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OLAW and APHIS: Common Areas of Noncompliance

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OLAW's Compliance Oversight: Noncompliance with PHS Policy

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The welfare of animals used in research has been a concern of the Public Health Service (PHS) since the mid-1900s¹. Section 495 of the Health Research Extension Act of 1985 (HREA, Public Law 99-158)² is the statutory basis for the PHS *Policy on Humane Care and Use of Laboratory Animals*³, and is the most significant legislation that directly affects PHS.

The Office of Laboratory Animal Welfare (OLAW), formerly the Division of Animal Welfare of the Office for Protection from Research Risks (OPRR, *see* News Updates on p. 10), oversees compliance with the PHS *Policy*, and its oversight extends to institutions that use live vertebrate animals in research, research training, and biological testing activities conducted or supported by the PHS. PHS includes the Agency for Health Care Policy Research; the Agency for Toxic Substances and Disease Registry; the Centers for Disease Control and Prevention; the Food and Drug Administration (FDA); the Health Resources and Services Administration; the Indian Health Service; the National Institutes of Health; and the Substance Abuse and Mental Health Services Administration.

The Institutional Promise

To receive PHS support for activities involving animals, each awardee institution must provide a written Animal Welfare Assurance of Compliance (Assurance) to OLAW, describing how it will comply with the PHS *Policy*. OLAW carefully negotiates these Assurances to ensure that the described institutional policies and practices are consistent with the *Policy*, while giving consideration to the unique characteristics of individual institutions.

OLAW approval of the Assurance commits the institution, its officials, committees, investigators, and any of its other agents to full compliance with provisions of the PHS *Policy*, including the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (Principles)⁴, the *Guide for the Care and Use of Laboratory Animals (Guide)*⁵, and, as applicable, the Animal Welfare Act (AWA) Regulations⁶ and other federal statutes and regulations applying to animals.

Institutional Self-Regulation and Other Monitoring

With respect to compliance with the PHS *Policy*, OLAW expects that institutions will adhere to the promises made and procedures described in their Assurances. Under the terms of approved Assurances, institutions are required to send annual reports to OLAW describing any changes that may have occurred in animal care and use programs, dates on which program evaluations and facility inspections were conducted, and minority views, if any. By signing the Assurance, the Institutional Official (IO) also commits the institution to report promptly—along with corrective actions taken—any serious or continuing noncompliance with the *Policy*, any serious deviation from provisions of the *Guide*, and any suspension of an activity by the Institutional Animal Care and Use Committee (IACUC). In other words, institutions are expected to regulate their own animal-related activities through oversight by their IACUCs—correcting instances of noncompliance and apprising OLAW of actions taken. The record shows that this system of

monitored institutional self-regulation is highly successful, as the majority of recorded *Policy* violations and infractions of the *Guide* have been brought to OLAW's attention and corrected by the institutions themselves.

In addition, OLAW conducts site visits on short notice to randomly selected institutions for the purpose of evaluating compliance and providing technical assistance. The breadth and depth of oversight is also enhanced by inspection activities conducted by other organizations that notify OLAW of institutional activities that they believe to be in violation of the PHS *Policy*. These include PHS funding components and, under the terms of a 1995 Interagency Memorandum of Understanding, the US Department of Agriculture (USDA) and the FDA⁷. OLAW's oversight also extends to evaluating complaints and allegations received from any other sources, including anonymous individuals, current and former institutional employees, private individuals, animal-activist organizations, and reports in the media.

Compliance Evaluations

On receipt of a complaint or report involving noncompliance with the PHS *Policy*, OLAW first determines whether it has jurisdiction on the basis of PHS support or an applicable Assurance, and whether the matter involves alleged noncompliance with the PHS *Policy* or deviation from the *Guide*. OLAW then acknowledges the institution's report if the matter was self-reported or notifies the IO of possible noncompliance, and requests a written response to the specific concern(s) by a specified date. When a complainant is identifiable, OLAW generally requests the provision, beforehand, of any and all evidence he or she may have to support the allegations.

After evaluating the report submitted by the institution, and any other information it has acquired, OLAW determines whether the matter has been settled, and, if not, may request additional information. Most compliance evaluations are resolved through correspondence, and do not require site visits or formal reports. When noncompliance matters have been concluded and OLAW determines that a formal report is in order, copies of the report are submitted to the IO and the complainant(s) with invitations to identify errors of fact. OLAW then appends and addresses any factual errors in the preface and issues the report to the IO and the complainant(s). Once issued, the report, with appendices, becomes available under the Freedom of Information Act (FOIA).

Anonymity, Whistle-Blower Protections, and Other Issues

Complainants sometimes request anonymity or "whistle-blower" protection as a condition of lodging a complaint. Although it is OLAW's policy not to release predecisional documents pertaining to cases that are under investigation or inquiry, most documents related to compliance-oversight evaluations become publicly available under the FOIA when OLAW issues its findings. In addition, the PHS *Policy* does not contain explicit whistle-blower protections, and OLAW is not able to guarantee that requests for anonymity or whistle-blower protection will be honored. Accordingly, the decision of the complainant to provide personal identifiers should be made on that basis. With regard to situations involving USDA-covered species, on the other hand, the AWA Regulations state that institutional personnel shall not be discriminated against or subjected to any reprisal for reporting violations of any regulation or standard under the AWA.

Although the purpose of the PHS *Policy* is to ensure the welfare of animals involved in PHS-supported activities, animal care and use issues are sometimes used as pretexts for involving OLAW in agendas that are really focused on institutional personnel policies or actions, "power and turf" issues, or interpersonal conflicts. OLAW notes that responsibility for resolving these

kinds of problems is best left to the IOs and the other individuals involved, with appropriate assistance from human resources personnel, legal advisors, and facilitators.

Outcomes

The potential outcomes of inquiries and investigations are varied. Based on the results of its evaluation, OLAW may determine that the institution is either in compliance with the *Policy*, with or without the requirement to consider recommendations for improvement, or that it is not in compliance. In the latter instance, OLAW may restrict its approval of the institution's Assurance in such a way as to ensure that PHS-supported animal-related activities are not jeopardized, or it may withdraw its approval of the Assurance. Without an approved Assurance, facilities may not conduct PHS-supported activities involving animals. Other possible outcomes include recommendations to PHS officials to suspend or remove an institution from participation in specific projects. Except in unusual circumstances, OLAW does not take action against an institution without first notifying it of any identified noncompliance with the *Policy* or deviation from the *Guide*, and giving it reasonable opportunity to take corrective action in accordance with provisions of the HREA.

Common Issues of Noncompliance

Failure to adhere to any provision of the *Policy* or the institutional Assurance constitutes noncompliance. Inasmuch as some problems occur more frequently than others, this section briefly describes some of the more common and serious ones.

IACUC Constitution

Inadequacies in the constitution of IACUCs can seriously affect the legitimacy of actions taken by the Committee, and constitute noncompliance with the *Policy*. Most frequently these involve an IACUC whose membership—because of member resignations, failure to replace individuals whose terms have expired, or member deaths—lacks one or more of the requisite members specified by and defined in the PHS *Policy* (*i.e.*, a veterinarian, a practicing scientist, a nonscientist, and a person who is unaffiliated with the institution). In these cases, the review and approval of animal-related activities, such as animal study protocols, may be invalid and may require suspension until appropriate review and approval have occurred.

A related problem is the absence of a convened quorum. Although the previously mentioned members mandated by the *Policy* do not necessarily have to be present at all meetings, the results of IACUC votes are valid only when more than 50% of the members of the appropriately constituted IACUC are in attendance. Careful attention to PHS *Policy* language regarding IACUC membership, quorums, and functions should prevent these problems from arising. In addition, appointing more than the minimum number of members who meet the respective PHS *Policy* criteria (IV.A.3.b) may prevent the occurrence of such problems when unexpected vacancies arise.

Lack of IACUC Approval

The conduct of animal activities that have not been reviewed and approved by an appropriately constituted IACUC is also a serious problem, as is the implementation of significant changes to previously approved activities without IACUC approval. These problems, and many others, are often traceable to institutional training programs that fail to adequately inform investigators of institutional and federal policies, guidelines, and regulations, and that lack provisions for periodic reinforcement or continuing education.

If an institution fails to establish ongoing monitoring systems to ensure that the actual animal work being conducted is the same as that which the IACUC approved, this also contributes to noncompliance in some cases. While the vast majority of noncompliance issues have their origins in a lack of understanding by investigators or other personnel about their responsibilities, there are instances where they occur because individuals either deliberately circumvent or choose to ignore the provisions of the *Policy* or requirements of the *Guide*.

While the PHS *Policy* does not contain specific sanctions other than suspension, most institutions have developed procedures for disciplining such individuals to avoid the termination of specific grants by the funding agency or the withdrawal of the institution's Assurance. Institutionally imposed sanctions vary in severity from counseling, temporary suspensions of privileges, and imposition of monitored probation to permanent withdrawal of animal-use privileges and the termination of employment.

Failure to Report

Institutions are expected to report promptly to OLAW any instances of serious or continuing noncompliance with the *Policy*, serious deviations from the *Guide*, and suspensions of animal-related activities, along with descriptions of the corrective actions taken, in accordance with the PHS *Policy* (IV.F.3) and the terms of their Assurances. Failures to report usually appear as the result of carelessness or inattention to promises contained in Assurances, misinterpretations of the term "serious," or apprehension regarding "self-incrimination" and punitive measures that may be imposed.

OLAW has provided guidance and given examples of serious incidents that should be reported by IACUCs^{8,9}. It also reminds institutions that *Policy* oversight is based on monitored self-regulation and that considerations of adverse actions, as described above, are normally activated only when institutions have been notified of, and fail to correct, conditions that do not meet the requirements of the PHS *Policy*².

Post-Procedural Pain and Distress

Key provisions of the PHS *Policy* and the Principles are concerned with avoiding or minimizing discomfort, distress, and pain in animals. In OLAW's experience, problems in these areas most commonly involve aspects of post-procedural care. In accordance with the *Policy*, all proposals should be evaluated by the IACUC and when the potential for producing discomfort, distress, or pain is found to exist, the IACUC is obligated—in the absence of a written scientific justification—to insist that appropriate measures (*e.g.*, application of the three "Rs"¹⁰, use of drugs, and provision of appropriate physical accommodations) will be employed to avoid or minimize it.

OLAW finds that the deficiencies frequently entail failures of investigators to communicate with technical, animal care, or veterinary staffs—or assumptions that support personnel will automatically provide the appropriate care. To prevent such a scenario from happening, IACUC reviews should not only consider the appropriate chemical or physical methods for preventing or alleviating post-procedural problems, but should also ensure that suitable measures are in place for their implementation, monitoring, and documentation. Establishment of clear accountability is vital to prevention of deficiencies in this area.

Record-Keeping

Inadequate record-keeping, including the documentation of veterinary care, is an issue that comes to OLAW's attention from its evaluations of IACUC investigations, USDA inspection reports,

and other sources. Failures to document can be interpreted as failures to perform, and bring into question the adequacy of IACUC monitoring and oversight. OLAW suggests that documentation enhances credibility, and may be an institution's or an individual's best defense against false accusations.

Complaint Mechanisms

Some complaints have their foundation in the absence of clear-cut, credible institutional mechanisms whereby employees may bring their concerns about animal care and use to the IACUC for consideration, including assurances that there will be no reprisals for doing so. OLAW has initiated a number of investigations in response to complaints that could have been avoided, had those individuals originally recognized the appropriate institutional procedures to express their concerns directly.

Education and Communication Channels

Many of the aforementioned compliance issues are directly related to deficiencies in training and communication within the institutions. Problems like these are largely preventable through ongoing education programs that inform and update everyone who cares for or uses animals (investigators, veterinarians, laboratory and veterinary technicians, animal caregivers, IACUC members, etc.) of their individual obligations with respect to institutional policies, procedures, and expectations, as well as the requirements of the PHS *Policy*, the *Guide*, and the AWA Regulations. Institutions can adapt published guidelines about training in the humane care and use of laboratory animals¹¹ to individual institutional requirements, accounting for institutional size; institutional complexity; numbers of people involved; numbers and species used; and the nature of the research, testing, and educational activities involved.

Summary

OLAW's compliance oversight is founded on negotiated institution-specific Assurances and subsequent monitoring of institutional self-regulatory activities, and is based secondarily on the results of site visits and other sources of information. When OLAW receives reports or allegations of instances of noncompliance with the PHS *Policy* and determines that it has jurisdiction, it conducts an evaluation that may take various forms. If OLAW verifies violations, institutions receive notification and have an opportunity to take appropriate corrective action. Written reports may or may not be issued to document findings. Failure to comply with provisions of the *Policy* may result in restriction or withdrawal of approval of an Assurance and other actions initiated by funding agencies.

Unlike three or four decades ago, when physical plant and equipment issues headed the list of institutional animal care problems, today's compliance concerns tend to center around a number of inter-related programmatic issues. Most commonly, these include the IACUC, its composition, and the review of proposed and ongoing animal-related activities; mechanisms to ensure that institutional policies and procedures are implemented; record-keeping considerations; institutional guidelines for registering concerns about animal care and use; prompt reporting of instances of noncompliance; and effective training programs.

Despite the complex nature of animal-based research, testing, and teaching, most institutions can avoid potential pitfalls and achieve compliance with the various regulations, policies, and guidelines that apply to animal care and use by implementing appropriate administrative and management mechanisms to ensure the effective execution of institutional policies.

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USDA APHIS on AWA Compliance: Data Review and VMO Survey

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The Animal Care (AC) division of the US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for conducting inspections of biomedical research facilities registered under the Animal Welfare Act (AWA). The recent upgrading of AC's Licensing and Registration Information System (LARIS 8) permitted a query of the database to determine the most common violations of the regulations (Title 9, Code of Federal Regulations, Subchapter A, Animal Welfare) documented in USDA inspections.

The USDA regulation violation search covered from January 1, 1998 to January 10, 2000. LARIS 8 did not become completely functional until October 1, 1999, and not all inspections conducted before October 1, 1999 had been retroactively entered into the system by the date of the search. However, because the inspections entered were random and recorded 873 violations, it is felt that the analysis of the data ([Table 1](#)) is valid and provides meaningful insight into the relative

frequency of certain violations.

TABLE 1. Summary of research facility violations from January 1998-December 1999.

IACUC	322
Facilities	153
Cleaning and Sanitizing	153
Veterinary Care	116
Primary Enclosures	34
Feeding	28
Miscellaneous	16
Personnel Qualifications	12
Annual Report	11
Psychological Well-Being of Nonhuman Primates	8
Exercise of Dogs	6
All Other	14
Total	873

Due to creation of a new database, not all violations documented during this period are included in this report. However, the violations were randomly recorded and are therefore believed to consist of a valid representation of the actual violations found on inspections during this period.

IACUC Violations

One particular section of the regulations that deals with the Institutional Animal Care and Use Committee (IACUC) system (§2.31) accounted for 322—almost 37%—of the violations. The IACUC violations can be further broken down (Table 2) into the specific paragraphs of §2.31 that were found to be in violation, with more than 70% violating sections §2.31(c) and §2.31(d). The first area, §2.31(c), is entitled “IACUC Functions,” and lists the specific activities that all IACUCs are required to perform, specifically:

- Conducting semiannual reviews, inspections, and evaluations;
- Reviewing and investigating internal and external complaints regarding the care and use of animals at the institution;
- Making recommendations to the Institutional Official;
- Reviewing proposed animal care and use activities, as specified in §2.31(d);
- Suspending animal care and use activities, as specified in §2.31(d)(6).

The second area, §2.31(d), is entitled “IACUC Review of Activities Involving Animals,” and includes all relevant activities related to the protocol review process, such as approving protocols, requiring their modification, annual review, review of significant changes, and protocol suspensions.

Fifty-five violations were recorded in a third area, §2.31(e), which addresses the five required components of every protocol. These are:

- The identification of species and approximate numbers of animals;

- A rationale for involving animals and for the appropriateness of the species and numbers of animals to be used;
- A complete description of the proposed use of the animals;
- A description of procedures designed to limit animal discomfort and pain to that which is unavoidable;
- A description of any euthanasia method to be used.

TABLE 2. Summary of IACUC violations from January 1998-December 1999.

Appoint IACUC [2.31(a)]	9
Membership [2.31(b)]	22
Functions [2.31(c)]	117
Protocol Review [2.31(d)]	110
Protocol Components [2.31(e)]	55
Not specified [2.31]	9
Total	322

Facilities and Cleaning & Sanitizing Violations

Violations in the “Facilities” and “Cleaning and Sanitizing” sections tied for the second most common major areas of noncompliance. For each of these areas, 153 violations were recorded, accounting for a total of 35% of the violations. For the most part, the facility citations were related to inadequate maintenance and repair of the physical plant, and included items such as structural strength of the facilities; proper storage of food and bedding; proper waste disposal; and protection from the elements for animals housed outdoors. The “Cleaning and Sanitizing” section of the regulations requires periodic cleaning and sanitizing of primary enclosures, adequate housekeeping of the premises, and programs for pest control.

Veterinary Care Noncompliance

“Veterinary Care” was the fourth most common area of major noncompliance with 116 occurrences (13.3%). These citations include everything from inadequate delivery of veterinary care to lack of a written program of veterinary care for those facilities with a contract, part-time veterinarian.

Comparison Survey

The results of the database query as it relates to IACUCs are consistent with a recent survey of the AC Veterinary Medical Officers (VMOs) who conducted these inspections, and their direct supervisors. All 49 VMOs and their supervisors responded.

The VMOs and supervisors commented on the overall effectiveness of IACUC regulations, and where improvements are needed. Of those surveyed, 94% felt that the IACUC regulations are generally effective and that great strides have been made in improving humane care and use of animals at research facilities since the regulations were adopted. However, three general areas were commonly identified as needing improvement: acceptable consideration of alternatives to painful or distressful procedures by the Principal Investigators; review of painful procedures by the IACUC; and monitoring of animal use to ensure compliance with approved protocols and institutional policies and procedures.

The respondents felt that AC needs to provide clear guidance to the industry and to the VMOs on:

- What constitutes a painful or distressful procedure for AWA purposes;
- AC’s expectations on how facilities should minimize pain and distress;

- How to appropriately report various painful and distressful procedures under the current categorization scheme.

Future Plans

AC has already initiated action to address most of these concerns. All VMOs attended a work conference from late February through early March dealing specifically with inspection of registered research facilities. Many outside experts were included on the agenda, and much of the program dealt with the issues identified above. Additionally, AC is currently in the process of revising Policy #11 (“Painful/Distressful Procedures”) to clarify the definition and reporting, and Policy #12 (“Written Narrative for Alternatives to Painful Procedures”) to clarify expectations for the consideration of alternatives.

By identifying the most common areas of noncompliance with the AWA regulations, and clarifying our expectations for these areas, it is our hope that AC and the lab animal community can work together to improve compliance with the regulations and promote the well-being of research animals.

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