

## NIH Regional Seminar Research Involving Animal Subjects

March 30-31, 2006  
Boston, MA

Axel Wolff, M.S., D.V.M.  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
Office of Extramural Research, NIH, DHHS

## Office of Laboratory Animal Welfare (OLAW)

- Policy guidance and interpretation
- Animal Welfare Assurance negotiation
- Compliance evaluation
- Education
- Policy waivers
- Advise NIH institutes regarding implementation

## PHS Policy on Humane Care and Use of Laboratory Animals, revised August 2002

Health Research Extension Act of 1985  
Public Law 99-158  
"Animals In Research"  
November 20, 1985



## Key Elements

- Institutional self-regulation
- Animal Welfare Assurance
- Oversight by Institutional Animal Care and Use Committee (IACUC)
- Record keeping
- Reporting

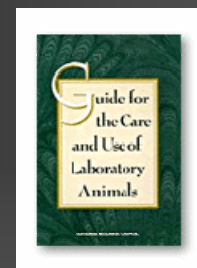
➡ PHS Policy Tutorial at:  
<http://grants.nih.gov/grants/olaw/tutorial/index.htm>

## Foundation of institutional self-regulation

- Flexibility
- Use of performance standards
- Institutional self-evaluation
- Institutional self-monitoring
- Institutional self-correcting
- Institutional self-reporting

## Guide for the Care and Use of Laboratory Animals

- National Academy of Sciences' Institute for Laboratory Animal Research
- Performance Standards
  - Published data
  - Expert opinion
  - Scientific principles



## US Government Principles

- Transportation
- Relevance
- Species, numbers
- Alternatives
- Pain and distress
- Analgesia, anesthesia
- Humane endpoints, euthanasia
- Living conditions
- Veterinary care
- Trained personnel
- Exceptions

## Acceptable methods of euthanasia

- 2000 Report of the AVMA Panel on Euthanasia, JAVMA, Vol 218, No. 5, 5/1/2001
- Deviation permitted if
  - scientific justification
  - approved by IACUC

## Animal Welfare Assurance

- Condition of grant award
- Description of institution's program for animal care and use
- Description of IACUC procedures
- Compliance mechanism
  - Annual reporting
  - Self-reporting of noncompliance

## Components of an institutional program for animal care and use

- Delineation of authority and responsibility
- Qualified Veterinarian with program authority
- Institutional Animal Care and Use Committee
- Institutional policies and procedures
- Occupational health and safety program
- Training for those involved in animal care/use
- Facilities, animal husbandry
- Veterinary care program

## IACUC Membership

- Minimum of five members
  - veterinarian
  - scientist
  - nonscientist
  - nonaffiliated

## IACUC Functions

- Oversight of animal care & use program
- Semiannual evaluations and inspections
- Schedule and plan for correcting deficiencies
- Review protocols
- Review concerns
- Advise Institutional Official
- Suspension authority

## What does the IACUC approve?

IACUC protocol form?

Grant application?

Do they match? How do you know?

## Prompt Reporting

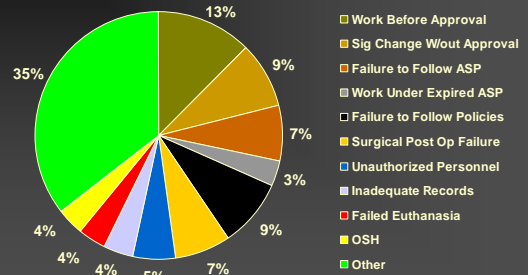
- Institution must promptly report:
  - Serious or continuing noncompliance
  - Serious deviations from standards
  - IACUC suspension
- Evidence that oversight is effective
- Usually results in corrective actions and improved systems 😊

➔ OLAW Guidance on prompt reporting, NIH Guide NOT-OD-05-034, 2/24/05

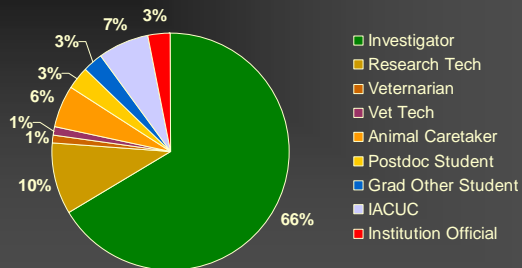
## OLAW Compliance Data

- Results of coding 758 cases
- Represents all cases in 2000-2003
- "Case" refers to:
  - Institutional self-reports (96%)
  - Third party allegations (4%)

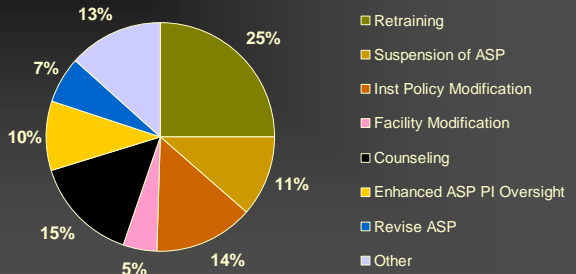
## Type of Noncompliance



## Responsible Individual(s)



## Institutional Corrective Action



## To receive an award involving animals...

- Applicant addresses 5 points in the Research Plan of application
- Institutional Animal Welfare Assurance
- Verification of IACUC approval

→ "How to Write an Application Involving Research Animals" <http://www.niaid.nih.gov/ncn/clinical/researchanimals/tutorial/index.htm>

PHS398 application (Research Plan, 8f) or SF424 PDF attachment 2.

### Research Plan #11

Vertebrate Animal Section

- Number and species
- Rationale
- Description of use
- Procedures to minimize pain
- Method of euthanasia



## Investigator Responsibilities

- Scientific and technical aspects of project
- Comply with IACUC decisions
- Follow institutional policies
- Obtain IACUC approval before introducing *significant* changes

## IACUC Responsibilities

- Oversee institutional program
- Protocol review
  - PHS requirement
  - Quality assurance
  - Facilitate humane research
- Identify and correct noncompliance

## Institutional Responsibilities

- Appropriate use of funds
- Appropriate performance of activities
- Resources for animal care and use
- IACUC
- Reporting to OLAW

## Success:

- Institutional climate that promotes compliance
- Institutional policies
- Institutional training
- Checks and balances
- Communication, internal and with NIH

## Stay Informed

- visit us at: <http://grants.nih.gov/grants/olaw/olaw.htm>
- email us at: [olaw@od.nih.gov](mailto:olaw@od.nih.gov)
- register for listServ at: <http://list.nih.gov/>

