



**CALIFORNIA  
SOCIETY FOR  
BIOMEDICAL  
RESEARCH**

## What is Regulatory Oversight?

Research using animal models in the United States is highly regulated and is subject to extensive oversight and regulation by the federal government.

Many research facilities may also be licensed by their state and/or international organizations, depending on the research and teaching they conduct, and the species involved. In California, many research facilities are additionally regulated by the California Department of Fish and Wildlife.

### **The Animal Welfare Act**

The federal [Animal Welfare Act](#) (AWA) is the key law governing research with animal models in the United States. It includes detailed requirements for research protocol, veterinary care, housing, feeding, lighting, handling, sanitation, ventilation, and the enrichment of all animals involved in research. It also requires that all animal care and methods of research be conducted in accordance with the Public Health Services' [Guide for the Care and Use of Laboratory Animals](#).

The AWA mandates that research facilities register with the U.S. Department of Agriculture (USDA), which is responsible for administering and enforcing the AWA, and for making at least one, unannounced, inspection to each facility every year. The [Health Research Extension Act](#) (HREA) provides for further federal regulatory guidance and oversight for all research that is funded by the federal government, as do the [U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#); the [International Guiding Principles for Biomedical Research Involving Animals](#); and the [American Veterinary Medical Association Guidelines](#). Additional federal and state laws address the care and treatment of laboratory animals as well.

### **Institutional Care and Use Committees (IACUCs)**

Under these laws and regulations, and the detailed guidelines for the care and treatment of all animals, research facilities must also have in place a committee, called the Institutional Care and Use Committee (IACUC), that must review and approve, or veto, all research protocols using animal models at a facility before any research can begin.

These IACUCs must monitor and inspect every research study as it moves forward, and keep abreast with, and require research scientists to use, state-of-the-art methodologies to prevent pain in laboratory animals, to prevent the unnecessary duplication of research, and to participate in the continuous search and utilization of alternatives to animal models whenever possible.

The IACUC membership must include, at a minimum, an experienced scientist, a veterinarian, and an individual who is not affiliated with the institution in anyway (such as a local veterinarian, minister, or employee of the local Society for the Prevention of Cruelty for Animals).

### **The Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)**

In addition to state and federal permitting, inspection, and 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. Accreditation is a complex process requiring months or years.