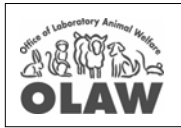


NIH Regional Seminar on
Program Funding & Grants Administration

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

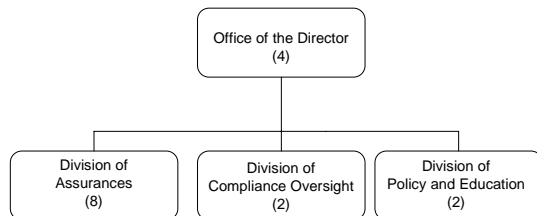


Eileen Morgan
Senior Assurance Officer
Office of Laboratory Animal Welfare
Office of Extramural Research
March 5 - 6, 2007

OLAW provides guidance and interpretation of PHS Policy, supports educational programs, and monitors 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.

OLAW mission statement, April 2005

Office of Laboratory Animal Welfare
(OLAW)



OLAW org chart
Updated 1/25/07

OLAW Educational Program

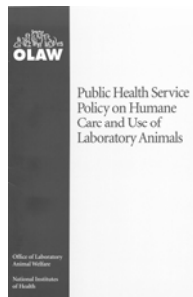
- Partnerships with organizations & institutions
- Workshops, meetings, conferences
- IACUC 101 training program
- IACUC Guidebook, 2nd edition
- Web-based tutorial, resources
- Published articles, FAQs, commentary
- Policy interpretations published in NIH Guide for Grants and Contracts

Authorizing Legislation
Public Law 99-158 (11/20/85)
Health Research Extension Act

- NIH Director to establish guidelines for research funded by NIH and other PHS agencies
- Animal Welfare Assurance mechanism
- Institutional Animal Care and Use Committee (IACUC) with oversight authority
- Institutional opportunity to correct deficiencies

PHS Policy

- Animal Welfare Assurances
- Establish institutional program of animal care and use
- CEO appointment of IACUC
- Designation of Institutional Official
- Institutions self monitor and self report



Public Health Service Agencies

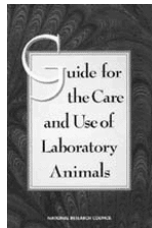
- National Institutes of Health
- Food and Drug Administration
- Centers for Disease Control and Prevention
- Substance Abuse and Mental Health Services Administration
- Health Resources and Services Administration
- Indian Health Service

PHS Policy: Standards for Animal Care and Use

- Guide for the Care and Use of Laboratory Animals
- U.S. Government Principles
- AVMA Panel on Euthanasia
- USDA Animal Welfare Regulations

Guide for the Care and Use of Laboratory Animals

- National Academy of Sciences' Institute for Laboratory Animal Research (ILAR)
- Performance Standards
 - Published data
 - Expert opinion and experience
 - Scientific principles



**U.S. Government Principles
for the Utilization & Care of Vertebrate Animals Used in
Testing, Research, and Training** (page 4 – PHS Policy)

- Basic tenets of animal care and use
- Implemented by all U.S. Federal agencies that perform or sponsor research
- Similar to the International Guiding Principles of the Council for International Organizations of Medical Sciences (CIOMS)
- Used by IACUCs in their review of proposals

**Grant Applicant to Address
Vertebrate Animal Use** (electronic submission)

- SF 424 ~ Research & Related Application
 - Project / Performance Site Location(s)
 - Other Project Information (Section 2 & 2a)
- PHS 398 ~ Research Plan
 - Research Plan Attachments
 - Other Research Plan Sections (11. Vertebrate Animals)
 - PDF format
 - Five Points of Vertebrate Animal Section (VAS) addressed

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? Yes No

1a. If YES to Human Subjects
Is the IRB review Pending? Yes No
IRB Approval Date:
Exemption Number: 1 2 3 4 5 6
Human Subject Assurance Number:

2. * Are Vertebrate Animals Used? Yes No

2a. If YES to Vertebrate Animals
Is the IACUC review Pending? Yes No
IACUC Approval Date:
Animal Welfare Assurance Number:

3. * Is proprietary/privileged information included in the application? Yes No

4.a. * Does this project have an actual or potential impact on the environment? Yes No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? Yes No

4.d. If yes, please explain:

5.a. * Does this project involve activities outside the U.S. or partnership with International Collaborators? Yes No

5.b. If yes, identify countries:

5.c. Optional Explanation:

6. * Project Summary/Abstract [Add Attachment](#) [Delete Attachment](#) [View Attachments](#)

7. * Project Narrative [Add Attachment](#) [Delete Attachment](#) [View Attachments](#)

8. Bibliography & References Cited [Add Attachment](#) [Delete Attachment](#) [View Attachments](#)

9. Facilities & Other Resources [Add Attachment](#) [Delete Attachment](#) [View Attachments](#)

10. Equipment [Add Attachment](#) [Delete Attachment](#) [View Attachments](#)

11. Other Attachments [Add Attachments](#) [Delete Attachments](#) [View Attachments](#)

OMB Number: 4540-0001
Expiration Date: 04/30/2008

OLAW Responsibilities

- Oversee implementation of PHS Policy
- Provide interpretation and guidance
- Negotiate Animal Welfare Assurances
- Evaluate compliance
 - Institutional self reporting
 - Third party allegations
- Educational activities
 - Workshops
 - Resources
 - Training sessions

Animal Welfare Assurance

- Description of animal care and use program
- Lines of authority and responsibility
- Institutional Animal Care and Use Committee
- Procedures to implement the PHS Policy
- Program of veterinary care
- Occupational safety and health program for employees
- Training of personnel (investigators, technicians, IACUC)
- Facilities
- Species

IACUC Responsibilities

- Review animal use protocols (including significant changes to ongoing protocols)
- Inspect facilities every six months
- Review program of animal care and use every six months
- Report to Institutional Official for Animal Welfare every six months
- Review concerns about animal care and use
- Advise Institutional Official
- Authority to suspend PHS-supported activity in noncompliant

Criteria for Protocol Review

(IV.C.1. of Policy, p 13-14)

- U.S. Government Principles
- Standards of the Guide
- Minimization of pain and distress consistent with sound research design
- Appropriate use of anesthesia and analgesia
- Humane endpoints

Criteria for Protocol Review (con't)

- Living conditions and husbandry of animals appropriate for species (husbandry)
- Medical care available and provided by veterinarian
- Qualifications and training of personnel conducting procedures on animals
- Method of euthanasia appropriate and consistent with AVMA Panel on Euthanasia unless scientific justification provided in writing and approved by IACUC

Prompt Reporting to OLAW by Institutional Official

- Serious or continuing noncompliance with the PHS Policy
- Serious deviations from the *Guide*
- Any suspension of an activity by the IACUC

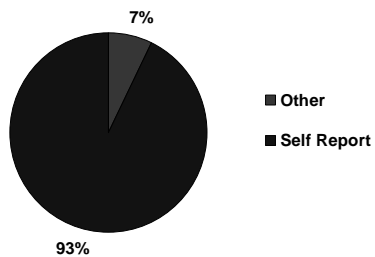
What Happens When Institutions Report Noncompliance / Suspensions?

- Evidence that oversight is effective
- OLAW provides assistance / advice
- Institution takes corrective actions
- Institutional program is improved
- Research goes forward
- Rare cases: institution is unable to take corrective actions and NIH applies sanctions (withdraw or restrict funding)

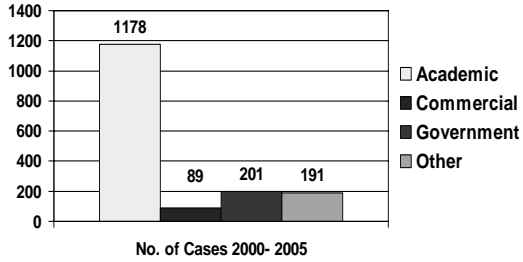
Compliance Data Analysis

- All cases opened from 2000 through 2005
- "Case" = institutional self-reports, complaints, allegations, etc
- 1659 total cases

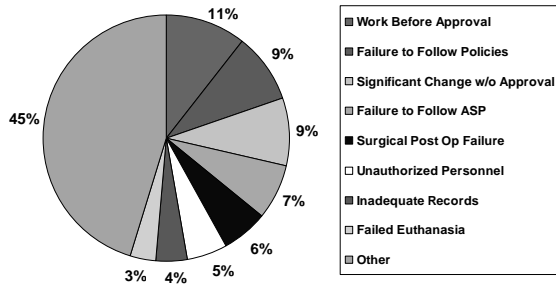
Source of Concern



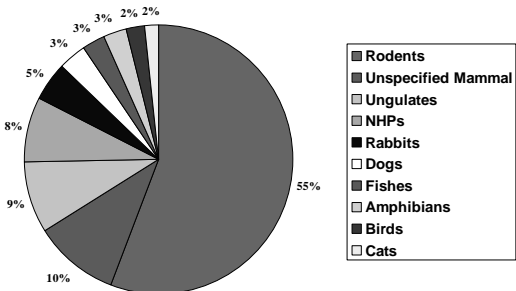
Types of Organizations Reporting



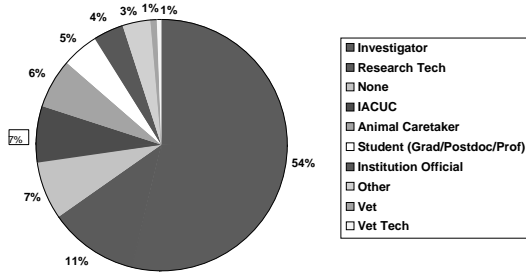
Type of Noncompliance



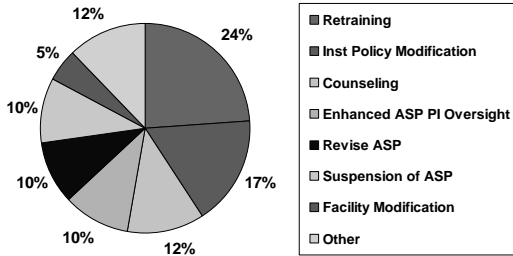
Types of Animals Involved



Responsible Individuals



Institutional Corrective Action



New Guidance for Grantees

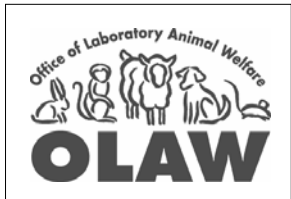
- Guidance on Use of Telecommunications for IACUC Meetings. Published in Guide for Grants & Contracts 3/24/06.
- Frequently Asked Questions. Posted 9/11/06 <http://grants.nih.gov/grants/olaw/faqs.htm>
- NIH Policy on Allowable Costs for Activities with Animals when Terms and Conditions are not Upheld. Published in Guide for Grants & Contracts 1/26/07.

New Educational Resource

- *What Investigators Need to Know About the Use of Animals*
- 40,000 already distributed
- Directed at Investigator applying for a grant

Contacting OLAW

- General e-mail: olaw@od.nih.gov
- Division of Assurances:
olawdoa@mail.nih.gov
- Division of Compliance Oversight:
olawdco@mail.nih.gov



<http://grants.nih.gov/grants/olaw/>
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