACUC to detect changes in operating procedures from those published (such as in this manual), thereby allowing revisions to one or the other, as appropriate. The program review is assigned to the IACUC Chair and Vice Chairs or their designees. The Semiannual Program and Facility Review Checklist is used for guidance.

The IACUC will review and approve a draft report. Deficiencies identified are categorized as minor or significant. Information from the draft report is sent to the supervisors responsible for the areas cited and corrective action plans, including a timetable, are requested for all deficiencies.

Facilities Inspection

PHS Policy and USDA Regulations require the IACUC to inspect all University of Pittsburgh animal facilities every six months. This includes all DLAR animal facilities, animal facilities managed by other University departments and all locations outside the DLAR where animals are housed or taken, including the Dietrich School of Arts & Science. These inspections provide an ongoing mechanism for ensuring that the university maintains compliance with applicable animal care and use policies, guidelines, and laws. The inspections also benefit the program for animal care by serving as an educational opportunity for animal care personnel, research staff and IACUC members. The interaction of the IACUC and the animal care personnel at the University of Pittsburgh is to be constructive, and not adversarial, as both ultimately share the same goals of responsible animal care.

Before the inspections commence, IACUC members receive a listing of all facilities to be inspected on specific dates and are asked to sign up for inspections. When applicable, at least two IACUC members inspect each facility, as required by USDA Regulations. No IACUC members wishing to attend a particular inspection are excluded, and additional ad hoc consultants may be requested, if necessary. The inspection team must have a working knowledge of the *Guide* and USDA Regulations to perform effective evaluations. In addition, each IACUC member can avail themselves to the Semiannual Program and Facility Review Checklist.

USDA Regulations require inspection of all other animal containment facilities in which

animals are held longer than twelve hours, while PHS Policy requires inspection of all surgical facilities and areas in which animals are maintained longer than 24 hours. The ARP office maintains a list of all such facilities. These facilities are also inspected every six months. The inspection criteria are the same as used in DLAR facilities.

The ARP office notifies the supervisory personnel of housing facilities and animal-use sites to be inspected of the date and time of an inspection. Advance notification allows individuals to be available to answer questions. Apparent deficiencies are discussed with the person in charge of the facility to ensure the accuracy of the team's findings.

ARP prepares a draft report after the visit, noting any deficiencies which are categorized as minor or significant. USDA Regulations and PHS Policy define a significant deficiency as one of significant threat to animal health or safety. Copies of the draft report are sent to the supervisors responsible for the areas cited and DLAR leadership. ARP requests a corrective action plan for all deficiencies found during the inspection. Deficiencies and corrective action plans are presented to the IACUC during one of the monthly IACUC meetings. The following tabular format is used:

SITE
DATE OF VISIT
VISITORS COMMENTS / DEFICIENCIES
CORRECTIONS

The IACUC reviews the report to verify that all comments have been reported and that the corrective actions planned are adequate. The IACUC Chair and ARP Director then use this information to prepare the semi-annual report to the IO on the status of the animal care and use facilities at the University of Pittsburgh. When applicable, if the institution is unable to meet the corrective action plans proposed in the semi-annual report, the IACUC, through the IO, must inform Animal and Plant Health Inspection Service (APHIS) officials within fifteen working days of the lapsed deadline. If the activity is federally-funded, the relevant agency also must be informed.

Animal Welfare Concerns

The IACUC 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. Deborah L. Chapman, Chair, IACUC	dlc7@pitt.edu	412-624-0774
Mr. Jeremy DeRicco, Director, ARP	jsd71@pitt.edu	412-383-2009
Dr. Amy Cassano, Attending Veterinarian	cassano@pitt.edu	412-624-1180

DLAR Emergency On-Call Veterinarian	412-624-VETS	(8387)
Pitt Concern Connection (Confidential)	1-800-468-5768	
https://www.iacuc.pitt.edu/report-concerns		

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 Pitt Concern Connection 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.

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 ARP Office and immediately distributed to the IACUC Chair, Attending Veterinarian, ARP Director/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 ARP Director will refer allegations related to biological, chemical, or radiological safety of University personnel to the appropriate University office.

The Attending 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 IO 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 Attending Veterinarian, the IO, or by vote by a quorum of the full IACUC committee, 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 ARP office 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 IACUC meeting.

At its convened meeting, the IACUC shall:

- Review the incident report and discuss the allegations with the PI(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 IO delineating the noncompliance issues and the recommended corrective actions/sanctions. The IO, 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 PI describing the noncompliance issue(s) and the required corrective actions/sanctions, with related deadlines, prescribed by the IACUC. The letter will also inform the PI 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.

Unless the originator of the allegation wishes to remain anonymous, the IACUC Chair, ARP Director or the Compliance Officer will also inform the originator of the IACUC's disposition of the allegation.

Determination of Corrective Actions and 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.
- Take such other action as the IACUC deems appropriate.

Termination and Suspension

Serious or repeat noncompliance 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 IO, in consultation with the IACUC.
- the Attending Veterinarian

Animal research-related activities may be suspended if the activity is 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 outside that described in the approved IACUC protocol. 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 IO
- the IACUC Chair, in consultation with the IO
- the Attending Veterinarian, in consultation with the IO 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 revocation 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 IO, the 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 PHS 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 IO, 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 and non-purpose bred birds. Purpose bred mice, rats and birds used for research purposes are exempted from this requirement, as the use of these animals is not regulated by the AWAR.

For Minor Noncompliance Issues

Acts of noncompliance are deemed minor if they do not impact the health, safety or well-being of animals or personnel. If the IACUC determines that the reported problem represents a minor noncompliance with federal regulations and/or IACUC requirements it may take one or more of the following actions:

- Elect to make corrective action 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 require 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.

Requests for Reconsideration

A principal investigator may request that the IACUC reconsider its findings and any sanctions if there is evidence that 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 Chair or ARP Director. 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.
- The IACUC Chair or ARP Director will acknowledge receipt of the appeal.
- 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 IO.
- If the investigator is dissatisfied with the result, further reconsideration of the matter may be requested by appealing to the IO in writing. Such written requests must be filed with the ARP Director within ten (10) days of the IACUC reconsideration decision being rendered.
- The IO 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 IO and a summary provided to the investigator along with the final decision on the issue.

Protocol Review and Approval

The IACUC is responsible for assuring that the research, husbandry, teaching, and testing programs involving animals at the University of Pittsburgh comply with all applicable regulations and policies and responsibly address concerns regarding animal welfare. To fulfill this responsibility, the IACUC reviews all animal research, teaching and testing procedures. **No animal experimentation or use is permitted at the University of Pittsburgh without written approval by the IACUC.** This requires all animal users at the University to complete a protocol application using the Institution's online protocol management system. This system manages the review process from beginning to end and allows the research team access to the protocol and its state in the review process. The system stores all protocol information in an online database so that the IACUC may accommodate requests for information from the OLAW), the US Department of Agriculture (USDA), and any other regulatory or internal requests.

Protocol Application Process:

Investigators must submit all new IACUC protocol applications via [Animal Research Online](#) (ARO), the IACUC's online protocol management system. A guide for completing online applications can be found on the ARP website. Applications are processed in the order that they are received at the IACUC Office. There are no expedited reviews.

The IACUC Chair oversees the protocol review process. The Chair assigns Designated Member Reviewers to one or more Subcommittees formed to review protocols of certain species. There are three rodent /aquatics subcommittees and one large animal subcommittee. Each subcommittee contains scientific members, nonscientific members, veterinarians, Biorisk, administrative and other individuals, such as a radiation safety reviewer, necessary for the review of any protocol so assigned.

A Coordinator responsible for guiding the protocol through the review process is assigned to each protocol. The Coordinator reviews all applications for accuracy and completeness. Incomplete applications or applications with administrative errors must be returned to the PI for revision before being sent to reviewers. The assigned Coordinator also ensures that all required training for the protocol has been completed by each member of personnel listed on the protocol and will notify the PI of any pending requirements.

Based on the species of the protocol, the Coordinator, using the online protocol management system, sends each protocol application to the five assigned Subcommittee's Designated Member Reviewers (DMR) – two scientific members, one veterinarian, one administrative reviewer and one Biorisk analyst. Initial reviews are expected to be completed in two weeks (10 business days). Reviewers may approve the application, request revisions to or ask questions about the application, or refer the protocol to the full IACUC for review.

Once all Designated Member Reviewers have returned their reviews of the application,

the Coordinator sends any questions to the PI. The PI must answer all questions and revise their application accordingly.

If the PI does not respond to the reviewers' questions after four weeks, a reminder will be sent. If six weeks passes with no response, the IACUC Office may withdraw the protocol from review.

After the PI sends responses (completed review form and appropriately revised protocol) the Coordinator sends the materials back to the IACUC DMR for approval. At this time the reviewers are given 1 week (5 business days) to complete the re-review. This process will continue until all IACUC reviewers have approved the application, at which time the protocol will be approved by the IACUC Chair or Vice-Chairs by electronically signing a letter of approval.

All personnel listed on a protocol must satisfy all IACUC- and Biorisk-mandated training and safety requirements prior to approval.

The entire IACUC receives a weekly listing of new protocols submitted to the IACUC Office. The listing provides the name(s) of the PI(s), the project title, the funding agency, a project description narrative, the species of experimental animal, and the number of animals to be used in the study. Any IACUC member with an interest in a protocol on the list, may request to be assigned as a reviewer and submit a review of the protocol and/or refer it to the full committee for review.

No IACUC member can participate in the IACUC review of a protocol or activity in which that member has a conflicting interest except to provide information requested by the IACUC.

Full Committee Review

If a protocol is referred to the full IACUC, a vote of approval at a convened meeting with quorum present is required for the application to be approved, unless the IACUC votes to refer the application back to the original subcommittee. If the full committee has questions, the decision regarding approval will be tabled until the next convened meeting.

Applications may be referred to the full IACUC for any reason by any IACUC member. Typical reasons for referral to the full committee include:

- Applications including death as an endpoint
- Studies including animal pain or distress that is not scientifically justified
- Requests for >12 hour housing outside of a DLAR-managed facility (such as a laboratory)
- Questions concerning a harm/benefit analysis

The results of the IACUC's deliberations are sent to the PI along with any questions or requirements that must be satisfactorily addressed to grant approval of the application by

the next scheduled committee meeting.

The PI will be notified of the committee's decision following the full committee meeting. If the committee decides not to approve the application, the PI will be informed of the reason for the action.

Committee Decisions

Approval

If the IACUC considers that all significant points have been addressed by the PI and that all questions that have been raised during review have been satisfactorily addressed, the protocol will be approved. Once a protocol has been approved, the PI has permission to conduct the experiments described in the proposal on the number of animals justified.

At the time of approval, the ARP office will generate an approval letter and the IACUC Chair will be informed of the results of the review. The IACUC Chair then verifies that the review was conducted in accordance with all regulations and IACUC policies. If the review is deemed appropriate, the IACUC Chair sends the approval letter electronically. The application is not approved until the IACUC chair has issued an approval.

Approval letters are addressed to the PI for submission and verification to granting agencies to verify IACUC review and approval. They are available for download any time thereafter. A copy of the approved protocol and Risk Assessment, which delineates the hazards associated with the application and the training/medical surveillance requirements, is always available online to all personnel listed on the protocol.

Once the application is approved by either the subcommittee reviewers or the full committee, the IACUC assigns an eight-digit number to the protocol. The first two digits of the protocol number designate the year of approval, the third and fourth digits designate the month of approval and the last four digits identify the application. For example, 24020033, indicates the application was approved in February of 2024 and assigned number 0033.

IACUC protocol approval is provided for a period of three years, as specified by PHS Policy IV C 5. This policy requires *de novo* review of the protocol after three years. Protocols that have not significantly changed in the three years since their original submission can be easily resubmitted for review through the ARO online system.

Disapproval

If a PI refuses to modify a proposal in accordance with the full IACUC's directions or fails to supply information showing that their laboratory has appropriate facilities and staff for the proposed research, the full IACUC may, at a convened meeting with a quorum present, decide not to approve the protocol. The specific reasons for disapproval will be presented to the PI in writing.

Appeals of a decision not to approve an application may be submitted to the IACUC Chair. Appeals must include additional evidence that was not previously made available or the

solicitation of experts able to assist the IACUC in their deliberations.

Disapproved proposals cannot be administratively approved by a higher authority. However, an IACUC-approved protocol can be administratively disapproved due to financial, facility-related or other considerations.

Termination

The IACUC may terminate an approved protocol due to the following reasons:

- Non-compliance issues (see **Receiving and Handling Allegations**)
- Failure to complete required training

Withdrawal

The IACUC may withdraw any pending protocol from the review process if the PI does not respond in a timely fashion during the review process. This occurs when questions are sent to the PI and the PI takes longer than 2 months to respond. The ARP Office will send a notice to the PI that the protocol will be withdrawn from the review process if a response is not forthcoming. The ARP Office may also withdraw applications for review if any training requirements are not satisfied in a timely manner.

Other Committees

Some protocols may require the approval of other committees within the Office of Research Protections (ORP) before the IACUC will issue a final approval or before animals may be obtained, even if all the reviewers and/or the full IACUC has approved it. The following conditions always hold:

- If the PI identifies a conflict of interest in the protocol, the Conflict of Interest Office must issue its approval before the IACUC protocol will be approved.
- If the application describes the use of human stem cells, the Human Stem Cell Research Oversight Committee (hSCRO) must issue its approval before the IACUC protocol will be approved.
- If the application describes the use of genetic engineering, including rDNA use or the breeding of transgenic animals, approval from the Institutional Biosafety Committee (IBC) must be secured before animals may be obtained.
- Applications making use of the Regional Biosafety Laboratory (RBL) must submit an RBL Pre-Project form prior to IACUC submission. To obtain this form, contact the Center for Vaccine Research, info@cvr.pitt.edu.

Protocol Modifications

Both the AWA and PHS Policy require that the IACUC review and approve, prior to initiation, proposed modifications to ongoing activities using animals. Modifications are submitted to the IACUC through the online protocol management system. All modification requests are reviewed using the same process and have the same requirements. The

following modifications cannot be requested using this process:

- Changing the species used
- Adding procedures that do not logically relate to the specific aims of the original protocol
- An unrelated change in the scientific aims of the original protocol application
- Switching from non-survival to survival surgery
- Switching from single to multiple survival surgeries.

A new protocol application must be submitted to incorporate any of the above changes, because the IACUC is required to review new issues arising related to animal welfare. Any changes to an IACUC protocol that present animal welfare issues not addressed in the original protocol will require the submission of a new protocol. The new protocol submission is required to address how all animal welfare issues will be mediated.

Two types of modifications are recognized. An Administrative Modification is an addition or deletion of personnel, protocol title changes or additional protocol titles, a change in the funding source, a change in the animal source or vendor, a request for animal housing or use outside the Institution that meets established IACUC requirements or a request for additional animal strains that do not require additional husbandry or housing considerations beyond those in the approved protocol. Administrative Modifications are reviewed by ARP Office personnel, and if appropriate changes have been made to the protocol and records, they grant approval usually within two to three business days. Requests for additional personnel require that the new personnel satisfy all IACUC and EH&S mandated training and safety requirements prior to approval.

Distress Category, requests to use additional test agent(s), and other changes that logically relate to the specific aims of the original protocol application require that the Investigator clearly explain why the modification is being requested and how it relates to the original specific aims of the previously approved protocol.

Other acceptable modifications to an IACUC-approved protocol include: changes in anesthetic or the analgesic agents, changes in euthanasia method(s), changes in any surgical procedures or addition of a surgical procedure, requests for additional animals, changes in nonsurgical procedures involving animals, changes in the animal strain, any changes that will affect the previously approved USDA Pain/Distress Category, requests to use additional test agent(s), and other changes that logically relate to the specific aims of the original protocol application.

The Investigator must clearly explain why the modification is being requested and how it relates to the original specific aims of the previously approved protocol.

Modifications are reviewed using nearly the same process as new protocols. The modification request is assigned to the species-appropriate Subcommittee and is reviewed by at least four Designated Member Reviewers: 1 scientific member, 1 veterinarian, a Biorisk analyst, and an administrative reviewer. The reviewers are given 2

weeks (10 business days) to review the modification. Questions and answers circulate between the reviewers and PI. After all issues have been resolved, and all reviewers have issued an approval, the request is approved and, after review by the IACUC Chair, an approval letter is issued. The approved protocol, with all approved changes integrated, is then available through the online protocol management system.

Certain modifications are administratively flagged for full committee review, such as modifications involving death as an endpoint or those with animal welfare concerns.

Post-Approval Monitoring

As part of the IACUC's responsibility to oversee and evaluate the institution's animal program, the ARP office conducts protocol audits. These audits provide an ongoing mechanism for ensuring that the University maintains compliance with the applicable animal care and use policies, guidelines, and laws. The audits also benefit the program for animal care by serving as an educational opportunity for the animal care personnel, research staff and IACUC members. The audit procedure is conducted with an IACUC member using the following procedures:

Study Selection

Semi-annually the ARP may submit a list of studies selected for audit to the Executive IACUC for review and approval. Studies may also be selected at random or for-cause audit. Once a list of protocols to be audited has been identified, a time is set, in consultation with the Investigator and IACUC member, for the audit to take place.

Protocol Review

The protocol, including all approved modifications, as well as the questions asked during the review process, is reviewed by the audit team. The protocol review serves to compare animal care and use issues described in the protocol with actual procedures performed in the laboratory and described in research logs. In addition, the protocol review audits the workings of the IACUC protocol approval process.

Study Audit

The research team must have knowledge of the IACUC-approved protocol, particularly the specific procedures in which they are involved. The audits are intended to verify that the study meets the following requirements:

- Procedures with animals avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- Procedures that may cause more than momentary or slight pain or distress to the animals are performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved are painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- The living conditions of animals are appropriate for their species and contribute to

their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

- Medical care for animals is available and provided as necessary by a qualified veterinarian.
- Personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in those procedures.
- Methods of euthanasia used are consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

Audit Report

Following the audit, the ARP office collects all issues and comments for preparation of any corrective actions, which may include a request to modify the protocol or sanction by the IACUC. Audit reports may be incorporated into the Semi-Annual Report.

Approval of Work Performed Outside the University

There are many circumstances that involve partnerships between collaborating institutions or relationships between institutional animal care programs. There are also many instances of work contracted from an institution with a company involving the use of live animals.

Collaborations with Other Institutions

OLAW and APHIS agree that, in cases of collaborations between institutions, individual research projects need not be reviewed and approved by more than one IACUC. It is, however, imperative that institutions define their respective responsibilities. If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees.

The IACUC requires that the Pitt PI notify the ARP Office before work commences. The requirements below represent the IACUC's responsibilities and policies.

For animal work performed at a collaborating institution, the Pitt IACUC requires:

- The performing institution must have a PHS Assurance.
- The performing institution must be AAALAC-Accredited (or, for Canadian institutions, certified by the Canadian Council on Animal Care (CCAC)).
- If the species used is regulated by the Animal Welfare Act, the performing institution must have a USDA registration.
- The Pitt IACUC must receive a copy of the approved protocol and approval letter from the performing institution.
- The Pitt IACUC must receive any approved modifications to the protocol.
- The ARP office must receive information about significant questions or issues (such as compliance issues) raised during the semi-annual inspection.

After adherence to the requirements has been verified and all required materials received, a letter will be written and sent to the Investigator.

Animal Work Contracted with a Company

The University of Pittsburgh may have contractual arrangements for certain aspects of the animal care and use program with other animal care agencies or facilities. Such offsite locations may include contract laboratories, collaborating universities, and other types of research facilities. If the university owns these animals, then the Pitt IACUC has the responsibility of ensuring the health and well-being of the animals while they are housed at the offsite location.

For animal work contracted with a company, the Pitt IACUC requires:

- The company must have a PHS Assurance.
- The company must be AAALAC-Accredited.
- If the species used is regulated by the Animal Welfare Act, the company must have a USDA registration.
- The Pitt IACUC Office must receive a copy of the approved protocol and approval letter from the performing institution. If the protocol cannot be obtained for proprietary reasons, a statement of work from the company is acceptable.

If these conditions are met, the IACUC will issue a letter granting permission to use the company for the work.

A listing of all organizations with a PHS Animal Welfare Assurance is available at the following web site: <http://grants1.nih.gov/grants/olaw/assurance/300index.htm>. Note that some companies are subsidiaries of a larger organization that has filed an Animal Welfare Assurance for all its components. If the company is not listed on the web site indicated above, the Investigator should contact the company to ascertain whether its animal welfare assurance was filed through a different business name. The Investigator must also have a Pitt IACUC-approved protocol in place prior to shipment of animals to the University.

PHS prohibits the use of NIH funds to pay for animal work performed by a company that has not filed an animal welfare assurance with PHS.

Custom Animal Production

Most animals used in research are ordered from a catalog of already available strains from University-approved vendors. The purchase of these animals requires an IACUC-approved protocol onto which the animals are placed upon receipt and orders for such animals must be processed through the DLAR Anorder system. However, if an investigator makes a contractual arrangement with a company to construct a unique gene-modified or surgically manipulated animal, specifically for their federally-funded research (i.e., the animal would not have been generated without your order and the animal is made to your specifications), then you must obtain IACUC approval, via the adherence to the requirements above, for this unique animal production prior to initiation of the project.

Appropriate Modifications of Protocol

If a study includes work performed at another institution or company, the relevant protocol(s) must be modified appropriately. To do this, submit a modification request to the ARP Office. If all requirements have been met, the request will be handled administratively.

Rederivation or Cryopreservation with Jackson Laboratories or Taconic: Because the University has negotiated master agreements with Jackson Laboratories (JAX) and Taconic, Inc., rederivation and cryopreservation work done at these companies, under said

agreements, can be quickly approved without protocol modification, following the process below:

- The PI must submit a statement of work from the company that includes a project number.
- The PI must send the appropriate protocol number.

Please note that the Investigator must ensure that the protocol given is approved for the strain and number of animals to be shipped. If the protocol is not approved for the specific number and strain, the PI must submit a modification request, which must be approved before animals can be shipped to the University.

Requests for Exemption to AAALAC-Accreditation Requirement

Requests for an exemption to the requirement for AAALAC Accreditation may be considered by submitting a request to the ARP office if the following conditions are met:

- The University of Pittsburgh does not own the animals.
- The University of Pittsburgh IACUC receives a letter from the University of Pittsburgh faculty member sponsor formally requesting an exemption from this policy. This letter must explain in detail why work must be done specifically at the performing institution.
- The University of Pittsburgh IACUC receives a description of the country's animal welfare laws and regulations as they pertain to animal research (links to government websites are acceptable if in English) and a description of the official certifications and accreditations the performing institutions has attained (with appropriate documentation of each).

The request is forwarded to the IACUC Chair and is brought to the Executive Committee for deliberation. If the request is deemed satisfactory, it will be presented at the next IACUC meeting for vote.

Personnel Training

The University of Pittsburgh provides training to all personnel who use or care for animals.

All individuals listed on IACUC protocols must complete the necessary training modules. This includes:

- PIs
- Research Fellows, Technicians/Assistants
- Animal Care Technicians
- Any individual involved in the design and implementation of research studies using laboratory animals.

All listed individuals are required to complete the **Responsible Conduct of Research** module, which covers laws and regulations, and either the **Working with Small Animals** or **Working with Large Animals** module. Recertification for all training modules is required every four years. All modules are accessible through Pitt's [CITI Portal](#).

In addition, everyone involved in the use of animals is required to complete the appropriate online species-specific training modules, corresponding to the species listed on the protocol. These sessions include Small Animal (rodents), various Aquatics (e.g., fish and zebrafish), Large Animal (rabbit, ferret, cat, dog, pig, sheep, goat, and calves, etc.), and Primates. Species-specific animal training modules require certification every four years.

Additionally, all personnel on protocols that make use of controlled substances must complete the **Use of Controlled Substances in Basic and Animal Research** module.

Other Training, offered by the Environmental Health & Safety Department such as Chemical Hygiene, Bloodborne Pathogens, Formaldehyde training, etc. may be required.

For more information regarding the IACUC's training requirements, please contact the ARP training coordinator at 412-383-1737.

External Program Review

National Institutes of Health Office of Laboratory Animal Welfare (OLAW)

Annual Report to OLAW

Each year, the University of Pittsburgh must submit a report to OLAW that includes:

- Changes in the institution's program of animal care and use,
- Changes in the IACUC membership
- Dates that the IACUC conducted its semiannual program evaluations and facility inspections
- Minority IACUC views (e.g., minority opinions expressed during a semiannual evaluation or inspection, in the course of a protocol review or IACUC evaluation of animal welfare concerns, or in recommendations to the IO).

The IO and the IACUC Chairperson must sign this report. The report is submitted on or before December 1 each year, coinciding with the Annual Report to the IO.

Reporting Noncompliance, *Guide* Deviations, and Suspensions to 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): (a) any serious or continuing noncompliance with the PHS Policy; (b) any serious deviation from the provisions of the [*Guide for the Care and Use of Laboratory Animals*](#); and (c) 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 deliberately chosen to permit the judicious application of professional judgment by the IACUC to determine what incidents should be considered serious and reportable to OLAW. To assist IACUCs in making such judgments, OLAW offers the following examples of occurrences that they have determined meet these reporting criteria:

- 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
- 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

- Suspension of an activity by the IACUC, which is any IACUC intervention that results in the temporary or permanent interruption of an activity involving animals

The IACUC can fulfill the requirement that information be reported promptly by contacting [OLAW](#). OLAW will ask for a confirmation of resolution of the matter.

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.

United States Department of Agriculture (USDA)

USDA Annual Report

As required by Section 13 of the AWA and further explained in 9 CFR, Part 2, Section 2.36, the University of Pittsburgh must submit an annual report (APHIS Forms 7023 and 7023-A) to the Animal Care Regional Office located Raleigh, NC. This report is due in the Regional office on or before **December 1** of each year. These forms must be signed and certified as correct by the Chief Executive Officer (CEO) or legally responsible IO (IO) and must include all species covered by the AWA used in research, tests, experiments, or for teaching and those on hand at the end of the U.S. Department of Agriculture's (USDA) fiscal year (FY) (October 1 through September 30). By signing the report, the CEO or IO is also certifying that the institution has adhered to the assurance statements at the bottom of the APHIS Form 7023. Reporting of animals used is based on the USDA FY (October 1 through September 30). Animals are to be counted only once, regardless of the number of proposals in which they were used. If an animal was used in more than one proposal, it must be counted in the most painful category. Animals used in multi-year studies will be counted once each fiscal year. Animals counted and listed in USDA Pain Category E must have a detailed statement explaining the procedure(s) and the basis for withholding pain-relieving medications. Entries in Category "E" must be explained in detail and attached to APHIS Form 7023. At a minimum, these statements should address the following:

- A complete description of the procedure(s) producing pain and/or distress in the animal(s). This explanation should include, as appropriate, the name of the test, the reference from the Code of Federal Regulations if the test is mandated by federal regulations, or other relevant guidelines.
- A complete explanation for withholding drugs for relieving pain and/or distress. For example, provide scientific justification that such drugs would adversely affect the test/study results, or cite all regulation(s) and/or Federal Agency policies that prohibit the use of these drugs.

A summary of IACUC-approved exceptions to the regulations or standards must also be attached to APHIS Form 7023. At a minimum, this summary should include the following:

- Identify IACUC-approved exception(s) to the regulations or standards, including

exceptions to the dog exercise plan and/or the nonhuman primate plan for environmental enhancement.

- Describe IACUC-approved exemption(s).
- Identify the species and number of animals used.

It is not necessary to report birds, amphibians, rats of the genus **Rattus**, mice of the genus **Mus** specifically bred for use in research, or any other animals not defined as animal by 9 CFR, Part 1- Definitions of Terms, Section 1.1. Wild rats, mice and birds *are* covered and must be reported.

Reporting Non-compliance to USDA

If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with full explanation to APHIS and any Federal agency funding that activity.

AAALAC International

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. The University of Pittsburgh maintains an Accredited status, the conditions of which, as set by the AAALAC International Board of Trustees, are as follows:

- The care and management of laboratory animals should be directed by qualified persons.
- All animal care personnel should be suitably qualified by training and experience in the care of laboratory animals.
- Physical facilities and the methods of care and use for animals should permit their maintenance in a state of well-being and comfort.
- The [Guide for the Care and Use of Laboratory Animals](#) shall serve as a basic guide to the establishment of specific standards for accreditation. For programs outside the U.S., AAALAC International may establish standards based on prevailing directives and conventions of the country in which the accreditable unit is located.
- The accreditable unit shall observe any and all statutes and governmental regulations which bear upon animal care and use including, but not limited to, the prevailing standards of sanitation, health, labor and safety of the jurisdiction(s) in which it is located.
- The accredited unit shall submit an annual report which describes elements of the animal care and use program as specified by AAALAC International. In addition, the accredited unit shall promptly notify AAALAC International (e.g., through copies of correspondence) of adverse events relating to the animal care and use program. Examples include investigations by the USDA or OLAW, as well as other serious incidents or concerns that negatively impact animal well-being.
- All qualified applicant units are initially site visited. Accredited units and those on provisional status are routinely revisited at 3-year intervals. Additional interim or follow-up visits may be required to confirm correction of deficiencies or if there are major changes in programs or facilities.
- If an accredited unit fails to meet the criteria of an active animal care and use

program, as defined above, the unit must notify the AAALAC North American Office at 5205 Chairman's Court, Suite 300, Frederick, MD 21703, tel: 301-696-9626, fax: 301-696-9627. AAALAC International will inform the unit that to maintain accreditation, an active animal care and use program must be resumed within twelve months. After failing to meet the criteria of an active animal care and use program for twelve consecutive months after notification by AAALAC International, accreditation of the unit will be revoked. If the unit resumes an active animal care and use program after revocation, a new application for accreditation must be submitted.