

**THE UNIVERSITY OF HOUSTON
IACUC POLICY**

Title: IACUC Review of Compliance Concerns and Reportable Events

Background:

The Animal Welfare Act (**AWA**) and Animal Welfare Regulations (**AWAR**), the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ("**PHS Policy**"), and **AAALAC International** all provide guidance clarifying the roles and responsibilities of the IACUC regarding review of potential noncompliance and reporting:

<p>AWA 2143(b)(4)(C); AWAR Part 2, Subpart C, §2.31(d)(7) (for USDA-covered species)</p>	<p>PHS Policy IV.C.6-7, IV.F.3</p>	<p>AAALAC FAQ #1.2. "Reporting Requirements"</p>
<p>AWA: In order to give the research facility an opportunity to correct any deficiencies or deviations discovered ... the Committee shall notify the administrative representative of the research facility of any deficiencies or deviations from the provisions of this chapter. If, after notification and an opportunity for correction, such deficiencies or deviations remain uncorrected, the Committee shall notify (in writing) the Animal and Plant Health Inspection Service and the funding Federal agency of such deficiencies or deviations.</p> <p>AWAR: 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.</p>	<p>The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:</p> <ul style="list-style-type: none"> a) any serious or continuing noncompliance with this Policy; b) any serious deviation from the provisions of the <i>Guide [for the Care and Use of Laboratory Animals]</i> ; or any suspension of an activity by the IACUC. <p>The IACUC may suspend an activity which it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the <i>Guide</i>, the institution's Assurance, or ... this Policy ... 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 ... the Institutional Official (IO) in consultation with the IACUC shall ... report that action with a full explanation to OLAW.</p>	<p>Adverse events to be reported promptly:</p> <ul style="list-style-type: none"> • Unexpected animal deaths • Natural disasters • Significant animal rights activities • Inappropriate euthanasia techniques and/or failure to confirm euthanasia • Allegations/complaints /reports regarding animal welfare concerns • Lack of veterinary care • OLAW/USDA investigations

Scope:

The intent of this policy is to outline IACUC procedures regarding review of potential animal welfare and protocol noncompliance with the above statutes, as well as with the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) and with the University of Houston (UH) PHS Assurance and other institutional documents.

Policy:

In accord with the PHS Policy IV.F.3, the IACUC, through the Institutional Official (IO), will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to any serious or continuing noncompliance with the PHS Policy, any serious deviation from the provisions of the *Guide*, or any suspension of an activity by the IACUC.

The IACUC procedures for collecting, reviewing, and reporting these issues to OLAW and other applicable parties are detailed in the proceeding policy.

I. Compliance Concerns

- A.** An initial report of noncompliance¹ is received by the Division of Research (DOR). A concern may come from any source, such as but not limited to: Animal Care Operations (ACO), UH faculty/staff, UH students, the public or media, a referral from the UH Fraud & Noncompliance Hotline, or an anonymous individual. The concern must be put in writing. In rare instances, a concern can be taken over the phone, but, if possible, the caller should review the text of the concern to ensure it was recorded accurately. Regardless of the method of initial report, this information and associated IACUC deliberations will be tracked in the ICON system.

With respect to compliance concerns,

- Employees reporting noncompliance in good faith may not be retaliated against²
- The IACUC retains the authority to suspend ongoing research procedures in animals in whole or in part; this may be implemented as an interim action during the review of a compliance concern (pending further investigation/resolution) or on any occasion in which the IACUC has an ethical concern about the ongoing work or about the health and safety of research animals or personnel.

¹ or reportable event

² SAM 01.C.04/Texas Government Code, Chapter 554

- B.** IACUC staff will conduct a preliminary review (review associated funding and related protocol/grant, request clarifications from complainant if necessary, consult IACUC policy and/or federal regulations).
- C.** IACUC staff will forward an initial brief summary of the concern and related information to date to the IACUC Chair and Vice-Chair, who will determine if further assessment is required.
- For minor issues (those for which information is clear and that do not appear representative of serious or continuing noncompliance), a clear communication to the PI and interim corrective action may be sufficient, to be reported at the next IACUC meeting.
 - If further assessment is required, the Chair assigns a subcommittee, to include at a minimum:
 - i. One member in a leadership role (Chair, Vice Chair)
 - ii. One DOR IACUC member (Research Integrity and Oversight office)
 - iii. One additional experienced IACUC member³

A veterinary and/or *ad hoc* member with expertise also may be added on a case-by-case basis, based on the nature of the concern.
 - If no further investigation is requested (the concern has no merit or is not under the purview of the IACUC), the case will be closed with recommendations to the Principal Investigator (PI) and/or referral to the appropriate party if applicable.
- D.** If further investigation is requested, the scope and an initial plan for investigation is determined by the subcommittee. It will be identified whether IACUC staff alone may obtain the information or if further IACUC member and/or veterinary involvement is necessary.
- E.** IACUC staff and other individuals as designated will work with the PI and research personnel to gather factual information related to the concern. In simple cases, this will involve primarily written and phone correspondence with the PI and research personnel; however, on a case-by-case basis, other methods may be employed as needed, such as in-person meetings, review of research records/logs/facilities, interviews of research personnel and/or ACO staff members, request for the respondent

³ An experienced member will be one with 1 or more years of Committee membership

to recommend a corrective action plan, and other methods agreed to by the subcommittee.

- F.** IACUC staff will compile a formal report, supplying factual information related to the concern, including applicable regulatory and/or policy references and information obtained from the investigation. The report is sent to the PI to review for errors of fact, for which a deadline is given. Responses from the PI will either necessitate updating of the factual information within the report or will be attached to the final report.
- G.** The final report is then forwarded to the subcommittee, who will review it to make an initial recommendation of the following to the IACUC:
- Substantiated noncompliance? (Y/N) – **If yes:**
 - i. Serious⁴ noncompliance?
 - ii. Continuing⁵ noncompliance?
 - iii. Neither serious nor continuing?
 - iv. Other reportable situation? (see NOT-OD-05-034, see attached **Appendix A**)
 - If noncompliance is substantiated by a preponderance of the evidence, a corrective action plan will also be part of the recommendation. This may take into consideration any corrective actions the PI has already implemented or suggested.
- H.** The final report, with the subcommittee’s recommendation, is reviewed at the next fully convened IACUC meeting. A final determination of the items in “**G**,” above, is made by the IACUC and a determination letter provided to the PI. Deadlines are given for corrective actions, if determined necessary. The IO is provided with updates during the progress of the investigation, as well as a final IACUC compliance report at the conclusion of the investigation.
- I.** Required reports to federal oversight and applicable funding agencies are made by the IO and copied to the PI. Required reports to the accrediting body, AAALAC International, are made by the AAALAC-designated contact. Charges to federally funded grants are

⁴ Serious noncompliance – noncompliant activity or deviations from the *Guide* that harm, or have the potential to harm research animals, research personnel, or the integrity of research data. “Harm” includes, but is not limited to, real or potential physical effects, psychological effects, and/or failure to minimize pain or distress.

⁵ Continuing noncompliance – repeated instances of noncompliance

reviewed by the Division of Research per NOT-OD-10-081 (see attached **Appendix B**) and action taken as necessary.

- J. IACUC staff, in conjunction with other parties designated in the IACUC's determination (e.g., ACO), will follow up with the PI on required corrective actions and will report back to the IACUC periodically until the case is closed. The PI is ultimately responsible for the completion of all corrective actions and for maintaining compliance moving forward.
- K. A PI may request reconsideration of the noncompliance determination if factual information is presented that was not previously considered by the IACUC during the investigation. All such information must be provided in written format to the IACUC office and will be forwarded to the Chair for review of merit and relatedness to the case. The case will be re-opened if warranted.

II. Reportable events

- A. The investigation of potentially reportable events, if noncompliance is suspected, will follow the procedure for investigation outlined above. However, under certain circumstances where noncompliance is not suspected (e.g., natural disasters, accidents, mechanical failures resulting in actual harm or death to animals), reports may be made to federal agencies/accrediting bodies prior to review by the fully convened IACUC. The IACUC will be informed of these reports at the next upcoming meeting.

III. Appendices

Appendix A: NOT-OD-05-034 - Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory

Appendix B: NOT-OD-10-081 - Noncompliance for Activities Involving Animals

IV. Additional references

USDA: Additional Guidance

(https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa/awa-inspection-and-annual-reports)

AAALAC Accreditation FAQ (https://www.aaalac.org/accreditation/faq_landing.cfm#H2)

Document Log

Version Number	Approval Date	Description of Changes
1	12/17/2012	Initial Policy created and approved
2	01/15/2014	Updated policy to include information regarding suspensions and lines of authority (e.g., reporting to IO)
3	02/19/2018	Updated policy to new format and made consistent with new online submission system. Minor updates to process.

Appendix A

Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

Notice Number: NOT-OD-05-034

Update: The following update relating to this announcement has been issued:

- [April 15, 2010](#) - See Notice NOT-OD-10-081 Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals.

Key Dates

Release Date: February, 24, 2005

Issued by

Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research
(<http://grants.nih.gov/grants/olaw/olaw.htm>)

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on the prompt reporting requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (<http://grants.nih.gov/grants/olaw/references/phspol.htm>). This guidance is intended to assist IACUCs and Institutional Officials in determining what, when, and how situations should be reported under IV.F.3 of the Policy, and to promote greater uniformity in reporting. This Notice supersedes the January 12, 1994 Dear Colleague letter from the former Division of Animal Welfare, Office for Protection from Research Risks (now the Office of Laboratory Animal Welfare, or OLAW).

Background

PHS Policy, IV.F.3, requires that:

"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 [for the Care and Use of Laboratory Animals]* ; or
- c) any suspension of an activity by the IACUC."

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The

Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

All institutions with Animal Welfare Assurances are required to comply with the provisions of IV.F.3. The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.

Reporting promptly to OLAW under IV.F.3 serves dual purposes. Foremost, it ensures that institutions deliberately address and correct situations that affect animal welfare, PHS-supported research, and compliance with the Policy. In addition, it enables OLAW to monitor the institution's animal care and use program oversight under the Policy, evaluate allegations of noncompliance, and assess the effectiveness of PHS policies and procedures.

The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting. Public Law 99-158 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>) requires that institutions be provided a reasonable opportunity to take corrective action before a grant or contract is suspended or terminated, and it is OLAW's role to assess whether the corrective actions reported by institutions under IV.F.3 are adequate. OLAW will assist the reporting institution in developing definitive corrective plans and schedules if necessary. Compliance actions affecting an award are rare because institutions are usually able to address incidents successfully and take appropriate actions to prevent recurrence.

Guidance on Prompt Reporting

A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will provide guidance with regard to specific situations. Situations that meet the provisions of IV.F.3 and are identified by external entities such as the United States Department of Agriculture or the Association for Assessment and Accreditation of Laboratory Animal Care International, or by individuals outside the IACUC or outside the institution, are not exempt from reporting under IV.F.3.

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.

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).

Time Frame for Reporting

Institutions should notify OLAW of matters falling under IV.F.3 promptly, i.e., without delay. Since IV.F.3 requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

Information to Be Reported

Include as many of the following items of information as possible in the initial contact with OLAW. A follow-up report may address anything not known at the time of the initial report and should summarize the institution's corrective action. If a long term plan is necessary, describe the plan and include a reasonable schedule. This information will allow OLAW to assess the circumstances and actions taken to correct and prevent recurrence of the situation.

Information to be included:

- Animal Welfare Assurance number
(<http://grants.nih.gov/grants/olaw/assurance/300index.htm>);
- relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS;
- a full description of any potential or actual affect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures);
- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by the institution to address the situation; and
- description of short- or long-term corrective plans and implementation schedule(s).

Preliminary and final reports should be made to:

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-594-2061
FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

Inquiries

For questions or further information, contact:

Director, Office of Laboratory Animal Welfare
Office of Extramural Research,
Office of the Director, National Institutes of Health
RKL 1, Suite 360
6705 Rockledge Dr .
Bethesda , MD 20892-7982
(For express or hand-delivered mail use zip code 20817)
Telephone (301) 496-7163
olaw@od.nih.gov

Appendix B

Noncompliance for Activities Involving Animals

Notice Number: NOT-OD-10-081

Key Dates

Release Date: April 15, 2010

Issued by

Office of Laboratory Animal Welfare (OLAW), (<http://olaw.nih.gov/>), Office of Extramural Research

Other Relevant Notices

- [January 26, 2007](#) – See NOT-OD-07-044, NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld
- [February 24, 2005](#) – See NOT-OD-05-034, Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

Purpose

This Notice provides additional clarification in reference to Notice [NOT-OD-07-044](#) regarding the grantee's responsibilities when animal activities have been conducted which do not meet the terms and conditions of grant award.

Background

As previously noted in Notice [NOT-OD-07-044](#), 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. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.

2. The conduct of animal activities in the absence of a valid Institutional Animal Care and Use Committee (IACUC) approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

Institutions are required to report such situations to the Institute/Center (IC) supporting the award and to OLAW. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. Consultation with the IC is encouraged regarding questions concerning allowable costs. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.

Policy

Grantees reporting instances of serious noncompliance with section IV.F.3 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals ([PHS Policy](#)) consisting of any of the aforementioned situations are to provide a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance. If such a certification cannot be made, a detailed accounting of unallowable charges made to each affected grant should be included with the report. If a detailed accounting has not been completed at the time of reporting, a date when it will be provided should be included. See [NOT-OD-05-034](#), Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals, for additional guidance on reporting requirements.