

IACUC 101 PLUS

HISTORICAL and CURRENT PERSPECTIVES

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GOALS: TAKE HOME MESSAGES

- Three major participants
 - Scientists
 - Government
 - Public
- Debunk myth of rules, regs, policies primarily driven by animal rights
- People care about humane use of animals


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PARTICIPANTS IN THE PROCESS

- Government
 - Congress
 - USDA—USDA enforces
 - HHS: PHS (NIH, FDA, CDC)—OLAW enforces
- Scientists
 - Animal Care Panel
 - AALAS
 - AAALAC International
 - ILAR
- Public
 - Animal-centric organizations
 - Health care consumers

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Setting the Stage:

- Mid 1800s on, increase use of animals in medical education
- Claude Bernard, "Introduction to the Study of Experimental Medicine" 1865 
- Increase use of rats and mice in early 1900s
- British *Cruelty to Animals Act of 1876*
- Establishment of several Antivivisection Societies:
 - 1867 Pennsylvania Society for the Prevention of Cruelty to Animals
 - 1883 American Antivivisection Society
 - 1908 California Antivivisection Society

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Setting the Stage:

- Nazi Germany
 - Focus on natural healing, organic living
 - Adoption of eugenics (“good birth”)
 - Sterilization clinics
 - Mass murder of handicapped, mentally ill,
 - Banned vivisection on animals, but experiments on Jews OK

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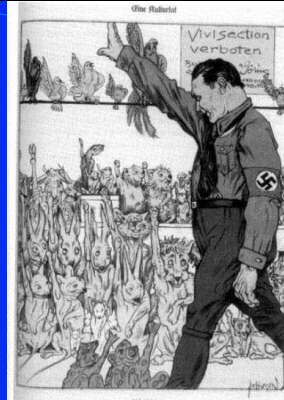


FIG. 5.2 “Heil Goring!” The lab animals of Germany saluting Hermann Goring for his order banning vivisection. The Reichsmarschal in August of 1933 announced an end to the “subversive torture and suffering in animal experiments” and threatened to commit to concentration camps “those who still think they can treat animals as inanimate property.” Source: *Ullsteinfoto*, September 3, 1933, with thanks to John Lockart.

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Nuremberg Code—10 Directives for Human Experimentation

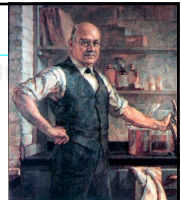
- Directive 1: “Voluntary consent of the human subject is absolutely essential”
- Directive 3: “The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment”

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Setting the Stage

Evolution of National Institutes of Health

- 1887 Hygienic Lab created within MHS (Marine Hospital Service)
- 1930 Ransdell Act
 - Hygienic Lab ► National Institute of Health
- Following World War II
 - Economic Boom
 - Large increase in scientific research
 - 1948 National Heart Act ► National Institutes of Health
 - Taxpayer based funding of health related research
 - Huge increase in NIH budget



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Four of Five “Founding Fathers”



Missing: Dr. Robert J. Schroeder

Picture from left to right:
Dr. Nathan R. Brewer
Dr. Elihu Bond
Dr. Robert J. Flynn
Dr. Bennett J. Cohen

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SCIENTISTS’ INVOLVEMENT

- 1950 Animal Care Panel (ACP)
- 1951 *Proceedings of the Animal Care Panel*
- 1953 Animal Care Panel incorporated
- 1952 Institute of Laboratory Animal Resources under National Research Council
- 1960 Animal Facilities Certification Committee (Board)
- 1963 *Guide for Laboratory Animal Facilities and Care*
- 1965 AFCB ⇒ AAALAC incorporated
- 1965 2nd edition of *Guide* (1968, 1972, 1978, 1985, 1996 8th edition 2011)
- 1967 ACP ⇒ AAALAS

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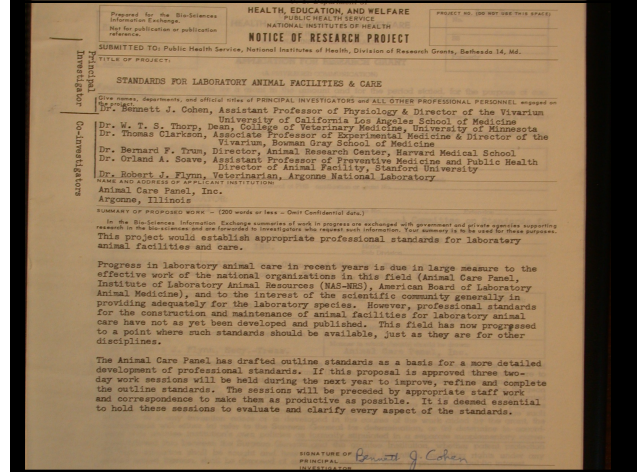
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SCIENTISTS' INVOLVEMENT

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- 1951 *Proceedings of the Animal Care Panel*
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- 1967 ACP ⇨ AALAS

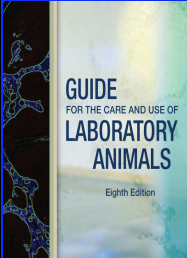
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The Guide — Our Bible

OVERVIEW



Chapter 1: Key Concepts
– Previous Introduction

Chapter 2: Animal Care and Use Program
– Previous Introduction and Ch. 1

Chapter 3: Environment, Housing, and Management
– Terrestrial vs. Aquatic

Chapter 4: Veterinary Care

Chapter 5: Physical Plant


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SCIENTISTS' INVOLVEMENT

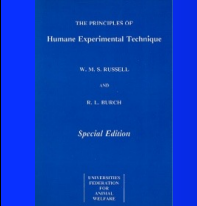
- 1950 Animal Care Panel (ACP)
- 1951 *Proceedings of the Animal Care Panel*
- 1952 Institute of Laboratory Animal Resources
- 1959 *The Principles of Humane Experimental Technique* by W.M.S. Russell and R.L. Burch
- 1960 Animal Facilities Certification Committee (Board)
- 1963 *Guide for Laboratory Animal Facilities and Care*
- 1965 AFCC ⇒ AAALAC incorporated
- 1965 2nd edition of *Guide* (1968, 1972, 1978, 1985, 1996 8th edition 2011)
- 1967 ACP ⇒ AALAS

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Scientists Involvement: Three Rs (Guide, Ch. 1)



- Replacement
 - Absolute (e.g. computer modeling)
 - Lower vertebrate
 - Early developmental stage
- Refinement
 - Improved husbandry
 - Improved experimental procedures
 - Goal-minimize pain, distress
- Reduction
 - Fewest number used to maximize information based on experimental design, advanced technologies, control of environmental variables



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GOVERNMENT'S INVOLVEMENT

- 1962 NIH Contract - first *Guide*
- 1966 *Laboratory Animal Welfare Act*
- 1970 LAWA → Animal Welfare Act (1976, 1985, 1990, 2002, 2007)
- 1971 NIH *Policy*
- 1973 Public Health Service Policy (1979, 1986, 2002 and 2015 revised)
- 1985 PHS Act (Health Research Extension Act)

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1966 Laboratory Animal Welfare Act

- Focus on preventing theft of dogs and cats
- Registration limited facilities with dogs/cats
- Holding areas only
- Only records of acquisition required
- Developed 8 areas of minimum standards:
 - Housing
 - Feeding
 - Watering
 - Sanitation
 - Shelter
 - Separation of species
 - Ventilation
 - Adequate vet care

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1970 Animal Welfare Act

- LAWA changed to AWA
- Extension into the laboratory
- Report number of animals by pain category
- Require appropriate use of anesthetics
- Include all warm blooded species except....

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1985 Animal Welfare Act Amendments

- Establishment of IACUC
- Assign responsibility to Institutional Official
- Review of **protocols (USDA "activity")**
- Semiannual program review & inspections
- Search for alternatives to painful procedures
- Personnel qualifications
- Environmental enrichment for NHPs
- Exercise for dogs

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FARM SECURITY AND RURAL INVESTMENT ACT OF 2002

Title X Miscellaneous **Subtitle D—Animal Welfare**

- **SEC. 10301. DEFINITION OF ANIMAL UNDER THE ANIMAL WELFARE ACT.** Section 2(g) of the Animal Welfare Act (7 U.S.C. 2132(g)) is amended in the first sentence by striking ‘ ‘excludes horses not used for research purposes and’ ’ and inserting the following: ‘ ‘excludes (1)birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, (2) horses not used for research purposes, and (3)’ ’.

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1971 NIH Policy

- Institution had to have Assurance
 - AAALAC
 - Local Committee
- Annual Inspections
- Compliance with AWA
- Follow *Guide*

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1973 Public Health Service (PHS) Policy

- Include animals for research, teaching, education, demonstration
- Continue accept AAALAC instead of IACUC
- Still no requirement for protocol review

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1979 PHS Policy Highlights

- A “Committee” now required for program oversight
- Assurance required before funding received
- All live vertebrates
- Annual reports required
 - Recommend protocol review

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1985/86 PHS Policy

- Health Research Extension Act-Nov. 20, 1985
- More detailed Assurance
- IO ultimately responsible
- CEO appoints IACUC members
- Minimum of 5 IACUC members:
 - DVM program authority
 - One practicing scientist
 - One NAM
- Protocol Review
- Semiannual reports of program review
- Detailed training program description

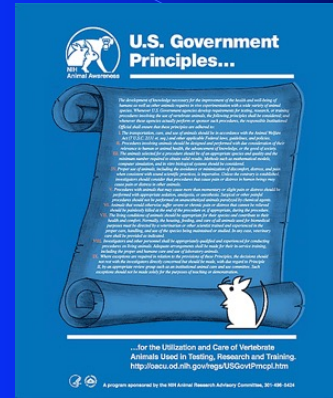
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U.S. Government Principles

- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
- Developed in 1983 by Interagency Research Animal Committee (IRAC)
- Incorporated into PHS Policy in 1986; endorsed by *Guide*
- Nine basic and elegant principles
- PHS Policy—p.4-5; *Guide*—App. B p.199-200

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- Basis for ethical discussion



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Table 1 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their inservice training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

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Principle IV: Questions for Discussion

- What is the impact of this principle?
- Share examples of the utilization of this principle.

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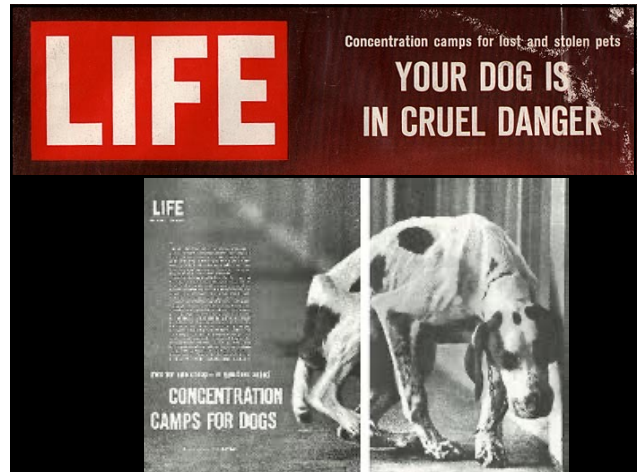
PUBLIC'S INVOLVEMENT

- 1962 *Silent Spring*, by Rachel Carson
- 1966 LIFE magazine article
- 1969 Greenpeace founded
- 1975 *Animal Liberation*, by Peter Singer
- 1981 The "Silver Spring Monkeys"
- 1984 University of Pennsylvania head injury studies

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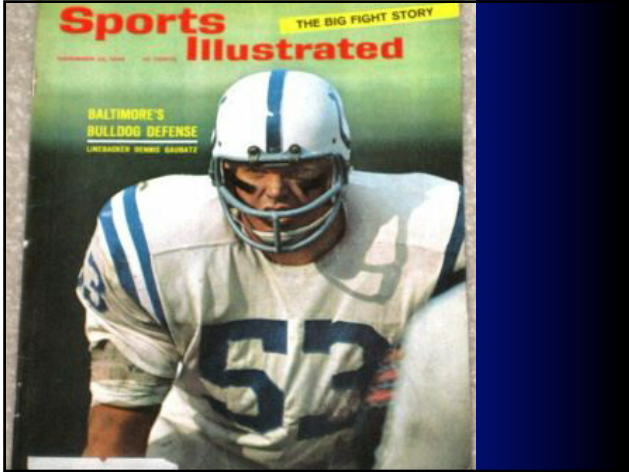
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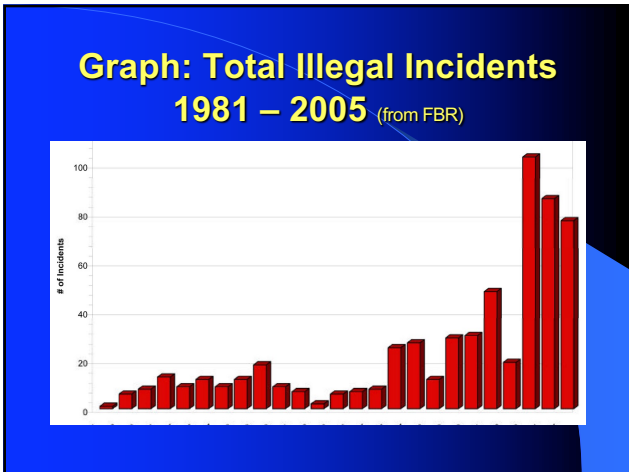


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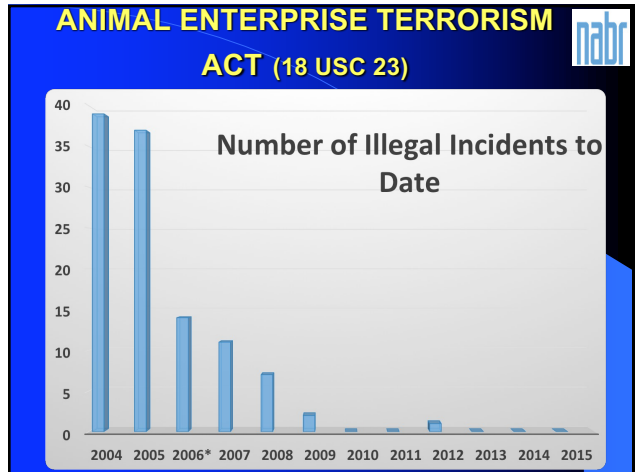
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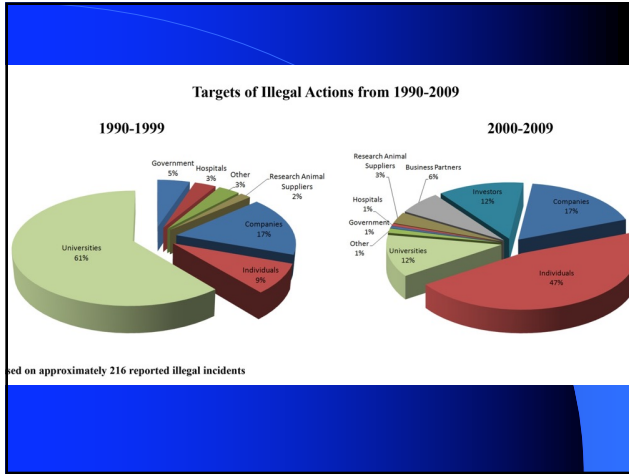
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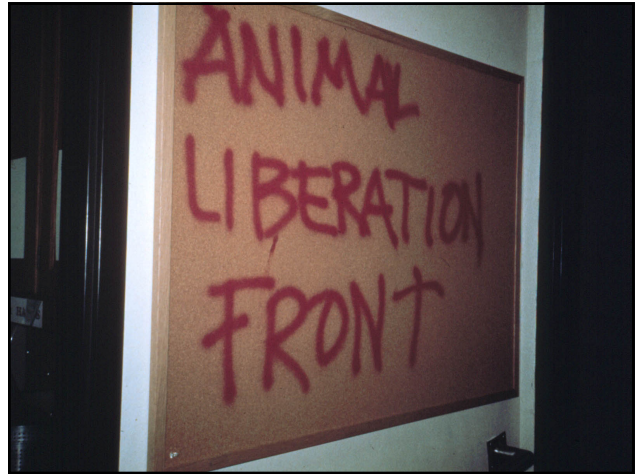
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Federal Legislation

Bill Number	Bill Name	Summary
S-2023-2655	AWA Modernization Act of 2023	This bill allows an applicant for market approval for a new drug to use methods other than animal testing to establish the drug's safety and effectiveness.
H.R. 5771	Animal Welfare Enforcement Improvement Act	Revises the licensing process of the Department of Agriculture (USDA) for animal dealers and exhibitors to expand USDA's oversight and enforcement of animal welfare requirements; the bill also authorizes citizens suits to enforce the Animal Welfare Act.
S. 501	CWST Act	Funding transparency bill (Waters). Championed by White Coat Waste Project.
H.R. 145	FAIR-2023 Act	Bill to require emergency preparedness plans for animal research facilities.
H.R. 370	ADP-2023 Act	Amends the Food, Drug and Cosmetic Act to allow the sponsor of a drug to file a non-animal test as an alternative to an animal test for purposes of demonstrating the safety and effectiveness of a drug under this section if such approach satisfies the requirements of the applicable statutes and regulations.
S. 1053 H.R. 2615	Dove Protection Act	Amends the AWA to require a sensitive-for-all series of requirements, adding to regulatory and legislative burden on the American biomedical research community by targeting breeding operations.
H.R. 134	Humane Research and Testing Act	This bill will publicly provide animal rights groups with information on the number of animals required, bred, and used in federally funded research and testing facilities. This will create an already-made targeting tool for because of campaigns by animal rights groups.
H.R. 101	FAWA Act	Transparency bill to increase reporting requirements on facilities using research animals and alternatives for toxicology.
H.R. 4104	HEARIS Act	Amends the Public Health Service Act to ensure that non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health.
S. 426	ACTIPB Act	Federal mandatory adoption bill. White Coat Waste Project backed bill to amend AWA to require research laboratories to have a national animal adoption program.
H.R. 4276	CABP Act	To require research facilities that use companion dogs, cats, or rabbits for research purposes and receive funding from the National Institutes of Health to offer such animals for adoption after completion of such research.
H.R. 1009	Animal Cruelty Enforcement Act	Establishes a new section in the Environmental and Natural Resources Division of the Department of Justice to enforce federal laws concerning animal cruelty. This could be used by the wrong Administrations to support animal rights activist and shut down research altogether.
S. 511	Chimp Sanctuary Act	To prohibit the leasing of chimpanzees at installations of the Department of the Air Force and relocate current chimpanzees to Chimp Haven in Louisiana.
H.R. 3167	Dog Safety and Accountability	This bill revises requirements concerning the sources of dogs and cats used by research facilities.

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