Laws and Regulations

Historical background
Government oversight

NIH/PHS
USDA
AAALAC
Other
Historical Use of Animals

- 1600s:
  - Blood transfusion developed in dogs
  - Need for oxygen discovered using rats
- 1700s
  - Small pox vaccine using livestock
- 1800s
  - Rabies vaccine developed using dogs, rabbits and primates
  - Tuberculosis vaccine developed using guinea pigs
Modern Use of Animals

• 1900s
  – Genetic research using mice begins at Jackson Labs
  – Insulin and diabetes studied in dogs, rabbits and fish
  – Value of penicillin studied in rats
  – Tetanus vaccine developed using many species.
  – Polio vaccine developed in mice and primates
  – Organ transplant/open heart surgery perfected in dogs, cats, swine.
  – Cancer research uses everything from immunocompromised mice to study tumor treatments to dogs to diagnose via smell.
Biomedical Models

• Laws that necessitate the use of animals in biomedical testing
  – 1938: Federal Food, Drug, and Cosmetic Act
  – 1978: Good Laboratory Practices Act
Federal Food, Drug, and Cosmetic Act

• Required safety testing of food, drugs, cosmetics, and pesticides.

• Response to death from cough syrup
  – Elixir of sulfanilamide in diethylene glycol
Good Laboratory Practices (GLP)

• Sets unbiased procedures for safety testing of food additive, drug, or medical devices intended for human or animal use
• Governed by FDA
• Test system: *in vivo* or *in vitro*; animal, plant, microorganism, or subpart thereof.
• Tests ingredients not formulations
Regulation of Animal Welfare

- 1966: Animal Welfare Act
- 1985: Health Research Extension Act
<table>
<thead>
<tr>
<th>USDA</th>
<th>NIH</th>
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<tbody>
<tr>
<td>Animal Welfare Act</td>
<td>Health Research Extension Act</td>
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<tr>
<td>Species - <strong>Certain mammals</strong></td>
<td>Species - <strong>All vertebrates used in research or teaching</strong></td>
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<td>Coverage - All of USA</td>
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<td>Penalties - Fines/revocation</td>
<td>Penalties - Loss of Funding</td>
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<tr>
<td>Regular inspections by USDA veterinarians</td>
<td>Peer review (AAALAC). Investigations for cause. A few random investigations</td>
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1966

• Animal Welfare Act
  – Empowers USDA to govern use and sale of animals
  – Responds to Life magazine exposé on dog “concentration camps”
  – Originally covers
    • Housing, care, sale, and transportation of dogs and cats
    • Housing and care of monkeys, guinea pigs, hamsters, and rabbits in research.
AWA--1970

• Extends coverage to all mammals with the following exceptions.
  – Livestock used for food or fiber
  – Domestic rats and mice
    • The Act allows USDA to regulate rats and mice, but USDA has chosen not to do so.

• USDA veterinarians make unannounced semi-annual inspections of any facility with covered species.
AWA--1970

- Also mandated appropriate use of anesthetic, analgesic or tranquilizing drugs
- As well as the use of aseptic surgical technique.
AWA--1985

- Institutional Animal Care & Use Committee (IACUC)
- Exercise of dogs
- Psychological well-being of primates
- Training for research personnel
- Written programs for veterinary care
Health Research Extension Act

• Oversight by National Institutes of Health (NIH)
  – Public Health Service (PHS)
    • Office of Laboratory Animal Welfare (OLAW)

• Regulates live, vertebrate animals used in research, teaching, or biological testing.

• Only institutions receiving government funding.
Health Research Extension Act

• Mandated the IACUC in the same year as the AWA

• Peer review: AAALAC—Association for the Accreditation and Assessment of Laboratory Animal Care. Accredit every 3 years.

• Follows the Institute of Laboratory Animal Resource (ILAR) Guide
AAALAC International

- Association for the Accreditation and Assessment of Laboratory Animal Care
  - Peer review inspection every 3 years
  - Inspections are voluntary, but without accreditation, all grant applications have to include assurances that the Guide is being followed.
  - Guide for the Care and Use of Laboratory Animals
    - National Research Council,
    - Institute of Laboratory Animal Research (ILAR)
AALAS

• American Association of Laboratory Animal Science (AALAS)
  – Designed to disseminate information to people in the field. Includes classes, tests, and networking.
  – Certify personnel:
    • ALAT: Assistant Lab Animal Technician
    • LAT: Lab Animal Technician
    • LATg: Lab Animal Technologist
    • RLAT(g): Registered—continuing education
  – SV AALAS
Three Rs Concept

• Advocated by the HRE act:
  – Reduction – Fewer Animals
  – Refinement –
    • Minimize pain, suffering and distress
    • Enhance well-being
  – Replacement – Use of other models
• Questions on the protocol are designed to evaluate the study in terms of this concept.
Animals Used in Research

- **Rats and Mice**: 95%
- **Cats, Dogs, and Primates**: 4.25%
- **Other (rabbits, guinea pigs, sheep, pigs, fish, frogs, insects, etc.)**: 0.75%
Annual Animal Deaths in the U.S.

- Livestock & Poultry for Human Consumption, Animals for Clothing and Domestic Use: 86.75%
- Dogs & Cats Euthanized at Pounds Due to Abandonment, Loss, or Homelessness: 0.17%
- Other Species for Research & Education: 0.03%
- Rats & Mice Bred For Research & Education: 0.66%
- Animal Deaths Related to Motorists: 6.94%
- Animal Deaths Related to Sport Hunters: 3.47%
- Rodents Bred for Reptile and/or Feeder Food: 1.98%
Institutional Animal Care and Use Committee (IACUC)

- Protocol Review
  - Ethical Guidelines
  - Reduce study duplication
  - Reduce animal discomfort
  - Justify species/number selection
  - Assure veterinary care
  - Appropriate euthanasia
  - Transportation

- Facility management
  - Semiannual Inspections
  - Program Reviews

- Personnel
  - Training
  - Occupational health
PROTOCOL FOR ANIMAL USE AND CARE

• Required for any “live” vertebrate animal work in teaching or research
• All protocols must be reviewed by the Institutional Animal Care and Use Committee (IACUC)