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# **Animal Research Regulation – The USA**

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February, 2008



# USA – Animal Research Oversight

GOVERNMENT		PRIVATE
U.S. Dept. of Agriculture	Dept. of Health & Human Services	AAALAC Intl.
Animal Welfare Act	PHS/Hlth Res. Ext. Act	
Regulations	PHS Policy/Guide	Guide
Animal Care	NIH/OLAW	PRIMR, SCAW
And some States	FDA	

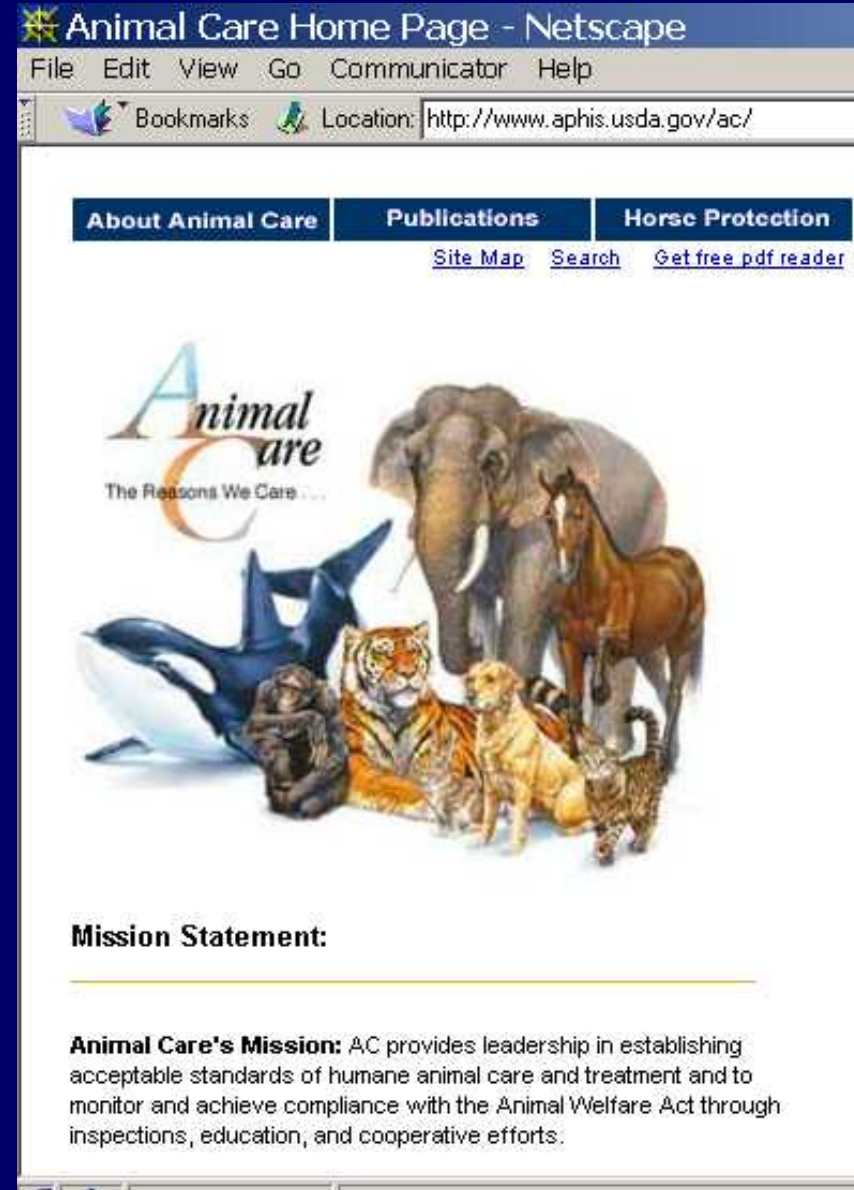
**MOU between USDA, NIH and FDA**

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# USDA

## Animal Welfare Act (amended 1985)

## Implemented by USDA/APHIS/ Animal Care through USDA Regulations



The screenshot shows a Netscape browser window titled "Animal Care Home Page - Netscape". The address bar displays "http://www.aphis.usda.gov/ac/". The page features a navigation menu with "About Animal Care", "Publications", and "Horse Protection". Below the menu are links for "Site Map", "Search", and "Get free pdf reader". The main content area includes the "Animal Care" logo with the tagline "The Reasons We Care..." and a collage of various animals: an elephant, a horse, a tiger, a dog, a cat, a monkey, and a whale. Below the collage is a "Mission Statement" section with a horizontal line and the following text: "Animal Care's Mission: AC provides leadership in establishing acceptable standards of humane animal care and treatment and to monitor and achieve compliance with the Animal Welfare Act through inspections, education, and cooperative efforts."

# God's Commandments: the 1st draft



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Medscape ©

<http://www.medscape.com>



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# Animal Welfare Act

- **Definitions**
  - **Animals**
  - **Research facilities**
  - **Dealers & Exhibitors**
- **Institutions – Institutional Official**
- **Institutional Animal Care and Use Committee**
- **Dog exercise and Primate enrichment**



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## **AWA Definitions**

- **Research Facility** – Higher education institution or research facility that uses dogs/cats, that purchases animals in interstate commerce, that receives research grants. Federal facilities expected to follow AWA but not inspected by USDA.
- **Animal** – live or dead dog, cat, monkey, guinea pig, hamster, rabbit and other animals as the Agriculture Secretary determines but not rats, mice and birds (per 2002 amendment).
  - Also does not apply to farm animals used in production agriculture trials



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# Implementing AWA

- **USDA Inspections**
- **IACUC Composition, Meetings & Protocol Review**
  - **Attending veterinarian**
  - **Public member**
  - **Non-scientist**
  - **Scientist**
- **Legal Sanctions – mainly fines**
- **Education also required**



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## IACUC System

- ❑ Follows approach used to govern human research – termed “Enforced Self-Regulation” (as opposed to self-regulation or government regulation).
- ❑ Many symposia and seminars to teach people how to run an IACUC but big differences exist from one institute to another.
- ❑ Challenge – when does regulation interfere with science (not meant to)



# IACUC Reliability

- **Plous and Herzog (Science 293:608-609, 2001)**
  - **Surveyed 50 IACUCS.**
  - **Used real protocols supplied by the 50 IACUCs.**
  - **Found low levels of agreement between original judgment and second and third rating.**
  - **Where IACUCs were provided with some guidance (e.g. a pain scale), agreement improved substantially**



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# Public Health Service

- PHS is mainly NIH (by far the largest amount of funding) with some activity by FDA and CDC.
- Several documents guide oversight:
  - **PHS Principles**
  - **The “Guide” for the Care and Use of Laboratory Animals**
  - **If you want public research funds, must comply.**



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

Office of Laboratory  
Animal Welfare

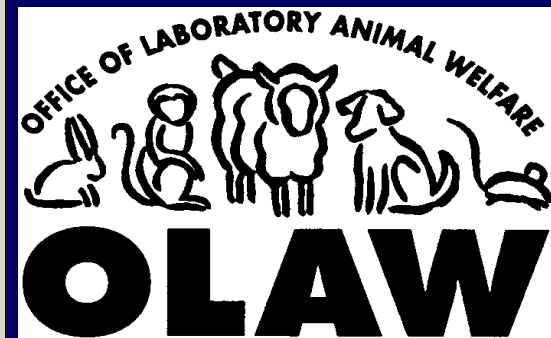
National Institutes  
of Health

**Public Health  
Service Act**

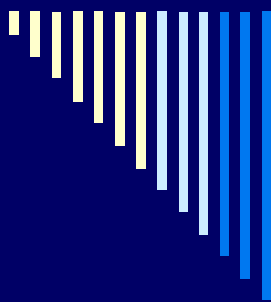
**DHHS**

**NIH**

**OLAW**



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Guide for  
the Care  
and Use of  
Laboratory  
Animals

NATIONAL RESEARCH COUNCIL

February, 2008



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# Office of Laboratory Animal Welfare

## □ Registration.

- Holds Animal Welfare Assurance on file

## □ Compliance.

- Receives annual reports on compliance with PHS principles
- IACUC Protocol reviews go to study sections

## □ Education.



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## **OLAW Looks For 5 Points**

- Number and Species**
- Rationale**
- Description of use**
- Methods to minimize pain and distress**
- Methods of euthanasia**



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# Key Aspects of PHS Policy

- Enforced self-regulation
  - Performance standards – flexible, self-correcting, based on animal welfare
- Animal welfare assurance
- IACUC
- Reporting requirements - semiannual
- Record-keeping requirements



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# **OLAW Assurance Elements**

- Reporting relationships – authority**
- IACUC membership and performance**
- Veterinary care**
- Occupational health**
- Personnel qualifications**
- Species**
- Facilities**



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# Issues in Protocol Review

- Analgesia and Anesthesia
- Euthanasia
- Species and numbers
- Relevance to Human/Animal Health
- Advancement of Knowledge
- Consideration of Three Rs (non-animal methods)

Office of Lab Animal Welfare

Table of Contents

Introduction

Relevant Documents

Terms and Concepts

Animal Programs

The IACUC

Reports and Records

Glossary and Resources

Sample Documents



# OLAW

## PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS TUTORIAL

A tutorial for new animal care and use committee members, institutional administrators, investigators, animal care personnel, veterinarians, or others who are interested in learning about the [PHS Policy on Humane Care and Use of Laboratory Animals](#).

### Introduction

[Health Research Extension Act of 1985](#)  
[Office of Laboratory Animal Welfare](#)  
[Applicability of the PHS Policy](#)

# AAALAC International - Private



ASSOCIATION FOR ASSESSMENT AND ACCREDITATION OF LABORATORY ANIMAL CARE INTERNATIONAL

CONTACT | SEARCH:  

ABOUT AAALAC

ACCREDITATION

PROGRAM STATUS  
EVALUATION

APPLY

RESOURCES

NEWS

PUBLICATIONS

where  
**science**  
and responsible  
**animal care**  
**connect**

AAALAC International promotes the humane treatment of animals in science through accreditation and assessment programs. Nearly 700 institutions in 27 countries have earned AAALAC International accreditation.



QUICK LINKS: [▶ ACCREDITED ORGANIZATIONS](#) [▶ MEMBERS ONLY](#) [▶ REFERENCE RESOURCES](#) [▶ PROGRAM DESCRIPTION](#) [▶ GLOBAL GATEWAY](#)

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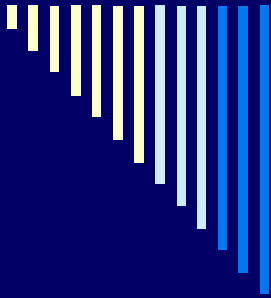
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# AAALAC International

- ❑ Started in 1960s
- ❑ Now helping to drive standardization across the world
- ❑ Uses the PHS Guide as a core document
- ❑ Need to harmonize different requirements



# Institutional Animal Care and Use Committee Guidebook

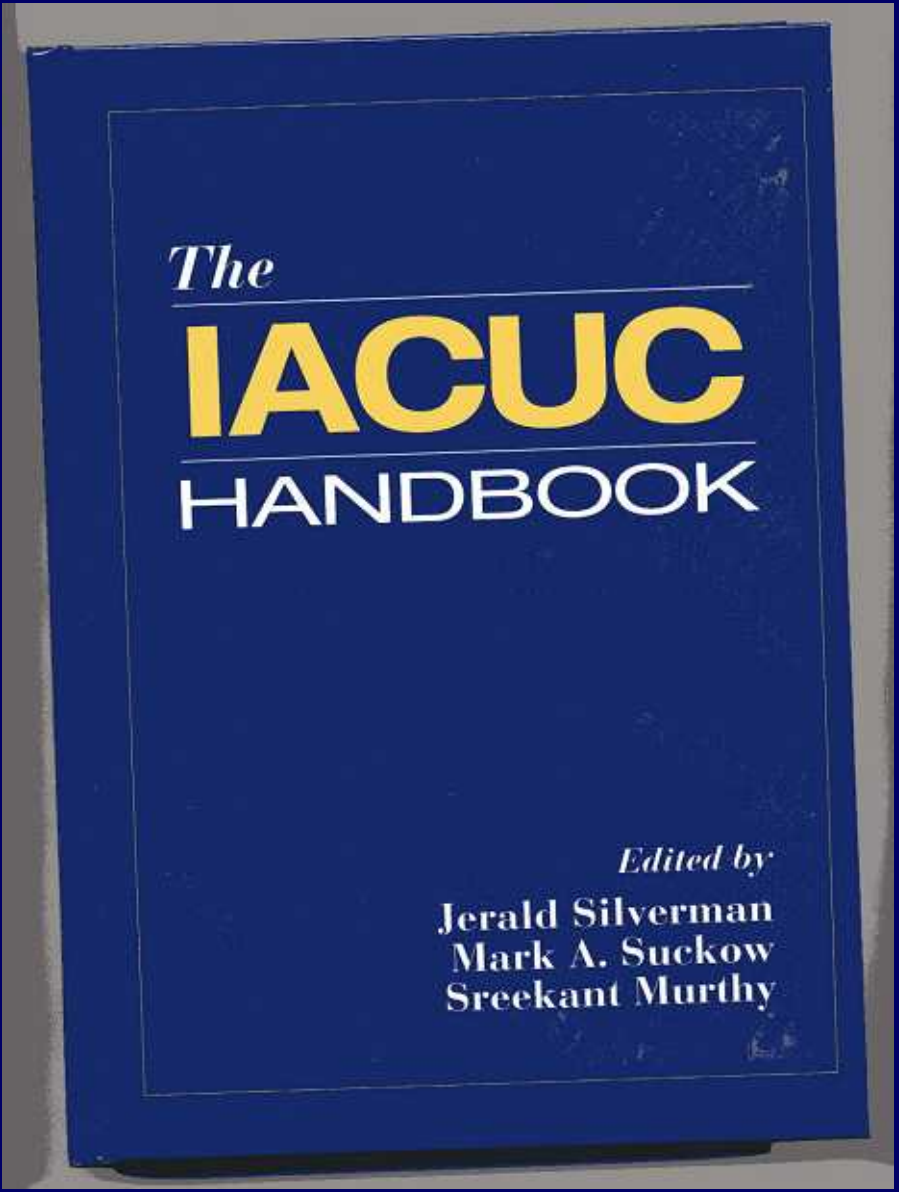
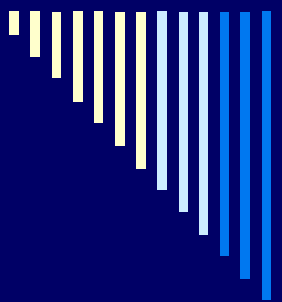
2nd Edition  
2002



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# Humane Science Online Course – Johns Hopkins CAAT

- ❑ <http://caat.jhsph.edu/programs/course/index.cfm>
- ❑ Enhancing humane science – Goldberg & Owiny
- ❑ Introduction to humane science – Rowan & Goldberg
- ❑ Rodent Surgery – quality matters – Brown
- ❑ Post-procedural care – Singletary & Newcomer
- ❑ Pain and distress – Peterson
- ❑ Impact of stress on data quality – Rowan
- ❑ Humane endpoints – Owiny
- ❑ The Five Freedoms – Watson
- ❑ Enrichment for rodents – Guilarte
- ❑ Non-invasive imaging in rodents – Gabrielson
- ❑ In vitro and replacement approaches – Goldberg & Yager
- ❑ Experimental design & statistics - Broman



*The*  
**IACUC**  
HANDBOOK

*Edited by*  
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**Mark A. Suckow**  
**Sreekant Murthy**