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Animal Use in Federal Biomedical Research: A Policy Overview

Animals commonly are used in federally funded biomedical research for a number of reasons—for example, to better understand the biology of disease or to test the safety and efficacy of medical products. The existing federal policy framework generally seeks to reflect a balance of animal welfare considerations with the scientific value of such research. Federal policy also encourages the development and use of alternatives to animals where possible. Different policies apply depending on the type of animals used, the entity conducting the research, and the source of funding. Many of the policy requirements place the primary responsibility for ensuring animal welfare on the funded research institution (e.g., a university). Separately, enacted legislation and other policy efforts have sought to reduce, refine, and replace the use of animals in biomedical research (principles known as the “Three Rs”). This In Focus provides an overview of certain laws and policies—focusing on the Animal Welfare Act (AWA, 7 U.S.C. §§2131-2156) and the *Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals* (PHS Policy)—that guide animal use and welfare in federally funded biomedical research. The Food and Drug Administration (FDA) also has regulations governing animal welfare, including for studies on regulated products (21 C.F.R. Part 58), that are not discussed in detail herein.

Background

Biomedical research frequently incorporates *animal models* to study biological processes, diseases, and potential treatments. Animal models, in this context, refer to living organisms used to simulate aspects of human biology. **Table 1** provides a summary of selected animals used in research and their common uses.

Table 1. Selected Uses of Animals in Biomedical Research

Animal	Summary
Mice and Rats	Comprise an estimated 95% of all laboratory animals. Modern genetics has enabled rodent models for many human diseases and biological systems.
Nonhuman Primates	Because of biological similarity to humans, used for studying complex systems for which other animals are incomparable, such as immune, reproductive, and neurological systems. Constitute an estimated less than 0.5% of all biomedical research animals.
Dogs and Cats	Dogs are used to study cardiovascular disease, spinal cord injury, medical imaging, diabetes, neurology, and infectious diseases. Cats are used for neuroscience and infectious diseases.

Animal	Summary
Swine (Pigs)	Pigs are used to study heart and lung diseases, skin conditions, reproduction and fetal development, and organ transplantation.

Source: CRS review of scientific and policy literature. Table is not exhaustive of all research uses for the selected animals or of all animals used in federal biomedical research.

Animal Welfare Act

The AWA governs the humane care and treatment of certain animals that are intended for research, bred for commercial sale, exhibited to the public, or commercially transported. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) develops and administers AWA regulations. These regulations (9 C.F.R. Part 2) establish minimum standards of care and treatment for certain animals used in research, among other uses. USDA must consult with the Secretary of Health and Human Services (HHS) before issuing AWA regulations.

With respect to research, the AWA requires nonfederal research facilities to register with APHIS and all research facilities (federal and nonfederal) to undergo periodic inspections, keep records, submit annual reports to APHIS, and train personnel involved in animal care and treatment on humane practices. Research facilities, both federal and nonfederal, must establish an Institutional Animal Care and Use Committee (IACUC), which reviews the facility’s compliance with AWA regulations and reports violations to APHIS (nonfederal facilities) or the head of the agency (federal research facilities). A federal agency may revoke a project’s funding if it finds that an AWA violation has not been remedied following a warning. Research facilities may be subject to civil penalties for AWA violations.

There are limitations on the application of the AWA to research, since it does not authorize USDA to regulate the design, guidelines, or performance of research or to interrupt the conduct of research (7 U.S.C. §2143(a)(6)).

Types of Animals: The AWA applies to any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or other warm-blooded animal determined by USDA to be used for research or exhibition or as a pet. The AWA’s statutory definition of *animal* excludes certain animals, including birds bred for research, and rats (of genus *Rattus*) and mice (of genus *Mus*) bred for research.

Covered Entities: Under the AWA, *research facilities* are those entities that use live animals for research, tests, or experiments and that (1) purchase or transport live animals or (2) receive federal funds. These entities include federal and nonfederal facilities.

Public Health Service Policy

The PHS Policy addresses the welfare of animals used in research conducted or supported by PHS agencies. These include the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, FDA, and others in HHS. Through interagency agreements, the PHS Policy also applies to research conducted or supported by the Department of Veterans Affairs (VA) the National Science Foundation (NSF), and the National Aeronautics and Space Administration (NASA). The statutory basis for the PHS Policy is Public Health Service Act Section 495 (42 U.S.C. §289d). The policy also is informed by the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*, promulgated in 1985 by the Office of Science and Technology Policy.

The PHS Policy places requirements on both the institutions conducting research and the federal agencies that fund such research. Covered institutions must have an Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) at NIH. Covered institutions also must have an IACUC that reviews and inspects all of the institution's animal research and facilities. (This IACUC requirement is separate from AWA IACUC requirements.) The IACUC is required to review new and modified research project proposals at the institution to ensure that they are in accordance with AWA requirements as applicable, they minimize discomfort and distress to animals consistent with sound research design, and they provide adequate veterinary care and living conditions, among other things. The PHS Policy also tasks IACUCs with ensuring that programs are consistent with the *Guide for the Care and Use of Laboratory Animals (The Guide)* and certain other guidelines, such as euthanasia guidelines.

Given that both the AWA and the PHS Policy include separate IACUC requirements, many institutions establish single IACUCs that satisfy both requirements. Institutions are subject to recordkeeping and annual reporting requirements. Noncompliance with the PHS Policy can be reported to and addressed by OLAW.

Research project applications to funding agencies involving animal use require a rationale for species, the approximate number of animals, and a description of procedures. Agencies can establish additional agency-specific policies. For NIH, the largest federal funder of biomedical research, animal welfare plans are reviewed during the grant review process (42 C.F.R. §52h.8). If an award is made, then prior to conducting any animal activities, the recipient must submit to the NIH awarding institute or center a research plan and meet the Animal Welfare Assurance and IACUC requirements of the PHS Policy. There is a similar review process for NIH intramural research.

Types of Animals: The PHS policy applies to research involving live vertebrate animals, including certain types of animals not covered by the AWA, such as rodents and fish. Per its policy, NIH does not fund invasive research with chimpanzees. In September 2023, OLAW issued proposed guidance for cephalopod (e.g., octopus) research (NOT-OD-23-176), which would require institutions to include cephalopods in animal research approval and oversight.

Covered Entities: The PHS Policy applies to (1) any institution conducting research funded by a PHS agency and (2) institutions conducting research supported by VA, NSF, and NASA (through interagency agreements). The Department of Defense, which supports considerable biomedical research, has its own animal welfare policy.

Guide for the Care and Use of Laboratory Animals

The Guide serves as a commonly accepted standard for recommended laboratory animal and research management practices, including detailed recommendations based on the type of animal and procedures involved. The PHS Policy requires that institutions base their animal care and use programs on *The Guide*. Developed by a committee of scientists and veterinarians, *The Guide* was first issued in 1963 and most recently updated in 2011 by the National Research Council.

Number and Types of Animals Used

There is no central public tracking of the number and types of animals used in all federally funded biomedical research. Based on annual reporting required by the AWA, USDA summarizes the number and type of covered animals used or held by federal and AWA-registered research facilities for research, testing, teaching, experimentation, and/or surgery in categories corresponding to the pain and distress the animals experienced. These data are available at the APHIS Research Facility Annual Summary & Archive Reports website. The data include animals used in biomedical as well as in other research and do not include mice, rats, and other animals not covered by the AWA.

Policy Efforts to Develop and Promote Alternatives to Animal Use

Efforts to develop alternatives to animal use, grounded in the “Three Rs” principles, have been ongoing. Scientific advances have enabled new technologies, such as “tissue chips,” designed to replicate human organ functions and replace animals in certain research. Federal efforts, including the Interagency Coordinating Committee on the Validation of Alternative Methods (codified by P.L. 106-545) and the Toxicology in the 21st Century program, seek to develop and promote the use of alternative methods. A 2019 Government Accountability Office (GAO) evaluation (GAO-19-629) found that agencies have not consistently evaluated such efforts, and in particular, some of the alternatives developed have not met regulatory and industry needs.

Concluding Observations

There are conflicting views on the current policy framework and its potential for reform. Some advocates in the biomedical science field contend that the existing policies impose administrative challenges on researchers, leading them to resist additional restrictions or requirements. Others maintain that the current policies fall short in safeguarding animal welfare and advocate for additional restrictions on some or all animal research. Congress may continue to weigh scientific and ethical considerations.

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