



California Biomedical Research Association

1008 Tenth Street, PMB 328, Sacramento, California 95814

Tel 916.558.1515 Fax 916.558.1523

E-mail: info@ca-biomed.org Website: www.ca-biomed.org

Fact Sheet

Laws Governing the Use of Animals in Research

How are research animals protected?

The federal **Animal Welfare Act (AWA)** is the key law governing research with animals. The AWA was first passed in 1966 and has been amended several times since then. The AWA requires appropriate veterinary care, housing, feeding, handling, sanitation, ventilation, and sheltering of all animals used in research. The AWA also requires that all registered-facilities have institutional committees that review and approve procedures and research projects involving animals. These are called Institutional Care and Use Committees (IACUCs). The Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA) is responsible for administering and enforcing the Animal Welfare Act. While the AWA does not cover rodents, the Health Research Extension Act of 1985 made Public Health Service Policy the law. The Public Health Service Policy specifically regulates the care and use of all vertebrate animals used in research, testing, and education, giving rodents (mice, rats, and birds) the same protections given primates, cats, and dogs. The U.S. Public Health Service supports approximately 40 percent of all biomedical research in this country.

The Animal Welfare Act, among other things:

- Regulates the use of dogs, cats, primates, guinea pigs, hamsters, rabbits and farm animals in research, teaching, and testing.
- Requires that all proposals to use animals be reviewed and approved by an institutional animal care and use committee whose membership includes, at a minimum, an experienced scientist, a veterinarian, and an individual who is not affiliated with the institution.
- Requires animals to be provided with adequate food, living space, and veterinary attention in buildings that are clean and properly lighted, ventilated, and temperature controlled. In addition, dogs must receive appropriate exercise, and primates must be provided with an environment that will assure their psychological well-being.
- Requires research facilities to register with and animal dealers to be licensed by the US Department of Agriculture (USDA), which conducts periodic inspections of their compliance with AWA regulations. Significant or repeated violations of the AWA may result in fines or other enforcement actions.
- Requires the USDA to report annually to Congress on the numbers of regulated animals used in research and involved in potentially painful experiments for which no pain-relieving drugs were used.
- Requires the USDA' regulatory enforcement arm, the Animal and Plant Health Inspection Service (APHIS), to make at least one unannounced inspection a year to each facility.

The United States Department of Agriculture (USDA) requires institutions to report the number of animals used in research and the number of animals that experience not only pain, but distress, along with an explanation of why the research had to be performed in this manner. A veterinarian must also be consulted for such research.

In addition to the AWA and the USDA, the 1985 Health Research Extension Act requires all medical research funded through **the National Institutes of Health (NIH)** to conform with the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*. The NIH, which funds more than half of all medical research in the U.S., conducts unannounced visits to ensure compliance with their regulations as well.

Most other federal funding agencies also require scientists to use *the Guide for the Care and Use of Laboratory Animals* to determine appropriate standards for animal care.

The Office of Laboratory Animal Welfare (OLAW), in the National Institutes of Health (under HHS and PHS) within the NIH significantly oversees laboratory animal care, maintenance, and use. The Institute of Laboratory Animal Resources (ILAR) under the National Academy of Sciences prepares the *Guide for Care and Use of Laboratory Animals*.

Under these agencies, each research facility *must* have an animal care and use committee (IACUC) that reviews every research project to ensure that animals are treated responsibly and humanely. Such committees are composed of veterinarians, researchers, representatives from the scientific community and at least one community member that is not affiliated with the facility, and they oversee and evaluate all aspects of the institution's animal care and use program.

The Guide for the Care and Use of Laboratory Animals:

- Offers expert advice and the latest scientific research on how to care for various species of animals to meet scientific, technical, and humane standards.
- Provides guidelines for designing and operating an animal care program that fulfills the requirements of the Animal Welfare Act and the Public Health Service Policy.

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

- Requires institutional animal care and use committee review and approval for all research using vertebrate animals that is funded by Public Health Service agencies.
- Requires animal care to be provided according to the standards set forth in the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals.
- Requires each institution conducting Public Health Service- sponsored research to file a written assurance with NIH detailing how it will provide an acceptable program of animal care and use oversight.
- Requires grantees to follow the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- Requires that significant problems with animal care must be reported to the Public Health Service. Failure to correct violations can result in the research funding being suspended or revoked.

The vast majority of research facilities voluntarily seek accreditation from professional associations such as the **Association for Assessment and Accreditation of Laboratory Animal Care International** (AAALAC International) and the **American Association for Laboratory Animal Science** (AAALAS), which require additional standards for laboratory animal care.

Laws that Prevent Research Animals from Unnecessary Pain During Research.

The use of research animals is strictly controlled, especially when there is the possibility of pain as a result of the study. Animal comfort is addressed from birth through shipping, housing and feeding, the duration of the research study, and the animal's death. Clauses in the Act also address exercise for dogs and psychological well-being for primates. Each research institution must establish an animal care and use committee that includes a member of the general public, such as a local veterinarian, church minister, or employee of the Society for the Prevention of Cruelty for Animals. Membership on this committee must also include a veterinarian with specific experience in laboratory animal care. This committee reviews, approves (or disapproves), monitors and inspects every research study to help ensure that animals are not subject to unnecessary pain and distress.

Review committees are charged with keeping abreast with, and requiring research scientists to use, state-of-the-art methodology of preventing pain in laboratory animals. For instance, an animal that undergoes a surgical operation, according to approved study, is now given pain medication that will last after the surgical anesthetic has worn off and the animal wakes up. The animal is spared immediate post-operative pain, and also spared pain during the recovery period. In contrast, small animal veterinarians in private practice don't always give post-operative pain medication to a pet dog or cat that has just been spayed or

neutered. In general, state-of-the-art procedures are introduced into laboratory animal medicine long before procedures become routine in private practice.

Interestingly enough, research studies have also demonstrated that when animals do not feel pain, they provide more reliable scientific results.