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Noncompliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals: An Exploratory Analysis

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The National Institutes of Health (NIH) is a major biomedical research-funding body in the United States. Approximately 40% of NIH-funded research involves experimentation on nonhuman animals (Monastersky, 2008). Institutions that conduct animal research with NIH funds must adhere to the Public Health Service (PHS) care and use standards of the Office of Laboratory Animal Welfare (OLAW, 2002a). Institutions deviating significantly from the PHS's animal care and use standards must report these incidents to the NIH's OLAW. This study is an exploratory analysis of all the significant deviations reported by animal-research facilities to OLAW during a 3-month period. The study identifies the most common issues reported and species involved. The study found that the majority of the incidents resulted in animal pain and distress and that 75% ended in animal death. This study offers preliminary recommendations to address the most common problems identified in this analysis. OLAW and other stakeholders are urged to analyze larger, more recent samples of reported deviations to compare with these results and ultimately improve adherence to animal welfare standards.

The Public Health Service (PHS) and its components, notably the National Institutes of Health (NIH), are major funders of biomedical research in the United States. Approximately 40% of this NIH-funded research involves experimentation on nonhuman animals (Monastersky, 2008). Institutions that receive PHS funding to conduct research on nonhuman vertebrate species are required to follow the PHS care and standards of NIH's Office of Laboratory Animal Welfare (OLAW, 2002a). Further, OLAW itself stipulates compliance with the Institute for Laboratory Animal Research (ILAR, 1996). These mandates are separate from those under the Animal Welfare Act (AWA) of 1966 or the voluntary accreditation program of the Association for the Assessment and Accreditation of Laboratory Animal Care International.

OLAW is responsible for ensuring compliance with OLAW (2002a) and ILAR (1996). Institutions receiving PHS funding to conduct animal-research activities must file an Animal Welfare Assurance (OLAW, 2002a) designed to be a "stand-alone document that succinctly describes the animal care and use program of an institution" (OLAW, 2006). There are more than 1500 OLAW-assured institutions. OLAW does not conduct prospective inspections of research facilities but instead relies heavily on these Assurances, which delegate the majority of the oversight responsibilities to the institutions' own Institutional Animal Care and Use Committee (IACUC).

According to (OLAW, 2002a), any research institution with an Assurance on file 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 [ILAR] *Guide*...; or c) any suspension of an activity by the IACUC. (p. 18)

In such reports to OLAW, institutions are to include, among other things,

1. Full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved;
2. Description of actions taken by the institution to address the situation; and
3. Description of short- or long-term corrective plans and implementation schedule(s) (OLAW, 2005).

We know of no published analyses of such reports, despite what they might reveal about the welfare of animals in laboratories and the degree of compliance with an important set of national standards. Consequently, The Humane Society of the United States (HSUS) examined a sample of these reports. Our aims were to profile the reported incidents, initiate a discussion about what steps might be taken to prevent or address them, and to spur other interested parties to undertake more definitive analyses of these reports than was possible in our exploratory study. We were particularly interested in any incidents that resulted in pain, distress, suffering, and/or death of animals; these outcomes are the central focus of our Pain and Distress Campaign (HSUS, 2007).

METHODS

Using the Freedom of Information Act (FOIA) of 1966, HSUS obtained all reports submitted to OLAW by research institutions nationwide during May, June, and July 2005 for any reportable noncompliance with OLAW (2002a), deviation from ILAR (1996), or suspension of activity by an IACUC. We judged that a 3-month time frame would provide at least a preliminary profile of such reports.

The documents provided to us included all case reports that were initiated during the 3-month period in question as well as all documents related to each case through the date that the request was fulfilled (9 months after the 3-month period ended). In its correspondence with reporting institutions, OLAW refers to “instances” of noncompliance, deviations, or suspensions. We refer to these as “incidents” for greater clarity. Some reports addressed multiple incidents. In cases in which the number of incidents was not specified, we deemed this as “at least one incident” (Appendix A). We profiled each incident according to the following criteria:

1. Species of animals involved;
2. Number of animals affected;
3. Number of deaths (not including those euthanized);
4. Number euthanized;
5. Number who potentially experienced pain or distress; and
6. Corrective actions prompted by either the institution, OLAW, or a whistleblower.

These profiles are necessarily incomplete in some cases given that some reports were unclear, lacked detail, or had significant information redacted.

Each incident was subject to being reported to OLAW because it involved one or more departures from the standards in OLAW (2002a) or ILAR (1996). We categorized these departures based on the issues that surfaced in our findings, and we used ILAR’s (1996) Table of Contents as our starting point in generating the categories.

RESULTS

In response to our request, OLAW released 124 reports from 91 institutions that it had received during May, June, and July 2005 concerning a total of at least 160 incidents. OLAW characterized approximately 69% of the incidents as noncompliance or deviations and 4% as suspended activities; 27% were not categorized without explanation.

Animals were known to have been affected in 67% (83) of the 124 reports and 74% (119) of the 160 incidents, accounting for at least 1,006 animals. We considered reports that clearly involved or affected animals, but did not specify the number of animals, to have involved at least one animal.

The vast majority of animals involved in the reported incidents were rodents: mice, rats, guinea pigs, and hamsters (Figure 1). Eighty percent of the animals affected died as a result of the incidents, including 36 animals who were euthanized.

The 160 incidents reported revealed a minimum of 216 “reportable departures” (our phrase) from OLAW (2002a) or ILAR (1996). One incident could have more than one “reportable departure”; thus there are 216 reportable departures and 160 incidents. For example, the following situation was labeled as one incident, but fell under more than one reportable departure for HSUS’ purposes given that there were both animal deaths and animal care and management issues:

The ... OLAW ... acknowledges receipt of your ... letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals...According to the information provided, nine neonatal mice died of malnutrition and dehydration due to the absence of the dam...due to miscommunication between the investigator and animal caretakers. (OLAW, 2005)

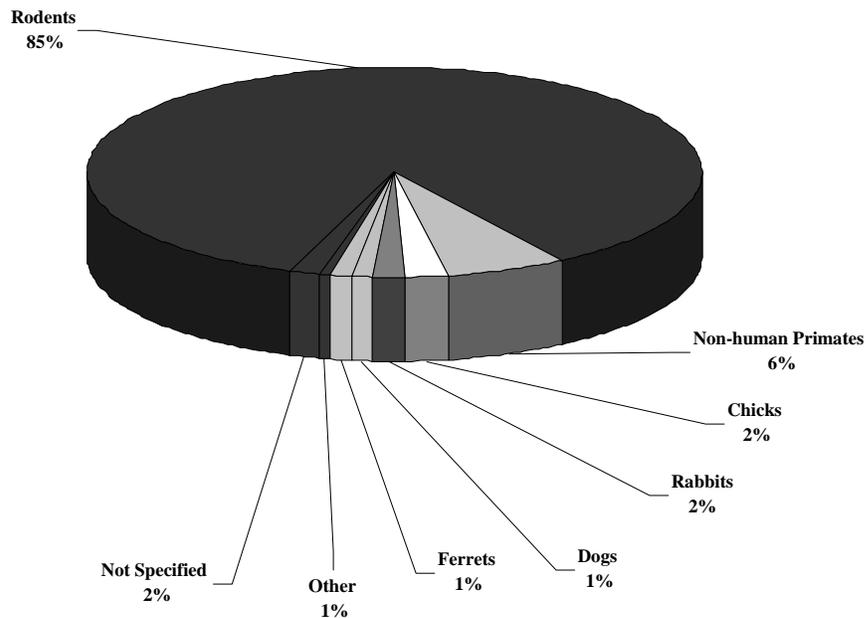


FIGURE 1 Types of animals involved in the reported incidents (n=160).

The actual total is unknown because 52% (65) of the 124 reports did not provide OLAW with all relevant information related to the incidents or OLAW-redacted information before releasing the information to us. In fact, 34% (42) of the 124 reports had nearly all relevant information missing or redacted.

Based on the nature of the reportable departures, we divided them into the following categories (Table 1):

1. Alternatives Search and Justification;
2. Animal Care and Management;
3. Animal Death(s);
4. Animal Housing, Environment and Transport;

TABLE 1

The Specific Nature of the Departures from OLAW (2002a) and ILAR (1996), Based on the Incident Descriptions Found in Institutional Reports to the NIH OLAW during May, June, and July 2005. (Classification Generated by the Authors)

<i>Category</i>	<i>Included in Category</i>
Alternatives Search and Justification	Inadequate alternatives search Inadequately justified exemptions to the Animal Welfare Act of 1966
Animal Care and Management	Inadequate monitoring Inadequate record-keeping Lack of training Lack of communication regarding animals Inadequate animal care (this does not include veterinary care) Improper animal care procedures Inadequate pain management
Animal Death(s)	Deviation from standard operating procedures Negligent animal deaths Accidental animal deaths
Animal Housing, Environment, and Transport	Deviation from appropriate temperature Inappropriate housing Poor ventilation
Euthanasia	Inadequate transportation Improper euthanasia Failure to ensure death
Protocol Related	Lack of approved protocol Deviating from/ Violating protocol Incomplete protocol Lack of Institutional Biosafety Committee protocol Expired protocol Institutional Animal Care and Use Committee approved protocol without a quorum
Veterinary Care	Inadequate veterinary care

Note. ILAR = Institute for Laboratory Animal Research. NIH = National Institutes of Health. OLAW = Office of Laboratory Animal Welfare.

5. Euthanasia;
6. Protocol Related; and
7. Veterinary Care.

The reported departures fell primarily into two categories (Figure 2): Animal Care and Management (37%) and Protocol Related (29%). We sought to determine the extent to which the animals in the reported incidents experienced pain or distress. In addition to incidents reported by the institution or OLAW as having caused pain and distress, we included incidents involving unexpected death to the animal or inadequate anesthesia or analgesia or those having the potential (in our view) to cause pain and distress in humans (Appendix B). Based on our analysis, fully 82% (827) of the 1,006 animals directly or potentially experienced pain or distress.

For 72 of the 124 total reports, we could infer whether actions taken to report the circumstances and correct the situation were initiated by the institution or prompted by OLAW or a whistle-blower (someone reporting to OLAW anonymously), or by a combination of these agents. Of the 72 reports, 85% (61) were initiated by the institution, 4% (3) by OLAW, one case by a whistleblower, and 10% (7) were by the institution with OLAW suggestions. Of the full 124 reports, OLAW requested additional information on 13 of them prior to completing its evaluation.

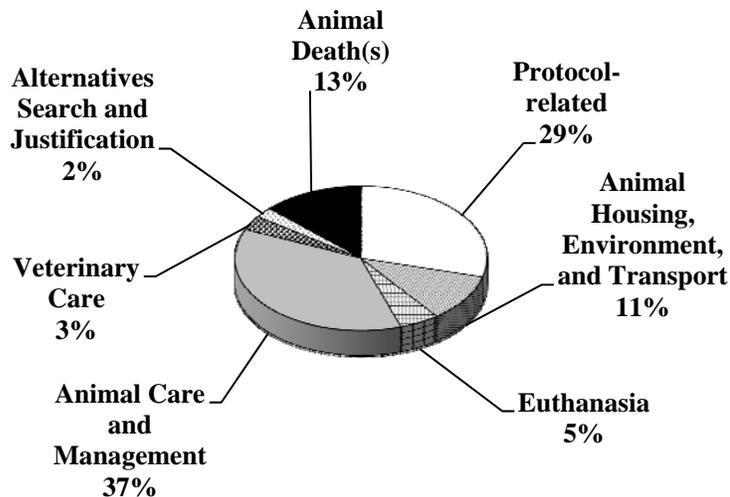


FIGURE 2 The general nature of the departures from the Office of Laboratory Animal Welfare (2002a) and Institute for Laboratory Animal Research (1996) based on the incident descriptions found in institutional reports to the National Institutes of Health Office of Laboratory Animal Welfare during May, June, and July 2005. (Categories generated by the authors; $N = 216$.)

DISCUSSION

Our exploratory analysis begins to build a profile of incidents of serious non-compliance with OLAW (2002a), deviations from ILAR (1996), and suspensions of research activity. Institutions reported a total of 160 such incidents during the 3-month period covered by this analysis. We do not know if this period was representative of the rest of the year in question (2005) or the more recent past. If the analyzed period is broadly representative, then the 160 incidents for a 3-month period would translate into approximately 640 incidents per year or 1.8 per day.

Two-thirds of the institutional reports described incidents in which animals were affected. A minimum of approximately 1,000 animals—mostly rodents—were affected, the vast majority of whom either died or were likely to have experienced pain and/or distress. Many institutions did not report the number of animals affected when cases clearly involved animals; therefore, the actual number of animals who died as a result of the reported incidents and experienced pain or distress is likely much higher than estimated. Furthermore, the estimate reflects only those institutions that complied by bringing reportable incidents to the attention of OLAW (2002a).

The reported incidents largely reflect departures from mandated standards concerning protocol-related events (such as deviating from, or conducting activities without, an approved protocol) or animal care and management (such as communication, training, animal monitoring, and pain management). Although almost all institutions self-implemented corrective actions, the case files on the submitted reports suggest that OLAW rarely, if ever, follows up firsthand to make sure that corrective plans are implemented and followed.

OLAW (2002a) should strive to minimize significant noncompliance with, and deviations from, ILAR (1996), especially those that jeopardize the health or welfare of animals. Some general remedies that probably would help include encouraging better education concerning government-mandated and internal standards, better training in animal-based procedures, establishment of standard operating procedures, and—where appropriate—disciplinary actions. However, in the following sections we discuss several specific issues raised by our analysis and offer our thoughts on improving adherence to OLAW (2002a) and ILAR (1996).

Pain and Distress

More than 80% of the animals involved in the reported incidents were likely to have experienced pain and distress as a result of noncompliance with OLAW (2002a) or deviations from ILAR (1996). Federally funded research institutions have a legal and ethical obligation to minimize pain and distress.

There are several resources and tools available regarding recognition and alleviation of animal pain and distress. Colorado State University's IACUC has found that the use of pain-scoring systems improved management of postprocedural pain and

distress (Stasiak, Maul, French, Hellyer, & VandeWoude, 2003). Silverman, Suckow, and Murthy (2000) note the following:

...signs of pain and distress may be very subtle and their recognition almost always requires a detailed knowledge of the normal behavior of the animal species. Recognition also requires that sufficient time be allocated for observation of the animal and, in some circumstances, it may be necessary to observe the animal's behavior in such a way that it is unaware of the presence of the observer, e.g., by using a video camera. (p. 250)

Animal Care and Management

Institutions are required by law to establish programs and systems for proper and adequate monitoring of animals, record-keeping, training, IACUC procedures, and pain management. Yet the most common concerns reported to OLAW were related to Animal Care and Management. ILAR (1996) requires a review of the entire animal care program and inspection of animal facilities and activity areas at least once every six months; however, the instances found in our analysis suggest that some institutions are not adequately fulfilling these requirements.

One way to ensure adequate monitoring of animals is to designate an appropriately trained person, other than the Principal Investigator, to perform the monitoring. Concerns relating to Veterinary Care comprised a much smaller percentage of reported incidents, perhaps suggesting that institutions should use their veterinary team as a source to help improve overall animal care (not just in regard to medical issues). The centralization of vivarium facilities and veterinary teams has been advocated as a means to improve quality of overall animal care (Hampshire, McNickle, & Davis, 2000). Some institutions have reported using a "Decision Tree" as a tool that lays out steps to take in different scenarios that affect animal welfare and as a guide for managing reportable incidents (VandeGiessen & Hoorn, 1996).

Animal Housing, Environment, and Transport

The fourth-largest category of reportable events was Animal Housing, Environment, and Transport. A good resource is ILAR (1996), which states that transportation of animals should

minimize transit time and the risk of zoonoses, protect against environmental extremes, avoid overcrowding, provide food and water when indicated, and protect against physical trauma. (p. 57)

According to ILAR (1996), after IACUC review and approval of proposed institutional housing, "...objective assessments should be made to substantiate the adequacy of animal environment, husbandry, and management" (p. 22). Based on a few occurrences seen in our analysis regarding injury caused by limbs stuck in cages and

overcrowding, it is also important to note that ILAR (1996) requires housing enclosures to “provide a secure environment that does not allow escape of or accidental entrapment of animals or their appendages.... [and should be] free of sharp edges or projections that could cause injury...” (p. 23). In addition, several reported incidents were associated with heating, ventilation, and air-conditioning problems.

There should be monitoring systems (electronic or otherwise, without reliance on humans) in place 24 hr per day and “an alternative or emergency power supply should be available” (ILAR, 1996, p.76) in order to prevent loss of heat or air-conditioning during times of extreme temperatures. OLAW (2008) also strongly encourages institutions to do the following:

Consider using available electronic technology to measure temperature in each animal room on a continuous basis. ... Sole reliance on employees to identify changes in animal room conditions or the use of high-low thermometers to track changes in temperature may not be sufficient to allow timely intervention and prevent catastrophic loss.

We urge OLAW to adopt a formal policy on this issue.

Euthanasia

Although only a small number of all reportable events related to euthanasia ($n = 11$), 73% of these incidents were related to carbon dioxide use. The typical case involved use of dry ice, which is considered unacceptable (American Veterinary Medical Association, 2007; OLAW, 2002b). There were also cases in which the animals survived the euthanasia procedure and were later found to be alive. Regarding CO₂ euthanasia, OLAW also specifies that death should be ensured such as by performing cervical dislocation. It is important to note, however, that many recent publications have highlighted concerns that CO₂ euthanasia likely causes pain and distress (Conlee, Stephens, Rowan, & King, 2005; Hawkins et al., 2006). In our view, institutions should not use CO₂ as a stand-alone euthanasia agent.

Adequacy of Reported Information

Institutions should submit reports that are sufficiently detailed to enable OLAW to adequately understand the incidents and proposed solutions. Many reports failed to provide information on the types of animals affected. In other cases, institutions apparently did not submit an official report after a first unofficial contact was made with OLAW to report the incident. We argue that OLAW cannot adequately exercise its oversight authority under such circumstances.

Furthermore, so that the scale of the situation can be properly weighed, OLAW should require institutions to report the number of animals affected by the reported incident. In addition, many of the institutional reports had enough information missing from them that they failed to convey an adequate picture of what had happened at the

institution. In some cases, information was redacted under questionable application of the FOIA (1966). Public accountability demands a fuller disclosure, especially when federal standards have not been followed.

Level of OLAW Oversight and Follow-up

The system of compliance oversight of federally funded animal research outlined in OLAW (2002a) relies heavily on self-reporting and self-correction by research institutions. We recognize that such self-oversight can, in principle, result in prompt attention and correction of an issue by the institution; however, federal oversight should dramatically ramp up when serious problems arise at the institutional level. In our view, this is not happening routinely.

According to our analysis, after institutions submitted reports of serious or continuing noncompliance, OLAW informed them as to whether OLAW believed that the actions taken by the institution were sufficient or if OLAW had further questions or suggestions. Having indicated that it was satisfied with the institution's response, OLAW did not determine firsthand whether the institution had actually carried out the action. Notably, OLAW—as far as we were able to determine—requested additional information in only 13 of the 72 reports before it closed out a case.

In our view, OLAW's hands-off response to reports of serious or continuing noncompliance is emblematic of the low level of OLAW engagement of its mission that has received media scrutiny and raised questions about the nature of the relationship between OLAW and the institutions it oversees. For example, according Brainard (2006).

The last time [OLAW]... suspended a license was in 1986...[b]ut some academic observers suggest that those partnerships [between universities and NIH] may be too cozy....and critics argue that [OLAW] ...should be moved out of the agency and made independent. (p. A26)

Based on our analysis, which is admittedly exploratory, we agree that OLAW should be more proactive about oversight, including site visits and follow-up action with institutions, particularly those that have recurring problems. A recent case in which the NIH ordered a university to return more than \$65,000 in research grant money after it was fined by the United States Department of Agriculture for AWA (1966) violations, may be an indication of OLAW playing a more forceful role (Merritt, 2008).

CONCLUSION

To conclude, HSUS has compiled a profile of serious or ongoing departures from federally mandated standards governing animal-research policy. The problems revealed should be systematically addressed. Although accidents are sometimes unavoidable, many of the incidents reported in this analysis were avoidable. Commonsense steps should be taken to reduce such incidents in the future. In the long run, OLAW's

performance should be judged not only on its ability to handle these incidents but also on its ability to reduce their occurrence. Positive action is important to animal welfare, quality of science, and public accountability. We urge oversight agencies and other stakeholders to analyze larger and more recent samples of reported deviations and take appropriate action to improve adherence to animal welfare standards.

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Appendix A

Examples of How the Authors Counted “Incidents” (the Office of Laboratory Animal Welfare’s [OLAW] “Instances”)

- I. Examples of OLAW statements excerpted from its response letters to institutions, illustrating what was counted by OLAW as “an instance” of serious or continuing noncompliance with OLAW (2002), a serious deviation from the provisions of the Institute for Laboratory Animal Research (1996), or suspension of an activity by the Institutional Animal Care and Use Committee:
 - a. “... OLAW ... acknowledges receipt of your ... letter reporting two instances of noncompliance...”
We counted this as two incidents.
 - b. “... OLAW understands that fifteen protocols were found to have expired.”
We counted this as 15 incidents.
 - c. “According to the information provided, nine neonatal mice died ... due to the absence of the dam ... due to miscommunication between the investigator and animal caretakers....”
We counted this as one incident.
- II. Examples of responses to institutions in which OLAW did not specify the number of instances (we counted these as “at least one incident reported”).
 - a. “...OLAW... acknowledges receipt of your ... letter reporting several incidences of noncompliance with the PHS Policy....”

- b. "...OLAW... acknowledges receipt of your ... letter reporting the accidental deaths of 564 mice..."

Although specifying details of what had happened, OLAW did not characterize it as "an instance" of noncompliance as it did in most of its other letters.

Appendix B

Examples of Reported Incidents That Were Counted as Causing Pain and Distress

(Any incident that pertained to more than one category listed here was placed in the most appropriate category.)

Unexpected Death or Euthanasia of Animals

Death of two rats from lack of food and water after unapproved invasive surgery and "not be[ing] checked for food and water intake over two weekends." (Office of Laboratory Animal Welfare [OLAW])
"...failure of the on call veterinarian to respond to a technologist's request to examine one pig in critical condition, which then died overnight." (OLAW)
"... one nine-week-old woodchuck pup was euthanized due to both front limbs being injured in an isolation cage." (Institutional Animal Care and Use Committee [IACUC] Chair)

Inadequate Anesthesia or Analgesia

"... monkey had craniotomy performed but no records were kept. Animal seized. No post-op analgesics given. Vet said to monitor and they only used a camera at night." (OLAW)
"... performance of cervical dislocation without anesthesia as a method of euthanasia." (OLAW)
"... mice did not receive post-operative analgesics as stipulated and the pre-determined time at which euthanasia was to be performed was not followed." (OLAW)

Potential to Cause Pain and/or Distress in Humans

"... a rat was inadvertently left in an operant chamber for 47 hours with no water, food, light, or sound." (OLAW)
"... post-surgical monitoring of three rabbits was not conducted and documented as specified in the [approved] Animal Study Proposal (ASP)." (OLAW)
"... rats had undergone surgical procedures resulting in hind limb paresis and the cage was overcrowded." (OLAW)
"... a visiting scientist had mistakenly conducted procedures on animals covered by another IACUC approved animal use application."

(continued)

Improper Euthanasia

“... four live rats were discovered in a morgue cooler due to a failure to ensure death following a euthanasia attempt.” (OLAW)

“... squirrel monkeys on a nerve injury study underwent tracheotomies although this procedure was not described in the protocol and the endpoint of the procedure was not always as described in the protocol.” (OLAW)

Institution or OLAW directly states in the report that pain and/ or distress could have been experienced or was experienced

“... five rabbits died as a result of heat stress experienced during transfer and transport to a procedure room. One of the animals was euthanized due to a spinal fracture which could have been due to agitation from the heat.” (OLAW)
