

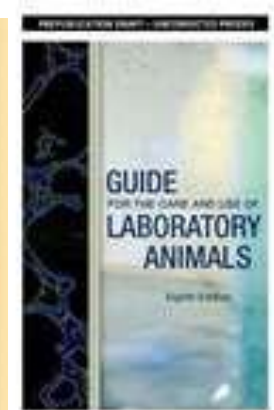
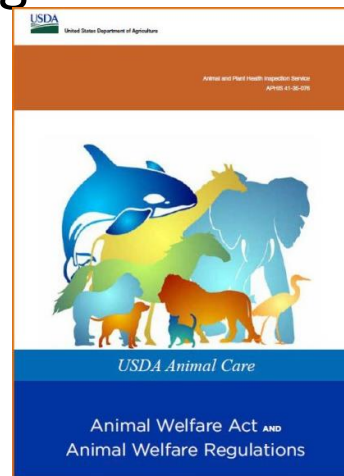


Oversight of Animal Research: A Primer/Refresher

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Oversight of Animal Care and Use in the U.S.

- “The use of laboratory animals is governed by an interrelated, dynamic system of regulations, policies, guidelines, and procedures.” (*Guide* -NAS - 2011 –pg. 12).
 - USDA – regulations
 - OLAW – policy
 - AAALAC – guidelines
 - Institutional – policies, guidelines and procedures (SOPs)



Regulation of the Use of Laboratory Animals

- Involuntary - mandated by law or exist as a condition of funding.
- Voluntary - those that an individual or institution adheres to as part of their overall commitment to research and academic excellence.

Regulation of the Use of Laboratory Animals

- Involuntary
 - Animal Welfare Act(AWA) - United States Dept. of Agriculture (USDA) - <http://www.aphis.usda.gov/ac/>
 - PHS Policy on the Humane Care and Use of Laboratory Animals - NIH - Office of Laboratory Animal Welfare(OLAW) - <http://grants.nih.gov/grants/olaw/olaw.htm>

Regulation of the Use of Laboratory Animals

- Involuntary

- Good Laboratory Practice Regulations (GLPs) - Food and Drug Administration (FDA)

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=58>

- Private Funding Agencies

Regulation of the Use of Laboratory Animals

- Voluntary
 - Accreditation - AAALAC International - <http://www.aaalac.org/>
 - Individual Users
 - Minimize non-experimental variables
 - Maintain the integrity of scientific process

Animal Welfare Act (AWA)

- History
 - Amended – 12 times
- Implementation (Administration)

AWA History

- August 24, 1966 – P.L. 89-544 - Laboratory Animal Welfare Act (May 25, 1967)
 - to protect the owners of dogs and cats from the theft of such pets, to prevent the sale of dogs and cats which have been stolen, and to insure that certain animals intended for use in research facilities are provided humane care and treatment, it is essential to regulate the transportation, purchase, sale, housing, care, handling and treatment....
 - only covered facilities using dogs and cats

AWA History

- December 24, 1970 – P.L. 91-579 -Animal Welfare Act
 - Expanded coverage to all warm-blooded animals, exhibitors and auctions
 - Language to exclude rats, mice and birds was added
 - Expanded definition of adequate veterinary care

AWA History

- April 22, 1976 – P.L. 94-279 Animal Welfare Act Amendments of 1976
 - Expanded guidelines for transportation to commercial carriers
 - Animal fighting

AWA History

- 1985 – Improved Standards for Laboratory Animals Act - Oct. 30, 1989 & Mar. 19, 1991
 - strengthened the standards
 - mandated collection and dissemination of information to prevent unnecessary duplication and mandated training.
 - standards for exercising dogs & the psychological well being of primates,
 - established an Institutional Animal Care and Use Committee whose members are representative of the community's concerns for animals.

AWA History

- November 18, 1990 – P.L. 101 624 - Pet Protection Act –
 - Farm Bill
 - Defined minimal holding periods for animal in pounds and shelters
 - Established record keeping requirements
- May 1, 2002 – P.L. 107-171 - Senator Helms Amendment
 - Farm Bill
 - Clarified the intent of Congress – rats, mice & birds

AWA History

- May 3, 2007 – P.L. 110-22 Animal Fighting Prohibition Enforcement Act
 - Set penalties at 3 yrs for each incident
 - Prohibited sale, transport or delivery of spurs
- June 18, 2008 – P.L. 110-246 – Food Conservation Act
 - Increased penalties from 3-5 years
 - Prohibited sale of imported dogs < 6 mos. old
 - Increased fines to \$10K per day per animal \$14, 206
 - Required report on class B dogs and cats

HISTORY

- January 10, 2013 - Public Law 112–261 - modify the definition of “exhibitor”
 - Section 2(h) of the Animal Welfare Act (7 U.S.C. 2132(h)) is amended by adding “an owner of a common, domesticated household pet who derives less than a substantial portion of income from a nonprimary source (as determined by the Secretary) for exhibiting an animal that exclusively resides at the residence of the pet owner,” after “stores,”.

HISTORY

- January 3, 2014 - Agricultural Act of 2014
 - §2133 - That a dealer or exhibitor shall not be required to obtain a license as a dealer or exhibitor under this Act if the size of the business is determined by the Secretary to be de minimis

HISTORY

- November 9, 2020 - Amendments to Licensing Provisions and to Requirements for Dogs
 - 3 yr. license process implemented
 - Eliminated the renewal process
 - Expanded circumstances requiring a change in license
 - 24 access to potable water for dogs
 - Written program of veterinary care for dogs
 - Annual physical
 - Medical records

History

- December 27, 2021 – AWA Research Facility Registration Updates, Reviews and Reports
 - Removed 3 yr. registration requirement
 - Removed requirement to request inactive status
 - Replaced annual review process 3-year resubmission and review requirement
 - IO no longer required to sign the annual report

History

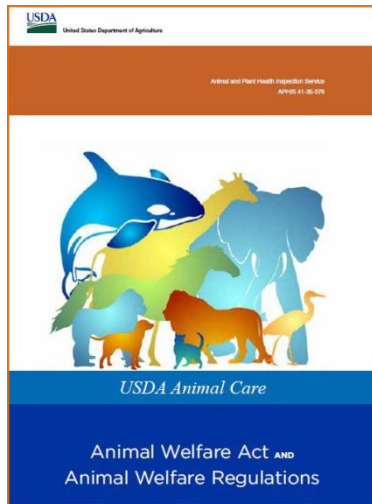
- January 3, 2022 - Handling of Animals; Contingency Plans
 - 12/31/2012 – Issued final rule
 - 7/31/2013 – issued stay of the final rule
 - Updated dates
 - Removed training documentation requirement
 - Provided an optional form

History

- February 24, 2023 - Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act
 - establishes standards governing the humane handling, care, treatment, and transportation of birds, excluding birds bred for use in research
 - 3.154 Environmental enhancement to promote psychological well-being

Implementation

- Animal Welfare Regulations -contained in the Code of Federal Regulations
 - Title 9 (Animals and Animal Products)
 - Chapter 1, Subchapter A (Animal Welfare) Parts 1-4
 - Part 1- Definitions
 - Part 2 - Regulations
 - Part 3 - Standards
 - Part 4 - Rules of Practice Governing Proceedings Under the Animal Welfare Act



Administration

- United States Department of Agriculture (USDA)
<http://www.aphis.usda.gov/>
 - Animal Care (AC) of APHIS <http://www.aphis.usda.gov/ac/>
 - Unannounced Inspections
 - RBIS
 - Annual Report
 - Investigative and Enforcement Services (IES)
<http://www.aphis.usda.gov/ies/>
 - Investigates alleged violations of APHIS-related Federal laws and regulations

Transparency



HOME | INSPECTION REPORTS | TEACHABLE MOMENTS | ANNUAL REPORTS | HELP

Welcome to the USDA Animal Care Public Search Tool

This site will provide information and records that shed light on the USDA Animal and Plant Health Inspection Service's (APHIS) administration of the Animal Welfare Act (AWA). APHIS' Animal Care program is responsible for the day-to-day administration of the AWA, including establishing acceptable standards of humane care and treatment for regulated animals and monitoring and achieving compliance through inspections, enforcement, education, and cooperative efforts.

The AWA and its associated regulations seek to ensure the humane handling, care, treatment, and transportation of certain warm-blooded animals used or intended for use in research, exhibition, or as pets. Animal dealers and exhibitors must obtain a license, and research facilities, carriers, and intermediate handlers must obtain a registration. Animal Care inspectors conduct inspections of licensee and registrant animals, records, and facilities to assess compliance with the AWA and its regulations, and document their observations and professional assessments in inspection reports. Licensees and registrants must notify Animal Care of changes in their operations and file periodic updates with Animal Care, including annual reports of animal use by research facilities.

This Public Search Tool provides a list of persons licensed and registered under the AWA, inspection reports, and research facility animal use annual reports. Individuals or businesses seeking information or records that are not available through this Public Search Tool may be able to find what they are looking for elsewhere on APHIS' website at <https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare>, or by submitting a request under the Freedom of Information Act (FOIA). Information on how to submit a FOIA request to APHIS can be found at <https://www.aphis.usda.gov/aphis/resources/foia>.

Subparts A & B

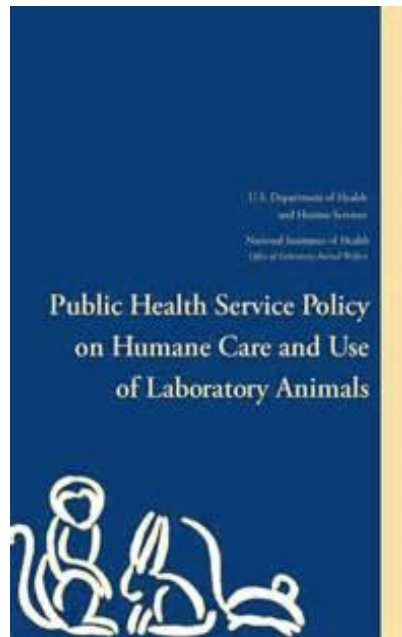
- Subpart A – Licensing
 - Dealers
 - Exhibitors
- Subpart B – Registration
 - Carriers and intermediate handlers

Subpart C – Research Facilities

- § 2.30 - Registration
- § 2.31 - IACUC
- §2.32 - Personnel Qualifications
- §2.33 – AVAVC
- §2.35 – Recordkeeping Requirements
- §2.36 – Annual Report
- §2.37 – Federal Research Facilities
- §2.38 - Miscellaneous

Public Health Service Policy

- Public Health Service Policy for the Care and Use of Laboratory Animals - <http://grants.nih.gov/grants/olaw/olaw.htm>



PHS POLICY: History

- Initiated by NIH in 1971 and was extended to all PHS activities January 1, 1979
- Revised in spring of 1985 with implementation January 1, 1986.
- Revised in Spring of 1986 reflected changes required by passage Public Law (PL) 99-158, November 20, 1985, Health Research Extension Act of 1985, Section 495, “Animals in Research.”

PHS POLICY

- The Office of Laboratory Animal Welfare (OLAW) is the general administrator of the Policy.

PHS Policy

- PHS Policy (2002) - intended to implement and supplement the IRAC Principles
 - Implementation by Awardee Institution
 - Animal Welfare Assurance -
 - Institutional Program - *Guide for the Care and Use of Laboratory Animals* (NAP - 2011)
 - Functions of IACUC - pg 12 PHS Policy
 - Institutional Status - AAALAC accreditation
 - Annual report filed by IACUC through the IO
 - Minority reports
 - Variances from USDA Regulations and Standards

Interagency Research Committee Principles (IRAC) -

- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Teaching
 - 1. In accordance with regulations for transportation, care and use.
 - 2. Procedures should be designed & performed with due consideration for advancement of knowledge.
 - 3. Appropriate species and quality of animals. The minimum number possible should be used. Should consider alternatives.

Interagency Research Committee Principles (IRAC) -

- 4. Avoid or minimize discomfort, distress or pain.*
- 5. Appropriate sedation, analgesia or anesthesia.
- 6. Termination when severe or chronic pain or distress that cannot be relieved.
- 7. Appropriate living conditions.
- 8. Training and experience of all personnel.
- 9. Exceptions for the purpose of teaching or demonstrations cannot be made

APPLICABILITY

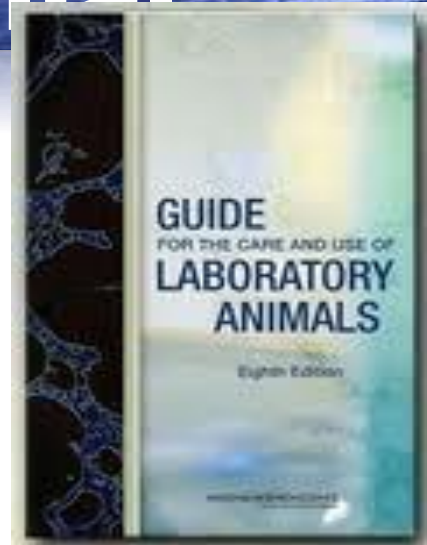
- All PHS support activities involving animals
 - NSF
 - NASA
 - FDA
 - VA
- Institution must also comply with other federal, state and local laws

Guide for the Care and Use of Laboratory Animal

- Guide
 - 1963 – Guide for Laboratory Animal Facilities and Care
 - Revised/Update (1965, 1968, **1972**, 1978, 1985, 1999 and 2011
 - 1985 Edition
 - Chapter organization change
 - Emphasis on the increasing role and responsibility of the institution

Guide for the Care and Use of Laboratory Animals

- 8th Edition
 - Five Chapters
 - Key Concept
 - Animal Care and Use Program
 - Environment, Housing and Management
 - Veterinary Care
 - Physical Plant



Guide for the Care and Use of Laboratory Animal

- Purpose – to assist institutions in laying the foundation for a comprehensive animal care and use program that relies on the use of performance standards and professional judgment to assure that such use is in accordance with the highest scientific, humane and ethical principles.

Food And Drug Administration

- 1978 – Good Laboratory Practice Regulations
 - Non-clinical laboratory studies – safety assessment
 - Formal protocols
 - Standard operation procedures (SOPs)
 - Independent Quality Assurance
 - Archival storage of data

Private Funding Agencies

- Record of Compliance
- PHS Assurance
- AAALAC Accreditation
- Special requirement

AAALAC

- AAALAC International
 - Founded in 1965 to promote responsible treatment of animals in science
 - Peer review process
 - Progressive standards
 - Rigorous self-assessment process
 - Guide

Individual Users

- Should provide the impetus for setting and maintaining high standards
 - Reducing Non-experimental Variability - good care = good science
 - The 3 Rs – Refinement, Reduction and Replacement
 - Maintain the integrity of the Scientific Process - self-regulation prevents costly regulatory oversight

Summary

- Ultimate responsibility for compliance
- Requires institutional programs
- Manage the interrelated, dynamic system
 - Institutional Official (IO)
 - Institutional Animal Care and Use Committee (IACUC)
 - Attending Veterinarian (AV)

IACUC

- ...evaluating the care, treatment, housing and use of animals
- ...certifying compliance
- Membership
 - Scientist
 - Non-scientist
 - Non-affiliated individual
 - Attending Veterinarian

IACUC

- Functions
 - Semi-annual reviews and inspections
 - Review and approve proposed uses of animals
 - Review and approve proposed modifications
 - Authorization to suspend

IACUC

- The Review
 - Procedures will minimize ...
 - PI has considered alternatives
 - PI assurance
 - Potential Painful or distressful procedures
 - Appropriate use of sedative, analgesics or anesthesia
 - Veterinary involvement
 - Euthanasia when needed

IACUC

- The Review
 - Appropriate living conditions
 - Medical Care
 - Personnel Qualifications
 - Surgical procedures
 - Methods of Euthanasia
 - Continuing review
 - Final word

In Closing

- “... governed by an interrelated, dynamic system of regulations, policies, guidelines, and procedures.”
- Proactive progress institutional programs
- Key participants
 - IO
 - IACUC
 - AV