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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 reflects a balance of animal welfare considerations with the scientific value of such research and encourages the development and use of alternatives to animals where possible. Various federal statutes and policies seek to ensure the welfare of animals used in such research. 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 report 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 Policy on the Human Care and Use of Laboratory Animals*—relevant to animal use and welfare in federally funded biomedical research. It does not address all relevant laws and policies, such as certain related Food and Drug Administration (FDA) regulations.

Background

In recent decades, rodents (e.g., mice, rats) have become the predominate type of animal used in biomedical research, driven by scientific advances that have refined rodent models for many types of diseases and biological systems. Large mammals, such as dogs, swine, and nonhuman primates, remain useful for certain studies. For example, a 2020 National Academies of Sciences, Engineering, and Medicine review (*Necessity, Use, and Care of Laboratory Dogs at the U.S. Department of Veterans Affairs*) found that some experiments with dogs “offer the potential for medically important discoveries that cannot currently be obtained elsewhere,” especially for studies related to cardiovascular disease and spinal cord injury.

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’s (USDA’s) 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. Each research facility 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. With few exceptions, the AWA 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, rats, and mice bred for research. There are restrictions on facilities’ procurement of dogs and cats.

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.

Research Outside the United States: The AWA and its regulations do not directly address federally funded research conducted by foreign entities. A 2018 Government Accountability Office (GAO) report (GAO-18-459) found that APHIS does not instruct federal research facilities outside of the United States to report on animal research activities and concluded that providing such instructions would increase AWA reporting consistency.

Public Health Service Policy

The *Public Health Service Policy on the Humane Care and Use of Laboratory Animals* (PHS Policy) addresses the welfare of animals used in research conducted or supported by Public Health Service (PHS) agencies. (PHS agencies include the National Institutes of Health [NIH], the Centers for Disease Control and Prevention [CDC], 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.

Under the PHS Policy, any institution that is subject to the PHS Policy and conducts animal research using live vertebrate animals must have an Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) at NIH. Each institution subject to the policy must have an IACUC that reviews and inspects all of the institution's animal research and facilities. 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 from the American Veterinary Medical Association (AVMA). Given that both AWA and the PHS Policy include separate IACUC requirements, many research institutions establish single IACUCs that satisfy both requirements.

Research project applications to funding agencies that involve the use of animals must include a rationale for the species, number of animals used, and the procedures involved. Projects are subject to annual reporting requirements on animal use. Noncompliance with the PHS Policy can be reported to and addressed by OLAW. 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.

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. There are also procurement-related restrictions for cats and dogs.

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.

Foreign Entities: Foreign entities directly receiving NIH funding must provide OLAW an Animal Welfare Assurance for Foreign Institutions, which ensures that the institution complies with applicable animal welfare laws of the jurisdiction in which the research is conducted and with

the *International Guiding Principles for Biomedical Research Involving Animals*. When a domestic funding recipient conducts animal research at a foreign site, the domestic institution is responsible for compliance.

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. These data are available at the APHIS Research Facility Annual Summary & Archive Reports website. They include animals used in research other than biomedical 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

Over the last several decades, the Three Rs have underpinned laboratory animal welfare standards, such as *The Guide*, as well as policy efforts to promote alternatives to animal use. Scientific advances have enabled the development of new technologies, such as “tissue chips,” designed to replicate the complex functions of human organs that can replace animals in certain research. Several federal efforts, such as 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 alternatives to animals in biomedical research and testing. A September 2019 GAO evaluation (GAO-19-629) found that agencies have not consistently assessed such efforts, and in particular, some of the alternatives developed have not met the research needs of federal agencies or industry.

Concluding Observations

There are conflicting views on the current policy framework and the need for reform. Some biomedical science advocates argue that existing policies create an administrative burden for researchers and oppose further restrictions. Some animal welfare advocates assert that current policies do not adequately protect animal welfare and argue for further restrictions on some or all animal research. Congress may continue to weigh scientific and ethical considerations.

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