Laws and Regulations
Governing Animal Care and Use

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

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
- Signed into law in 1966
- Administered by the USDA's APHIS
- Divided into 4 Parts

Animal Welfare Act
4 Parts
- 1 – Definition of Terms
- 2 – Regulations
- 3 – Standards
- 4 – Rules of Practice

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

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

Animal Welfare Act
Part 2 – Regulations

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

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

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

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

He wanted to go upstream? Yeah, on the first date. It's all they think about, spawn, spawn, spawn.

Distributed by Universal Uclick
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

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

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

 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

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.

I. Introduction

II. Applicability

III. Definitions
**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

**B. Functions of the IACUC**

**C. Review of PHS Supported Research**

**D. Information Required on Applications**

**E. Recordkeeping Requirements**

**F. Reporting Requirements**
- Annual reports to OLAW
- Prompt reports to OLAW regarding non-compliance

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

- 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

<table>
<thead>
<tr>
<th>AWA</th>
<th>PHS Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Agency</strong></td>
<td>Department of Agriculture (USDA)</td>
</tr>
<tr>
<td></td>
<td>US National Institutes of Health</td>
</tr>
<tr>
<td></td>
<td>Office of Laboratory Animal Welfare</td>
</tr>
<tr>
<td><strong>Legislative Authority</strong></td>
<td>Statute: 7 USC 2131-2156 Regulations: 9 CFR</td>
</tr>
<tr>
<td><strong>Species Covered</strong></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.</td>
</tr>
<tr>
<td><strong>Assurance/Registration</strong></td>
<td>Registration - updated every 3 years; registered on institution’s letterhead and signed by the Institutional Official (IO) who has the legal authority to do so and submitted to the APHIS, REAC Supervisor (on agency forms)</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

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:
  - 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 postsurgical care.

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.

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

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
- 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

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:
  - 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.

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).

Comparison of the AWA and the PHS Policy - IACUC

<table>
<thead>
<tr>
<th></th>
<th>AWA</th>
<th>PHS Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other reports</td>
<td>Report to APHIS and any federal</td>
<td>Notify OLAW when:</td>
</tr>
<tr>
<td></td>
<td>funding agency only suspension</td>
<td>- Serious or continuing noncompliance</td>
</tr>
<tr>
<td></td>
<td>of an activity involving a</td>
<td>- Serious deviation from the</td>
</tr>
<tr>
<td></td>
<td>animal and the appropriate</td>
<td>- Suspension of activity by IACUC</td>
</tr>
<tr>
<td></td>
<td>corrective actions are</td>
<td></td>
</tr>
<tr>
<td></td>
<td>carried out to a plan of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>providing a significant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>deficiency (report within 15</td>
<td></td>
</tr>
<tr>
<td></td>
<td>days)</td>
<td></td>
</tr>
<tr>
<td>Continuing review</td>
<td>Not less than Annually</td>
<td>At appropriate intervals with a</td>
</tr>
<tr>
<td>of IACUC protocols</td>
<td></td>
<td>complete review at least once every 3 years</td>
</tr>
</tbody>
</table>

Mental Break

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

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 except addresses agricultural animals more specifically
- Covers:
  - Institutional policies (e.g. protocol review, occupational health)
  - Animal health care (e.g. veterinary care, surgery, zoonosis)

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

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.
WALLY'S UNIQUE SKILL WAS, INITIALLY, SCORNED BY ALL THE OTHER KITS.

HA, HA, LOOK AT WALTER—WHAT A Dope.