

Detecting and Eliminating the Antecedents to Serious Programmatic Failure

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PRIMOR's

2016 Institutional Animal Care and Use Committee
Conference • Bellevue, WA March 30-April 2

Session E9 Speakers

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Learning Objectives

1. Highlight programmatic deficiencies, including inadequacies in IACUC oversight, as well as a wide variety of laboratory animal management and physical plant areas that have the capacity to negatively impact animal health and welfare, the institution's animal research endeavors, and overall programmatic quality.
2. Address administrative problems, such as policies and procedures that do not meet institutional requirements.
3. Share strategies and best practices for addressing these problems.

Disclosure of Conflict of Interest:

**Linda N. Brovarney, Tanise L. Jackson, and
Brent C. Morse**

*have no relevant personal/professional/financial
relationship(s) with respect to this educational
activity*

Welcome Brent Morse
to provide an
OLAW Perspective

Detecting and Eliminating the Antecedents to Serious Programmatic Failure

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National Institutes of Health



April 1-2, 2016
PRIM&R 2016 IACUC Conference
Bellevue, Washington

Office of Laboratory Animal Welfare
Office of Extramural Research
National Institutes of Health

OLAW Mission

To oversee PHS funded animal use, OLAW provides;

- guidance and interpretation of PHS Policy,
- support of educational programs, and
- monitoring of compliance with the Policy by Assured institutions and PHS funding components **to ensure the humane care and use of animals** in PHS-supported research, testing, and training and thereby contributing to the quality of research.

Authorizing Legislation and Implementing Policy

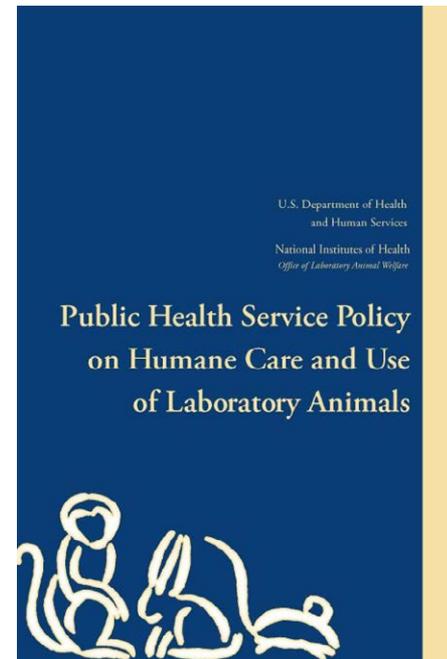
Health Research Extension Act of 1985

Public Law 99-158 "Animals In Research"

November 20, 1985

**Public Health Service Policy on
Humane Care and Use of
Laboratory Animals**

Revised, 2015



National Institutes of Health
Office of Extramural Research



- Compliance with PHS Policy is required if you accept PHS funds.
- Oversees the welfare of research animal subjects in PHS-funded activities.

Reporting Requirements per PHS Policy IV.F.3.

- The IACUC through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
- Any serious or continuing noncompliance with this Policy;
- **Any serious deviation from the provisions of the *Guide*, or**
- Any suspension of an activity by the IACUC



Serious deviation from the provisions of the *Guide*

- Conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual animal harm or death
- Shortcomings in programs of veterinary care, occupational health or training, identified during semiannual program review and not corrected within the institutional determined time frame



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

NOT-OD-05-034 February, 24, 2005

Information to Be Reported:

- “...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);”

How to Avoid Noncompliance

- Clear-cut institutional policies and procedures- including mechanism to register concerns
- Initial training at all levels
- Continuing education
- Ensure intra-institutional communication



Contact OLAW for Advice or Help

- If unsure if an item is reportable call, email
- Better to ask or report than not
- Consequences less desirable if reportable event withheld and discovered later
- OLAW can help with recommendations of what has worked at other institutions to prevent further noncompliance



Thank You

- E-mail: olaw@od.nih.gov
- Phone: 301-496-7163
- Website: <http://olaw.nih.gov>
- Twitter: [@NIH_OLAW](https://twitter.com/NIH_OLAW)
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policy interpretations.



Scenarios



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Scenario #1

- On a recent site visit from an outside oversight organization it became painfully obvious that members of the Animal Care and Use Program staff were either unfamiliar with or completely unaware of the location of some satellite housing and animal procedures areas. The level of sanitation and animal care in these areas was below that practiced in the central animal facilities. In fact, it was determined that a high percentage of noncompliance occurred within the satellite facilities compared to central facilities. What can be done to bring this situation under control?



Approach to Scenario #1

- Bring all, or select, animal housing into centralized facilities? Do the same with procedure areas when possible?
- Assign individual(s) to liaison with investigators and research staff.
- Provide animal care and veterinary technical assistance to satellite housing areas.
- Make sure all areas are visited by all(?) IACUC members over a year(?).
- Have satellite areas provide care and use documents to Animal Care Program on a regular basis.
- Provide training within those satellite areas.



Scenario #2

- Upon review of compliance case data, OLAW became aware that one PI at a large institution had caused the same type of recurring noncompliance (not administering required post-op analgesia) over a two-year period. The IACUC had provided the same “corrective” action each time.
- OLAW expects institutions to provide *effective* corrective actions and to escalate, or at least, vary those actions when previous attempts have failed.
- What should the institution have done initially and what can they do now?



Approach to Scenario #2

- Originally, the re-training required by the IACUC was appropriate, but ineffective for this individual.
- Retraining the entire lab staff may have prevented further incidents.
- PAM oversight may have caught antecedents.
- Emphasize negative consequences of repeated incidents.
- Suspend all or part of the protocol.
- Assign a temporary, experienced Co-PI.
- Review and adjust programmatic procedures for reporting and correcting noncompliance.
- This incident prompted a site visit by OLAW.



Scenario #3

During a visit from and outside oversight organization it was noted that that there was no periodic follow up with individuals that are enrolled in the occupational health program.

This is important because there may be changes in an individuals health status or the nature of the research being conducted.

Approach to Scenario #3

What procedures should be put in place to prevent this programmatic failure?

Scenario #4

Institution Z was in the throws of preparing for their impending AAALAC site visit when recent inspections of laboratory procedures areas identified serious problems with a number of PI's records involving documentation of survival surgery – specifically with documentation of anesthetics and analgesics.

Oh NO! What was the institution to do!

Approach to Scenario #4

Institution Z's IACUC immediately put out a call to all PIs that have approval to conduct survival surgery in their protocol requiring that they submit the most recent 5 records for review.

Those with non-compliances identified were brought to the attention of the IACUC.

Several mandatory Town Hall Meetings were held with researchers so that they understood the requirements. This allowed open dialog and the ability to review other programmatic issues of importance.

What else could, should be done in this case!

Is this reportable to OLAW?

Scenario #5

The Institution's Animal Resource Center (ARC) managers have reported 6 incidents of incomplete euthanasia of mice and rats over the past 2 months (live animals found in various vivarium coolers) to the IACUC office compliance staff. The IACUC reviewed these findings during an IACUC meeting and is extremely concerned about the negative impact on animal welfare and that this may represent a programmatic deficiency.

Approach to Scenario #5

The IACUC needed to know more information about how, where and who may have been involved in these instances. In the interim, the IACUC held town hall meetings with faculty to explain their plan:

1. The IACUC took immediate action and revoked facility access for all researchers at each location where live animals had been found. To be reinstated, each researcher was required to undergo hands-on euthanasia training.
2. The vivarium had cameras installed in all locations where euthanasia was being conducted with the ability for review of the tapes.
3. The IACUC instituted a new training requirement mandating hands-on euthanasia training for all existing and new researchers.
4. Facility access was not granted for new users until all training was completed.

Is this reportable to OLAW?

Scenario #6

An institution has reported over a few weeks several incidents of finding mice trapped on top of wire bar lids after the cage has been replaced onto the housing rack. Some of the mice have been found dead. Although the responsible individual has usually been identified and retrained, several labs have been implicated. What are some corrective measures that can be used to help reduce the incidence of this animal welfare problem?

Approach to Scenario #6

- SOPs and training were redone to remove the use of the tops of wire bar lids for sorting mice. Cardboard “cups” were provided instead. Signage was posted at all changing stations and caretakers instructed to carefully check tops of wire bars every day.
- Incidence of this issue was greatly reduced. Not totally eliminated, but may need a “cultural shift” over time. For this institution OLAW was able to provide the context for this issue relative to other institutions and assist with suggestions for corrective actions.

Scenario #7

During a visit from an outside oversight organization it was noted that hazardous agents noted in the protocol were not properly identified during the protocol review, therefore the proper signage was not in place for the proper personal protective equipment for use within the animal rooms.

Approach to Scenario #7

An SOP for ABSL-2 Use in Animals to assure proper procedures are being followed when potentially hazardous agents are used in the Animal Care Facility should be in place with a pre-review by the EH&S representative (as an appointed IACUC Member) to identify any potential biological or chemical hazards.

The EH&S representative should assure signage is posted on room prior to start of work.

Mandatory Online training for blood borne pathogens should be in place for all animal users listed on animal use protocols approved for ABSL-2 procedures.

Scenario #8

Institution Y has a very large program for animal care and use and during each semi-annual inspection, expired substances are found which can vary from anesthetics and analgesics to antibiotics, saline and suture material. The IACUC is concerned that this has become a programmatic deficiency. Even though the institution has a formal and very active PAM program and with the vivarium staff's assistance, there are still expired substances being found.

Approach to Scenario #8

The IACUC determined that the PI needed to be more accountable and that no matter how many IACUC or vivarium staff assisted in removing expired substances, it would never resolve the problem.

The IACUC instituted a policy that utilized a system of escalation if repeated findings of expired substances were found.

Expired anesthetics and analgesics were set apart and if those were identified, the PI was immediately issued a warning letter (which automatically moved it to the second level) and the PI's Department Chair was cc'd.

A second finding required inventory management training for the PI given by the IACUC staff.

A third finding resulted in the PI being required to send quarterly reports of their drug/supplies inventory to the IACUC for a year and attend a regulatory refresher with the IACUC Director, the AV and the IACUC Chair.

Questions?

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Thank you!

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