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## Fact Sheet

### Laws Governing the Use of Animals in Research

#### **How are Research Animals Protected?**

Biomedical research, teaching, and testing are the subject of and controlled by an extensive system of laws, guidelines, and regulations that protect the welfare of laboratory animals in the United States. This extensive federal oversight includes the Animal Welfare Act (AWA), the Health Research Extension Act, and a series of other laws and policies from the various federal agencies involved in the U.S. research effort (EPA, FDA, NSF, etc.). In addition, many facilities and researchers may also be licensed by their state and/or international organizations, depending on the research and teaching they conduct, and the species involved.

#### **Federal Laws and Regulations**

The federal Animal Welfare Act (AWA) is the key law governing research with animals in the U.S. The AWA was first passed in 1966 and has been amended several times since (1970, 1976, 1985, and 1990). It mandates that all research facilities (with some exceptions discussed below) register with the U.S. Department of Agriculture (USDA). The Animal and Plant Health Inspection Service (APHIS) within the USDA is responsible for administering and enforcing the AWA and for making at least one unannounced inspection a year to each facility.

Research facilities are also required by the Animal Welfare Act (AWA) (7 USC 2131 *et seq.*) to have an attending veterinarian “who shall provide adequate veterinary care.” The regulations implementing the AWA (9 CFR Ch. 1) go on to specify the requirements of adequate veterinary care. The qualifications of an attending veterinarian are also specified. The AWA requires appropriate housing, feeding, handling, sanitation, ventilation, and sheltering of all animals used in research. The AWA also requires that at registered-facilities all proposals to use animals in research must be reviewed and approved by an committee whose membership includes, at a minimum, an experienced scientist, a veterinarian, and a individual who is not affiliated with the institution (such as a local veterinarian, minister, or employee of the local Society for the Prevention of Cruelty for Animals). Membership on this committee must also include a veterinarian with specific experience in laboratory animal care. These committees, called Institutional Care and Use Committees (IACUCs), must review, approve or disapprove protocols, and monitor and inspect 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 to prevent pain in laboratory animals. The AWA also requires institutions to report the number of animals used in research and the number of animals that experience not only pain, but also 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. For additional information about the Animal Welfare Act and its regulations for biomedical research institutions the following websites are very useful.

<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm> and <http://www.nal.usda.gov/awic/legislat/regsq.htm>

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

While the AWA covers the majority of research animals, it does not cover rats, mice, or birds. The Health Research Extension Act of 1985, however, made Public Health Service Policy the law, and the Public Health Service Policy specifically regulates the care and use of *all* vertebrate animals used in research, testing, and education, *giving rodents and birds* the same protections given primates, cats, and dogs. In addition, the

Health Research Extension Act requires all medical research funded through the National Institutes of Health (NIH) to conform to 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., also conducts unannounced visits to ensure compliance with their regulations.

The Office of Laboratory Animal Welfare (OLAW), in the National Institutes of Health (under HHS and PHS), 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 and oversee and evaluate all aspects of the institution's animal care and use program. The *Guide* also offers expert advice and the latest scientific research on how to care for various species of animals to meet scientific, technical, and humane standards, and provides guidelines for designing and operating an animal care program that fulfills the requirements of the AWA and the PHS Policy. 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.

Research facilities that receive NIH funding are required to file an Assurance with the Office of Laboratory Animal Welfare (OLAW) of the National Institutes of Health (NIH). This Assurance is a legal commitment that the facility will comply with the NIH *Guide* and includes extensive descriptions of the institution's facilities, personnel, policies, equipment, etc., and in particular a description of its program of veterinary care. All vertebrate species are covered. An approved Assurance is a prerequisite for the award of federal research funding. Non-compliance with the Assurance may result in disqualification of the facility to receive federal research funds, and even withdrawal of funds already approved. There is also a possibility of prosecution under the Federal False Claims Act.

#### **State Laws and Regulations**

Research facilities that are registered with the USDA are not required to register with the State of California, signifying the intent of the state to defer to federal regulatory authority in this area. Facilities within California that are not registered with the USDA, not PHS Assured (they receive no funding from the NIH), and do not have species regulated by the AWA, must register with the State of California. Specifically, the Department of Health and in some cases, also with the Department of Fish and Game. See California Code of Regulations, TITLE 17, Div. 1, Chpt. 2 § 950 to 1021, and/or California Code of Regulations, Title 14, Div. 1, Sub 3. Chpt. 3. §671. The basis for regulation for facilities registered with the State of California is the NIH *Guide for the Care and Use of Laboratory Animals*. For those outside of California, please consult your specific state regulations as they pertain to research.

#### **Voluntary Monitoring and Self-Regulating**

In addition to state and federal regulation, most research facilities seek voluntary accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC), a private nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program administered by veterinarians specializing in laboratory animal medicine, among other experts. Accreditation is a complex process requiring months or years. Every aspect of an institution's facilities, policies, procedures, and personnel is examined in detail. One of the critical aspects to be considered is the program of veterinary care. Although AAALAC accreditation is voluntary, its benefits are so significant that accreditation is mandatory for all practical purposes in many situations. Some federal agencies, for example, require AAALAC accreditation of an institution to even apply for grants. OLAW has a separate and greatly simplified assurance procedure for accredited institutions.