

LAWS, REGULATIONS AND POLICIES THAT IMPACT ON THE CARE AND USE OF ANIMALS IN RESEARCH, TEACHING, TESTING, AND EXPERIMENTATION

Federal Regulations and Policies Affecting the Care and Use of Animals in Research, Teaching, Testing, and Experimentation:

Animal Welfare Regulations (AWRs).

The AWRs are described in the Code of Federal Regulations, Title 9 (Animals and Animal Products), Subchapter A (Animal Welfare), Parts 1-4.

The law as implemented is popularly called the **Animal Welfare Act**. The Act has been amended several times most recently in 2004.

The regulations contained in the Act are enforced by the **U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Animal Care**.

All research facilities that use or intend to use live animals, as defined by the regulations, in research, teaching, testing and experimentation must comply with the AWRs.

The most recently amended regulations became effective June 4, 2004. This amendment redefined the definition of animal as any warmblooded animal used or intended for use in research, teaching, testing, or experimentation except birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research; and horses and other farm animals used or intended for use in agricultural research and production. The new definition no longer excludes all birds, but just those bred for research and validates the legal exclusion of *Rattus* and *Mus*.

Amended regulations which became effective in October 1989 set rules for dealers, exhibitors, and owners of auction sales. They described requirements for licensing or registration, identification of animals, and recordkeeping. They detailed responsibilities of the attending veterinarian and prohibited the purchase, sale, use, or transportation of stolen animals.

Subpart C sets rules for research facilities and requires compliance with standards listed in Part 3 of the Act.

Title 9, Part 3 establishes minimum standards for animal husbandry, care, treatment, and transportation.

Amendments to the regulations in 1989 set standards for exercise for dogs and psychological well-being of nonhuman primates.

Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy).

The PHS Policy intends to ensure that PHS grantees and contractors care for and use animals humanely.

Has been in existence since 1971; underwent major revision in 1985 and minor revisions in 1986 and 2002.

Implements and supplements the U.S. Government Principles for the Care of Vertebrate Animals Used in Testing, Research and Training.

Law implemented: U.S. Code, Title 42, Section 289d (42 USC 289d); was amended in 1985 to

cover the care and use of animals in research by PL 99-158, the Health Research Extension Act.

Oversight is provided by the PHS Office of Laboratory Animal Welfare (OLAW).

Activities to which policy is applicable: All PHS-conducted or supported activities involving the use of animals; animal is defined as "any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes."

Requirements:

Compliance with the AWRs and the ***Guide for the Care and Use of Laboratory Animals***, which was revised most recently in 1996.

A written statement of Assurance, including: A description of the animal care and use program;

The qualifications, authority, and responsibility of the program's veterinarian;

A list of members of the institutional animal care and use committee and procedures these members will follow to fulfill the requirements of PHS policy;

A summary description of the institution's educational or training programs in humane animal care and use; and

An assurance that the institution is accredited by the American Association for Accreditation of Laboratory Animal Care or has been evaluated by the institution.

Penalty for noncompliance: Revocation of Assurance and loss of PHS support for entire institution.

Selected Requirements of AWRs and PHS Policy:

Institutional Animal Care and Use Committee (IACUC)

Membership:

Must be appointed by institution's chief executive officer

Number of Members: Chairman and at least two additional members (9 CFR 2.31); Chairman and at least four additional members (PHS, 1986)

At least one member must be a doctor of veterinary medicine with training or experience in laboratory animal science and medicine and with direct or delegated program responsibility for activities involving animals

At least one member must not be affiliated with the facility other than as a committee member and must not be a member of the immediate family of anyone affiliated with the institution

At least one member must be a practicing scientist with experience in research involving animals.

At least one member must be a nonscientist.

Functions:

Reviews semiannually institutional animal facilities and institutional program for humane animal

care and use and reports on these reviews to the institutional official

Reviews and approves protocols and modifications to protocols

Reviews concerns about care and use of animals

Suspends activities found no longer to be in compliance with the AWRs and PHS Policy

Makes recommendations to the institutional official concerning the animal care and use program, animal facilities, or personnel training

Training and Instruction:

Must be made available to all personnel involved in animal care, treatment, and use

Must include at least the following areas:

Humane methods of animal maintenance and experimentation

Methods that limit the use of animals or minimize distress

Proper use of anesthetics, analgesics, and tranquilizers for any species used by the facility

Methods for reporting deficiencies in care and treatment

Utilization of services, such as the National Agricultural Library, that provide information that could prevent unintended or unnecessary duplication of animal research and details about appropriate methods of animal care and use, alternatives to the use of live animals in research, and the intent and requirements of the Animal Welfare Act

Records that Facilities Must Keep:

Records of the IACUC

Minutes of meetings

Records of applications

Proposed significant changes in animal care and use and whether approval was given or withheld

Semiannual Reports:

Records on the description, identification, purchase, sale, transportation, and previous ownership of live dogs and cats (AWRs)

Records of accrediting body determinations (PHS Policy)

Required Reports:

AWRs

Annual report to APHIS Animal Care made by the facility and certified by the institutional official or the chief executive officer

Must contain assurance that professionally acceptable standards were followed in care, treatment, and use; that principal investigators have considered alternatives to painful procedures; and that the facility is adhering to the standards and regulations and have IACUC approval for all exceptions

Must state the location of all facilities where animals, as defined by the AWRs, were housed or used

Must give the numbers and common names of animals, as defined by the AWRs, used in nonpainful or nondistressing procedures, painful or distressing procedures in which appropriate pain-relieving or tranquilizing drugs were given, and painful or distressing procedures in which pain-relieving or tranquilizing drugs were withheld because they would have interfered with experimental results

Must give the numbers and common names of animals, as defined by the AWRs, bred for use in research, testing, and education but not yet used for such purposes

Requires prompt notification, with a full explanation, of any suspended activity

PHS policy:

Requires annual report to OLAW by the IACUC through the institutional official

Must note significant changes in the institution's programs, facilities, or animal care and use program

Must list changes in IACUC membership

Must provide dates of semiannual IACUC evaluations

Requires prompt notification with a full explanation of:

Any serious or continuing noncompliance with PHS policy or the *Guide for the Care and Use of Laboratory Animals*

Any suspension of activity by the IACUC

Institutional Policies Affecting the Care and Use of Animals in Research, Teaching, Testing and Experimentation:

NIH Policy Manual 3040-2, Animal Care and Use in the Intramural Program

Revised 8-1-94
Revised 6/17/2004

REFERENCES

NIH Policy Manual 3040-2, Animal Care and Use in the Intramural Program

Code of Federal Regulations, Title 9 (Animals and Animal Products), Subchapter A (Animal Welfare), Parts 1-4. Revised January 1, 2002.

Guide for the Care and Use of Laboratory Animals. National Research Council. National Academy Press, 1996.

Public Health Service Policy on Humane Care and Use of Laboratory Animals. 8/2002.

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. Interagency Research Animal Committee. In Federal Register, 1985, May 20, Vol. 50, No.97.