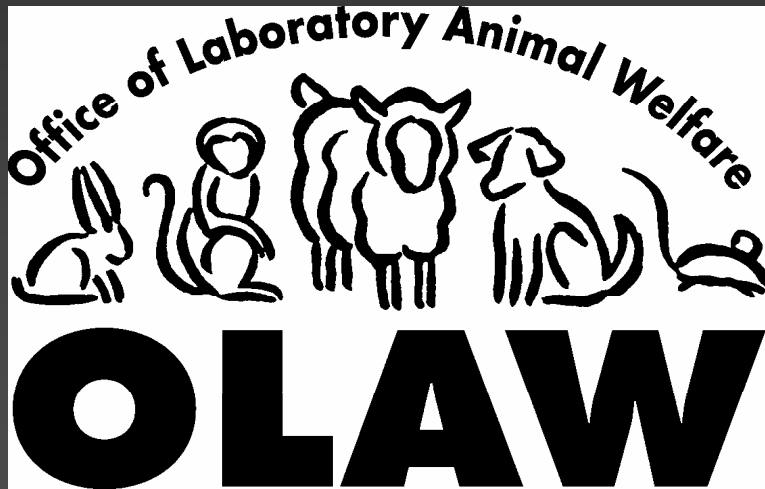


NIDDK New Investigator Workshop
September 27-28, 2004

ANIMAL WELFARE REQUIREMENTS



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



PHS Policy on Humane Care and Use of Laboratory Animals

An Overview

Authorizing Legislation and Implementing Policy

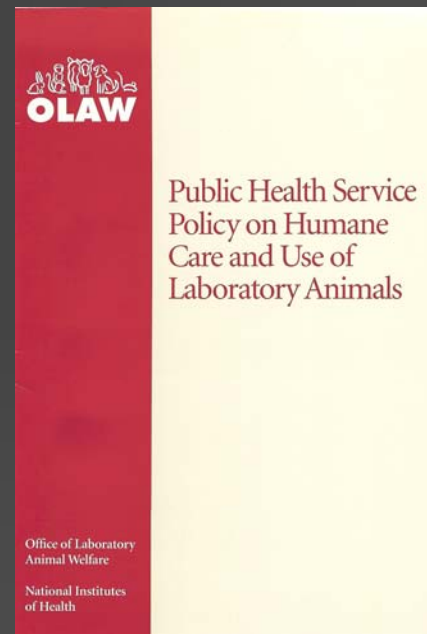
Health Research Extension Act of 1985

Public Law 99-158 "Animals In Research"

November 20, 1985

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

Revised August, 2002

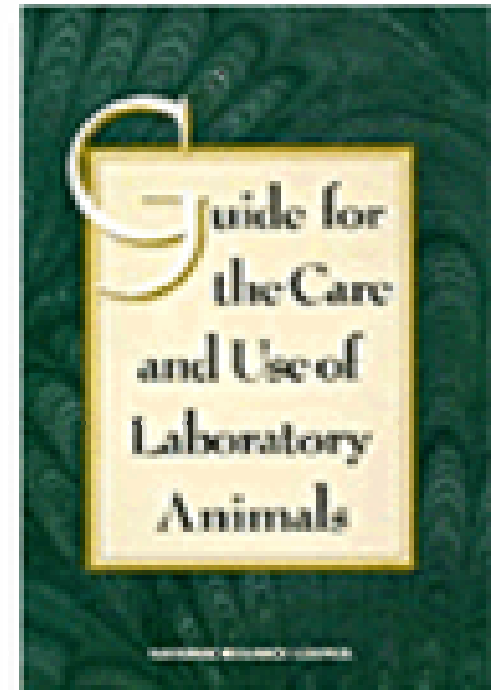


Standards for Animal Care and Use PHS Policy

- 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
- Performance Standards
 - Published data
 - Expert opinion and experience
 - Scientific principles



US Govt Principles for the Utilization and Care of Vertebrate Animals

- Basic tenets of animal care and use
 - PHS Policy – implements and supplements
 - Institutional commitment in assurance
 - IACUC incorporation into review of protocols
-

US Govt Principles in a Nutshell

- Transportation
 - Relevance to health, advance of knowledge
 - Appropriate species, quality and numbers, alternatives considered
 - Minimization of discomfort, distress and pain
 - Appropriate sedation, analgesia or anesthesia
 - Humane endpoints and euthanasia
 - Appropriate living conditions and provision of veterinary care
 - Trained personnel
 - Exceptions reviewed by IACUC
-

Additional standards

- 2000 Report of the AVMA Panel on Euthanasia, JAVMA, Vol 218, No. 5, 5/1/2001, **unless** deviation justified for scientific reasons in writing by PI and approved by IACUC
 - USDA Animal Welfare Regulations
 - Pain and distress categories
 - Consideration of alternatives
-

Other Federal Animal Regulators

- **USDA** – certain warm-blooded animals used in research, exhibition; includes vendors
 - **US Fish and Wildlife Service** – wildlife imports, exports, and research, and certain wild marine mammals
 - **US Customs** – animal imports under inhumane conditions – Lacey Act
 - **National Marine Fisheries Service** – certain wild marine mammals
 - **CDC** – importation of nonhuman primates and certain other animals
 - **FDA** – Good Laboratory Practices (GLPs)
-

OLAW Responsibilities

- PHS Policy interpretation and implementation
 - Animal Welfare Assurance negotiation and approvals
 - Compliance evaluation
 - Education
-

Key Elements of the PHS Policy

- Enforced self-regulation
 - Animal Welfare Assurance
 - Institutional Animal Care and Use Committee
 - Record keeping requirements
 - Reporting requirements
-

Enforced Self-regulation

- Performance standards
 - Flexibility
 - Self-monitoring
 - Self-correcting
 - Self-reporting
 - OLAW oversight
-

Animal Welfare Assurance

- Contract with federal government
 - Documentation of institutional commitment
 - Description of institutional programs and procedures
 - Principal method for compliance oversight
-

Program of Animal Care and Use

- Applicability
 - Lines of authority and responsibility
 - Institutional Animal Care and Use Committee
 - Procedures to implement the PHS Policy
 - Veterinary care
 - Occupational safety and health
 - Training
 - Facilities
 - Species
-

IACUC Membership

Minimum of Five Members

- Veterinarian
 - Scientist experienced in animal research
 - Nonscientist
 - Member unaffiliated with the institution
 - One other
-

IACUC Responsibilities

- Oversight of animal care and use program
 - Semiannual evaluation/inspection and report to Institutional Official
 - Review protocols and procedures
 - Review concerns
 - Advise Institutional Official
 - Suspend PHS-supported activity if necessary
-

Record Keeping

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

Annual Reporting

- Program or facility changes
 - IACUC membership changes
 - Dates of semiannual program evaluations and facility inspections
 - Dissenting views
 - Gain or loss of AAALAC accreditation
-

Prompt Reporting

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

Five Points of the Research Plan – Vertebrate Animals

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

PHS 398 Face Page

Item 5. Vertebrate Animals

No _____

Yes _____

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Item 5a. IACUC date

- Actual date of approval
 - Within last 3 years
 - “*Pending*” (just in time)
 - Date of performance site IACUC review
IF performance site is Assured (provide notation)
-

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Item 5b. Assurance Number

- ALWAYS applicant institution's Assurance
 - even if the animal work will be conducted at a performance site or collaborating institution
 - if applicant organization has no Assurance, write "*None*"
-

When IACUC review is pending...

- Application may go to peer review
 - Date must be received prior to funding
-

Submission of IACUC review after submission of 398

- Application number
 - Title of project
 - Principal investigator
 - Assurance number
 - Date of IACUC approval
 - Any changes required by the IACUC
-

Institutional Accountability

- The institution is accountable for:
 - financial and administrative aspects of the award
 - the animal care and use program (IACUC)
 - The investigator is accountable for:
 - the research
 - compliance with the animal care and use program
 - The IACUC, together with the Institutional Official, exercises oversight over institutional animal care and use
-

Institutional Official

- Designated representative of grantee organization in matters related to the award and administration of NIH grants
 - Accountable for appropriate use of funds and performance of activities resulting from application
-

Principal Investigator

- Designated by the grantee as responsible for the scientific and technical aspects of the project
 - Member of the grantee team responsible for ensuring compliance with the financial and administrative aspects of the award
-

Language from the face page of the 398:

SIGNATURE & ASSURANCE OF PRINCIPAL INVESTIGATOR/
PROGRAM DIRECTOR ASSURANCE:

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Implications of Noncompliance

- Corrective actions & improved systems
 - Restrict/withdraw approval of Assurance
 - Special terms/conditions of awards
 - Cost disallowance
 - Suspension/termination of award
 - Criminal prosecution
-

NIH Expectations

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

Electronic Access - OLAW

- **E-mail:** olaw@od.nih.gov
 - grants.nih.gov/grants/olaw/olaw.htm
 - **ListServ:** announcements, notices, policy interpretations, etc.
-

QUESTIONS

PLEASE ASK!
