Laws and Regulations Governing Animal Care and Use

Animal Welfare Act

- Signed into law in 1966
- Important amendments in 1970, 1976, 1985 & 1990
- Administered by the USDA's APHIS
- Divided into 4 Parts

Disclaimers

- This is not an ACLAM sanctioned presentation
- All information is deemed reliable and correct
  - No warranty for accuracy
- No information presented is known to be specifically included in ACLAM Board examinations

Animal Welfare Act

4 Parts

- 1 – Definition of Terms
- 2 – Regulations
- 3 – Standards
- 4 – Rules of Practice

Regulations Addressed in Presentation

- Animal Welfare Act & Regulations
- Public Health Service Policy and the Guide
- Good Laboratory Practices Act
- Guide for the Care and Use of Agricultural Animals in Research and Teaching
- International Agreements/Standards

Animal Welfare Act

Part 1 – Definition of Terms

- Animal
- Research Facility
- Dealer
- Exhibitor

Animal Welfare Act

Part 1 – Definition of Terms

- Animal
  - Warm-blooded vertebrates



Animal Welfare Act

Part 2 – Regulations

- Research Facilities
  - IACUC
  - Personnel qualifications
  - Veterinary care
  - Recordkeeping requirements

Animal Welfare Act

Part 2 – Regulations

- Licensing
- Registration
- Research Facilities
- Identification of Animals
- Stolen Animals
- Records
- Compliance with Standards & Holding Period

Animal Welfare Act

Part 2 – Regulations

- Identification of Animals
  - Tags or tattoos for dogs & cats
  - Tags must be "official"

Animal Welfare Act

Part 2 – Regulations

- Registration
  - Facilities must be registered with USDA
  - Must be updated every 3 years

USDA

Animal Welfare Act

Part 3 – Standards – Humane Handling, Care, Treatment & Transportation

- Facilities and Operating Standards
- Animal Health & Husbandry
- Transportation

Animal Welfare Act

Part 4 – Rules of Practice

- Suspended license
- Penalties

Animal Welfare Act

Annual Reports to USDA Must:

- Provide locations where animals were used
- Provide information regarding species used
- Categorize animal use based on pain & distress

Animal Welfare Act

- Register with USDA – update every 3 years
- Provide annual reports to USDA
- Permit unannounced inspections annually
- Inspection reports available to public through Freedom of Information Act (FOIA)

Animal Welfare Act

Four Categories for Annual Reports

- B – animals bred, conditioned or held
- C – no pain or distress
- D – pain or distress alleviated by drugs
- E – unalleviated pain or distress

Animal Welfare Act

Annual Reports to USDA Must:

- Be submitted by December 1
- Assure that standards were followed
- Assure that alternatives were considered
- Provide details of IACUC-approved exceptions

Mental Break

U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training

- Adherence to AWA
- Relevant to human or animal health
- Appropriate species and number
- Avoidance or minimization of pain & distress
- Use of appropriate drugs to alleviate more than momentary pain or distress

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

- Mandated by The Health Research Extension Act of 1985
- Implements the U.S. Government Principles for the utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
- Enforced by Office of Laboratory Animal Welfare (NIH)
- Required for funding by any agency of the PHS

U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training

- Employing euthanasia for animals in severe or chronic pain or distress that cannot be alleviated
- Appropriate living conditions for species
- Personnel qualifications
- Exceptions must be approved by appropriate review group

PHS Policy

- Defines “assurance” categories
- Defines IACUC function and structure
- Provides information required for applications for PHS funding awards
- Defines record keeping and reporting requirements
- Describes the implementation of the policy by the PHS
- Uses the Guide for the Care and Use of Laboratory Animals

The Health Research Extension Act of 1985, (Public Law 99-158)

- Gave the force of law to the US Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy).
- Established additional requirements for animal research
- Directed the Secretary of the Department of Health and Human Services (DHHS) to establish "guidelines" that must be followed by institutions that receive grants or contracts from DHHS.

PHS Policy

I. Introduction

II. Applicability

III. Definitions

PHS Policy

IV. Implementation by Institutions

A. Animal Welfare Assurance
B. Functions of the IACUC
C. Review of PHS Supported Research
D. Information Required on Applications
E. Recordkeeping Requirements
F. Reporting Requirements

PHS Policy

IV. Implementation by PHS

A. Responsibilities of OLAW
B. Responsibilities of PHS Agencies
C. Conduct of Special Reviews / Site Visits
D. Waiver

PHS Policy

IV. Implementation by Institutions

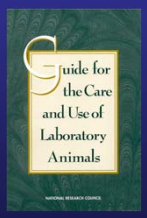
A. Animal Welfare Assurance

- Comprehensive document about Animal Care & Use Program, IACUC composition, Accreditation status
- Valid for 5 years
- Must be approved by OLAW prior to funding

PHS Policy

The Guide

- PHS expects institutions to use as the basis for developing animal care & use programs



PHS Policy

IV. Implementation by Institutions

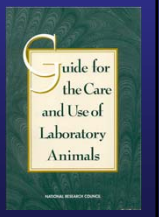
F. Reporting Requirements

- Annual reports to OLAW
- Prompt reports to OLAW regarding non-compliance

PHS Policy

The Guide

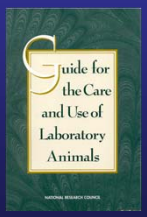
- Prepared by Institute of Lab Animal Resources (ILAR)
- Published in 1963 and last revised in 1996 and 2011
- Humane care, use and maintenance of laboratory animals



PHS Policy

The Guide

- Facility environment
- Housing requirements
- Sanitation standards
- Facility construction guidelines
- Personnel qualifications
- Surgical and post-surgical care
- Veterinary care
- Euthanasia



Components of an Animal Program

- The animal research program is maintained in balance and is supported by three components –the Institutional Official (IO), the IACUC and the Attending Veterinarian.
- Each component must perform its function in regard to animal welfare while not interfering with the function of the other.
- All function not only to ensure animal welfare but also support the research efforts.

Comparison of AWA and PHS Policy

	AWA	PHS Policy
Regulatory Agency	Department of Agriculture (USDA)	US National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW)
Legislative Authority	Statute: 7 USC 2131-2156 Regulations: 9 CFR	Statute: Health Research Extension Act of 1985 (PL 99-158) ("Law") Policies: PHS Policy on Humane Care and Use of Laboratory Animals, ("Policy") which includes the "Guide for the Care and Use of Laboratory Animals"
Species Covered	Any live or dead warm-blooded animal used in research, teaching, testing, experimentation, except birds, rats of the genus Rattus, and mice of the genus Mus bred for use in research.	Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
Assurance/Registration	Registration - updated every 3 years; signed by an official who has the legal authority to bind the Institution and submitted to the APHIS, REAC Supervisor (on agency forms)	Assurance - typed on institution's letterhead and signed by the IO. Valid for a specified time, no longer than 5 years. The most recent semi-annual report must be submitted with the Assurance.

Functions of the Institutional Official

- Must have the administrative and operational authority to commit institutional resources to ensure compliance with the appropriate regulations and standards.
- Bears ultimate responsibility for the animal program
- Ensures that the animal program is aligned with the institution's mission

Mental Break

Adequate Veterinary Care

- The USDA Regulations requires that the attending veterinarian have appropriate authority to "ensure the provision of adequate veterinary care and oversee the adequacy of other aspects of animal care and use."

Responsibilities of the Attending Veterinarian

- Be a voting member of the IACUC (or designee)
- Be responsible for the health and well-being of the laboratory animals
- Have access to all animals
- Manage the program of adequate veterinary care

Adequate Veterinary Care

- Adequate veterinary care includes "daily observation of all animals to assess their health and well-being".
- Is done under the direction of the veterinary staff. If not, it must be done by someone qualified to make such observation, as long as there is "direct and frequent communication" with the veterinarian so that information on animal health and well-being is conveyed in a timely manner.

Adequate Veterinary Care

- Each research institution must provide adequate veterinary care to its animals.
- The Guide and the AWA state that adequate veterinary care consists of:

IACUC

- Both AWA and the *Guide* require that each institution have an IACUC in place.
- Appointed by the Chief Executive Officer
- IACUC oversees and evaluates the animal care and use program.

Adequate Veterinary Care

- Using appropriate methods to prevent, control, diagnose, and treat diseases and injuries
- Providing guidance to users regarding handling, immobilization, anesthesia, analgesia, and euthanasia
- Monitoring surgery programs and post-surgical care.

Key IACUC Functions

- Review animal program
- Inspect facilities
- Prepare reports of above for IO (denote significant vs. minor deficiencies)
- Review concerns regarding care

Key IACUC Functions

- Make recommendations to IO concerning any aspect of animal program, facilities, or personnel training
- Review and approve, require modification, or withhold approval
  - proposed experimental activities
  - proposed changes (amendments)
- Suspend an activity

Animal Use Protocol Requirements

- Procedures involving animals will avoid or minimize discomfort, distress, or pain to the animal
- Procedures that may be painful distressful to animals will be performed with appropriate sedatives, analgesics, or anesthetics. Withholding such agents must be justified for scientific reasons and approved by the IACUC

Training

- Another institutional responsibility is to ensure "that all scientists, research technicians, animal technicians and other personnel involved in animal care, treatment and use are qualified to perform their duties."
- The new version of the "Guide" states that all training must be documented.

Animal Use Protocol Requirements

- PI has considered alternatives to procedures that may cause pain or distress.
- PI must provide a written narrative description of methods and sources used to determine that alternatives were not available.
- The veterinary staff will be consulted in planning a procedure that may cause more than momentary pain or distress.

Animal Use Protocol Requirements

- Each Principal Investigator (PI) must complete an animal use protocol, which documents the desired animal use activity.
- These forms are designed to generate the information required by the AWA and the *Guide*.
- The IACUC will review each protocol to determine among other things:

Animal Use Protocol Requirements

- PI has provided written assurance that activities do not unnecessarily duplicate previous experiments.
- Animal care will be species-appropriate and directed by trained and experienced personnel
- Veterinary care will be available and provided by a qualified veterinarian
- Personnel conducting procedures will be appropriately qualified and trained

Animal Use Protocol Requirements

- Activities that involve surgery must include appropriate pre- and postoperative care.
- Survival surgery has to be performed using aseptic procedures. No animal can be used in more than one major operative procedure from which it is allowed to recover, unless justified in writing for scientific reasons and approved by the IACUC.

Comparison of the AWA and the PHS Policy - IACUC

	AWA	PHS Policy
Other reports	Report to APHIS and any federal funding agency: •Any suspension of an activity involving a animal and the appropriate corrective action taken •Failure to adhere to a plan of correcting a significant deficiency (report within 15 days)	Notify OLAW when: •Serious or continuing noncompliance with PHS Policy •Serious deviation from the Guide •Suspension of activity by IACUC
Continuing review of IACUC protocols	Not less than Annually	At appropriate intervals with a complete review at least once every 3 years

Animal Use Protocol Requirements

- IACUC will review the animal use activity for compliance with the federal laws
- Euthanasia
  - Methods of euthanasia must produce rapid unconsciousness and subsequent death without evidence of pain or distress
  - Consistent with the recommendations of the AMVA Panel on Euthanasia (2000).

Mental Break

Comparison of the AWA and the PHS Policy - IACUC

	AWA	PHS Policy
Members	Three (3) or more • 1 Veterinarian • 1 member not affiliated with the institution • Where there are more than 3, not more than 3 shall be from the same administrative unit of the institution	Five (5) or more • 1 Veterinarian • 1 individual who is not affiliated with the institution • 1 practicing scientist • 1 non scientist • An individual may meet more than one category of membership.
Semi-Annual Review / Inspection	Uses Title 9 CFR as the basis.	Uses the Guide and USDA regulations as the basis
Annual Report	Written report to the AC Regional Director for the State assuring compliance with the Act, location of all facilities where animals are housed / used, and specific animal information.	Written report to OLAW describing: • Changes that would affect Assurance category • Changes in program description • Changes in IACUC membership • Dates of semiannual evaluations • Or state no changes

Good Laboratory Practices (GLP) Regulations

- Apply to nonclinical studies for assessing the safety of chemicals to humans, animals and environment
- Safety studies involving new medications, food or food color additives, medical devices, and biological products
- Studies involving pesticides

GLP Regulations

Require:

- Written Standard Operating Procedures
- Trained personnel with current training files
- Accurate record-keeping to allow reconstruction of study – even years later
- Quality Assurance Unit

Guide for the Care and Use of Agricultural Animals in Research and Teaching

- Covers:
  - Husbandry, housing, bio-security
  - Enrichment
  - Animal handling and transport
  - Specific standards for cattle, horses, poultry , sheep, goats, swine

GLP Regulations

- Sponsor
- Study Director
- Raw Data
- Test System
- Test Article
- Carrier
- Control Substance

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

- An agreement of nations throughout the world that controls commercial trafficking of endangered species, including nonhuman primates.
- The US is a participant and signatory nation to the Convention and therefore is bound by its requirements.
- Several nonhuman primate species are affected.

Guide for the Care and Use of Agricultural Animals in Research and Teaching

- Published by the Federation of Animal Science Societies
- Similar purpose as the Guide for the Care and Use of Laboratory Animals excepts addresses agricultural animals more specifically
- Covers :
  - Institutional policies (e.g. protocol review, occupational health)
  - Animal health care (e.g. veterinary care, surgery, zoonosis)

European Convention for the Protection of Vertebrate Animals Used for Experimental and other Scientific Purposes (European Treaty Series - No. 123 or ETS No. 123)

- Established by European Union and member states of the Council of Europe
- The Convention is designed primarily to reduce both the number of experiments and the number of animals used.
- It encourages Parties not to experiment on animals except where there is no alternative.
- Animals to be experimented on should be selected on the basis of clearly established quantitative criteria and must be well cared for and spared avoidable suffering whenever possible.
- The Parties meet regularly to examine the application of the Convention and, if appropriate, to extend or strengthen its provisions.


©2011 Scott Hilburn/Distributed by Universal Uclick
4/9
HA, HA, LOOK AT WALTER - WHAT A DOPE.
COMPRES -O- AIR
WALLY'S UNIQUE SKILL WAS, INITIALLY, SCORNED BY ALL THE OTHER KITS.