

Reporting Noncompliant Events to OLAW

Axel Wolff, M.S., D.V.M

Director, Division of Compliance Oversight, OLAW

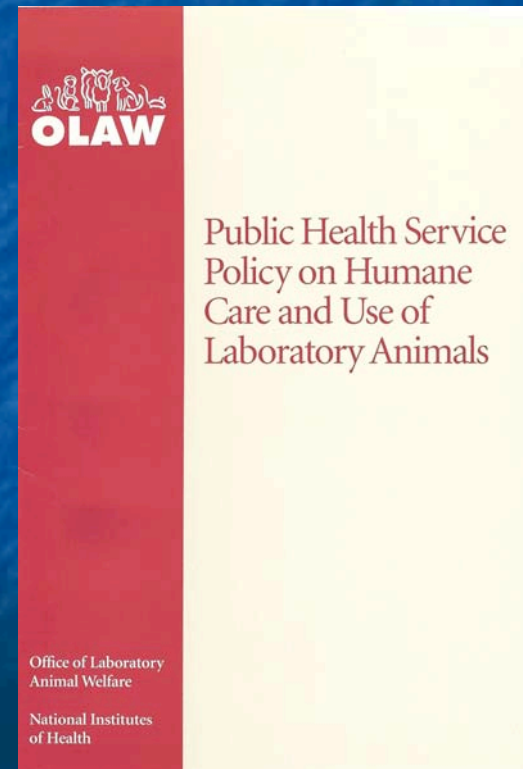
OLAW Online Seminar

March 5, 2009

The Law and How It's Implemented

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 August, 2002



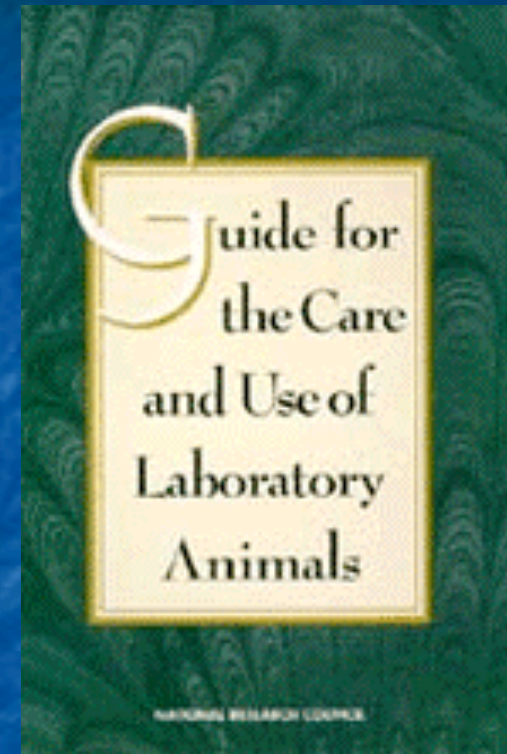
Reporting Requirements: PHS Policy IV.F.3.

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.

Guide for the Care and Use of Laboratory Animals

- National Academy of Sciences' Institute for Laboratory Animal Research
- Performance Standards
 - Published data
 - Expert opinion and experience
 - Scientific principles
- Currently under review for new edition



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

NOT-OD-05-034 (NIH Guide for Grants & Contracts)

- Issued 2/24/05
- Provides specific examples of reportable items
- Provides examples of situations not normally required to be reported

Serious or Continuing Noncompliance with PHS Policy

- Conducting animal related activities without appropriate IACUC review and approval
- Failure of animal care and use personnel to adhere to IACUC-reviewed and -approved protocols, institutional policies, or procedures
- Failure to correct deficiencies identified during the semiannual evaluation in a timely manner

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 institutionally determined time frame

Suspension of an Activity by the IACUC

- An IACUC intervention that results in the temporary or permanent interruption of an activity involving animals
- IACUC suspends after review by a convened quorum, with majority voting for suspension
- IO, in consultation with IACUC, takes corrective action and reports to OLAW

Serious Noncompliance Must Be Reported

Serious noncompliance with the PHS Policy and deviations from the *Guide* must be self-reported by the Assured institution, even if identified initially by other agencies, site visitors, or consultants such as:

- Other NIH site visitors: funding component, Office of Extramural Research, grants officials
- AAALAC (Association for the Assessment and Accreditation of Laboratory Animal Care Int.
- USDA
- CDC
- FDA

Semiannual Program Review and Facility Inspection

- If the IACUC identifies a serious problem during the semiannual review, a prompt report to OLAW is required
- Semiannual reports are not routinely submitted to OLAW other than when non accredited institutions submit Assurances for review

Prompt Reporting

Self-reporting is a component of self-regulation

- Report as soon as possible
- Make initial report by telephone, fax, email...don't wait until problem is solved
- Don't wait until Annual Report is due
- Final report must contain specific and reasonable corrective plans and schedules

Funding Component Contact

- Suspension of an animal activity by the IACUC must be reported to the PHS funding component
- Provide clear statement of problem, planned or completed corrective action
- Include the length of suspension
- Funding component may withhold funds for animal related work during suspension period

Common Compliance Issues - 1

Conduct of activities not approved by the IACUC

- Failure to obtain initial approval
- Conduct of activities after protocol expired
- Conduct of activities during suspension
- Implementation of an unapproved significant change

Common Corrective Actions - 1

Conduct of activities not approved by the IACUC

- Stop unapproved activity
- Place animals on holding protocol
- Do not charge the PHS/NIH grant
- Counsel and retrain staff
- Implement better laboratory oversight, communication, tracking, understanding of protocol content

Common Compliance Issues - 2

The IACUC

- Lack of required membership
- Absence of a quorum
- Problems due to inadequate training or monitoring
- Allowing conduct of animal related activities beyond expiration date (maximum 3 yrs)

Common Corrective Actions - 2

The IACUC

- Provide additional training for IACUC members e.g., OLAW tutorial, IACUC 101, PRIM&R, SCAW
- Reapprove all official actions with appropriately constituted IACUC/quorum
- Provide adequate post-approval monitoring
- Ensure adequate communication between IACUC and PIs

Common Compliance Issues - 3

Clinical care

- Inadequate pre-, peri-, and post-procedural care, monitoring, records, analgesia
- Failure to ensure death after euthanasia procedure
- Failure to carry out veterinary orders
- Chronic cage overcrowding

Common Corrective Actions - 3

Clinical care

- Establish peri-operative SOPs and assign dedicated personnel
- Keep adequate records of procedures
- Ensure adequate training
- Ensure appropriate authority of vet
- Establish SOP for timely separation of weaned rodents

Recordkeeping Requirements

- Animal Welfare Assurance
- Minutes of IACUC meetings
- Records of IACUC review of protocols
- Semiannual reports, including dissenting views
- Accrediting body determinations (AAALAC status)

Implications of Noncompliance

- Corrective actions and improved systems
- Restrict or withdraw approval of Assurance
- Institute special terms or conditions of awards
- Disallow costs
- Suspend or terminate award
- Criminal prosecution

How to Avoid Noncompliance

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

Accountability

- Institution is accountable for:
 - Financial & administrative aspects of the award
 - The animal care and use program (IACUC)
- Investigator is accountable for:
 - Conducting research within the parameters of the approved protocol
 - Compliance with animal care and use program
- IACUC, together with the IO, exercises oversight over institutional animal care and use

NIH Expectations

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

Prompt Reporting: Summary

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

Contact OLAW for Advice or Help

- If unsure if an item is reportable - call or email
- Better to ask or report than not
- Consequences are less desirable if reportable event is withheld and discovered later
- OLAW needs information on serious noncompliance to represent institution to PHS, Congress, press

OLAW Electronic Access

- e-mail: olaw@od.nih.gov
- <http://olaw.nih.gov>
- ListServ
 - Receive current announcements, notices, policy interpretations
 - Register for ListServ on OLAW webpage
- Coming soon: OLAW RSS