

# Care And Use of Animals At Rutgers

## II. Federal, State And University Laws, Regulations, Guidelines And Policies



### Laboratory Animal Services Home Cage

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DOCUMENT/ORGANIZATION	STATUS	OVERSIGHT BY:
<a href="#">Animal Welfare Act</a>	Federal Law	<a href="#">USDA</a>
<a href="#">Principles for the Care and Use of Animals Used in Testing, Research and Education</a>	Principles endorsed by 9 federal agencies	Federal agencies including <a href="#">Health and Human Services</a> (including <a href="#">PHS</a> and <a href="#">NIH</a> )
<a href="#">PHS Policy on Humane Care and Use of Laboratory Animals</a>	PHS policy – applies to all PHS funded grants and contracts. PHS's implementation of the above Principles	<a href="#">Office of Laboratory Animal Welfare (OLAW, formerly OPRR)</a> , <a href="#">NIH</a> , <a href="#">PHS</a> , <a href="#">HHS</a>
<a href="#">Health Research Extension Act of 1985</a>	Federal law – gives statutory basis for pre-existing PHS Policy	<a href="#">NIH</a>
<a href="#">Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)</a>	Non-profit, "voluntary" accrediting organization	<a href="#">AAALAC</a>
<a href="#">Guide for the Care and Use of Laboratory Animals</a>	Guidelines used by PHS Policy and AAALAC. Revised 1996	Written by an <a href="#">NRC</a> committee, used by <a href="#">NIH</a> and other organizations
<a href="#">2000 Report of the AVMA Panel on Euthanasia</a>	The Guide defers to the <a href="#">AVMA</a> report as the standard for acceptable methods of euthanasia	Used by <a href="#">AAALAC</a> , <a href="#">NIH</a> , <a href="#">IACUC's</a> , etc.
<a href="#">Institutional Animal Welfare</a>	Required by PHS Policy in	

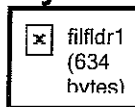
<u>Assurance of Compliance to PHS</u>	order to receive PHS funds for animal research at Rutgers	<u>OLAW</u> for PHS. ACFC at Rutgers
<u>Rutgers University Animal Welfare Policy</u>	Internal policy	Animal Care and Facilities Committee (ACFC)

The new era of the animal rights movement has meant a wide range of activities, from demonstrations to illegal break-ins, resulting in increased media attention and attendant activity in federal and state legislatures. Due to tremendous constituent pressure and in an effort to strike a proper social balance between scientific needs and animal welfare, the U.S. Congress passed two pieces of legislation in 1985 which directly affect the use of animals in research.

The intent of this chapter is to provide an overview of the laws and regulations governing animal research including the two new laws passed in 1985-the Health Research Extension Act of 1985 (P.L. 99-198) and the Improved Standards for Laboratory Animals Act amending the Animal Welfare Act (P.L. 99-148). Every investigator and staff member who uses animals in research projects is governed by one or both of these laws. It is therefore essential that you have a sound understanding of both your rights and responsibilities in relation to the conduct of animal research.

Both the Public Health Service Policy and the amendments to the Animal Welfare Act stress increased self-regulation and greater public accountability. The ultimate responsibility for all animal research lies with the institution, but in both laws, the mandatory animal care committees are vested with oversight responsibility.

### A. Rutgers University Animal Welfare Policy



On September 1, 1985, the Executive Office of the President issued an Animal Welfare Policy Governing the Use of Animals in Research, Instruction and Demonstration.

The University Policy requires adherence to the Animal Welfare Act, the NIH Guide and the PHS Policy. Most importantly, the University Policy applies to all procedures using live vertebrate animals at the University regardless of funding source or species.

### B. The Animal Welfare Act And Regulations



The Animal Welfare Act is the federal statutory authority for inspection of research facilities. It was originally passed in 1966 and subsequently amended in 1970, 1976 and 1985. The Act falls under the jurisdiction of the Secretary of Agriculture, with responsibility for administration delegated to the U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS). APHIS is responsible for regulating not only research facilities but also animal dealers, exhibitors (including zoos, aquariums, circuses, etc.) and intermediate handlers of animals, including air and truck lines.

Whereas the PHS Policy affects only those institutions receiving Public Health Service funding, the Animal Welfare Act covers all research facilities in the U.S. that use laboratory animals in basic and biomedical research, education and product safety testing. Wild rats and mice are covered by the Act. Laboratory rats and mice, birds and some farm animals are not covered by the Animal Welfare Act regulations, and facilities using only those species do not have to be registered with the U.S.

### Department of Agriculture.

The Animal Welfare Act was historically concerned primarily with basic animal husbandry and veterinary care. The Guide, PHS and AAALAC are concerned not only about animal welfare, but the whole animal research environment, including personnel safety, and factors which although they might not adversely affect animal welfare, might interfere with the integrity of animal research projects. In this sense, regulations of the Animal Welfare Act are less rigorous than the guidelines set forth in the NIH Guide. As federal law, however, the Act allows little room for interpretation, whereas the recommendations of the Guide are meant to be used with professional judgement.

Major regulations of the Animal Welfare Act include:

- Animal dealers must be licensed before they can sell animals to research institutions. Research facilities must be registered before they can purchase animals for research.
- Research facilities must keep records regarding the purchase, sale, transportation, identification and disposition of dogs and cats.
- USDA has established standards and record keeping requirements affecting the purchase, handling, care and use of laboratory animals. The standards include minimum requirements for: restraint, housing, feeding, watering, sanitation, ventilation, separation by species, veterinary care and appropriate use of anesthetic, analgesic or tranquilizer drugs. The regulations include cage size and space requirements that differ in some cases from PHS recommendations (see The Guide Chapter 2 Sec 3).
- Research facilities must demonstrate annually that professionally acceptable standards governing the care, treatment and use of animals are being followed. Rutgers must file an annual report that states the number of animals used each year, categorized by species and the level of pain and distress the animals experienced.
- USDA inspectors (veterinarians) must inspect each registered research facility at least annually. Inspectors are accompanied by Laboratory Animal Services personnel when they inspect University facilities. They have access to all animal facilities housing animals covered by the Act.
- Inspectors may confiscate or destroy animals found to be suffering as a result of failure to comply with any provisions of the Act, if the animals are not on experiment at the time.
- Inspectors may take photographs of animal facilities.
- Inspection of research facilities by law enforcement agencies is permitted, at reasonable hours, to search for lost animals. In New Jersey, state and municipal police have such authority. Animal control officers and humane society representatives do not.
- Violations of any provisions of the Act or of any of the rules, regulations or standards established by USDA under the Act are subject to a civil fines for each offense and each day such violations continue.

Existing statutory language prohibiting promulgation of rules or regulations with regard to "design, outlines, guidelines or performance of actual research" was revised to make exceptions for certain of the new standards.

- Research facilities are required to have an Institutional Animal Committee. (This was required of Rutgers by PHS Policy.)
- Research facilities shall provide training for scientists, technicians and others involved with animal care. [Hence this manual.] The National Agriculture Library, with the National Library of Medicine shall establish an information service to provide information on employee training, prevention of unintended duplication of research, and improved methods of reducing or replacing animal use and minimizing pain. The National Agricultural Library also maintains the Animal Welfare Information Center.
- Federal agencies will suspend or revoke funds when it is determined that conditions of animal care, treatment or practice in a particular project are not in compliance despite notification and an opportunity for corrections. Monetary fines for violations of the Animal Welfare Act were also increased.

- Nothing in the Act shall be construed to require a research facility to disclose publicly or to the Institutional Animal Committee during its inspection, trade secrets or commercial or financial information which is privileged or confidential." In addition, penalties for release of trade secrets are established.
- Standards for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care with the appropriate use of anesthetics, analgesics, tranquilizing drugs, and euthanasia must be established.
- Investigators must assure in writing that alternatives to painful procedures were considered. A veterinarian must be consulted in any practice which could cause pain to animals (PHS Policy).
- No animal may be used in more than one major operative experiment from which it is allowed to recover except in cases of scientific necessity.
- Exceptions to such standards may be made only when specified by research protocol and any such exception must be detailed and explained in a report filed with the Institutional Animal Committee.

As of August 15, 1990, all of the above regulations implementing the 1985 amendments were finalized. New regulations for Part 3, "Standards", were finalized at a later date. These new regulations include :

- Standards for exercise of dogs.
- Standards for a physical environment adequate to promote the psychological well-being of primates.

### **C. Principals for the Utilization and Care of Vertebrate Animals in Testing, Research, and Training**

The principles below were prepared by the Interagency Research Animal Committee. This committee, which was established in 1983, serves as a focal point for federal agencies' discussions of issues involving all animal species needed for biomedical research and testing. The committee's principal concerns are the conservation, use, care, and welfare of research animals. Its responsibilities include information exchange, program coordination, and contributions to policy development.

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research or training procedures involving the use of vertebrate animals, the principles shall be considered; and whenever these agencies actually perform or sponsor such procedures the responsible institutional official shall ensure that these principles are adhered to:

- The transportation, care, and use of animals should be in accordance with the Animal Welfare Act and other applicable Federal laws, guidelines, and policies.
- Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- The animals selected for a procedure should be of an appropriate species and quality and number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
- Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- Procedures with animals that may cause more than momentary or slight pain and distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical

agents.

- Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.
- Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

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



Institutions such as Rutgers which conduct U.S. Public Health Service (PHS) - supported animal research must comply with the Policy on Humane Care and Use of Laboratory Animals. The Policy, administered through the National Institutes of Health, Office of Protection from Research Risks, has evolved over the last twenty years. The Health Research Extension Act of 1985 Section 495 "Animals in Research," put a statutory foundation under the Policy.

As revised to meet new legal requirements effective in September 1986, following are the key elements of the Policy.

### 1. Assurances

Written documentation of Rutgers's commitment to animal welfare is required in the form of detailed information on the animal care and use program. Institutions are required to designate clear lines of authority and responsibility for those involved. Each institution must identify an official who is ultimately responsible for the institution's animal program and a veterinarian qualified in laboratory animal medicine who will participate in implementation. The program description must also give details concerning veterinary care, animal husbandry and all animal facilities. A synopsis of mandatory training or instruction in the humane practice of animal care and use as well as the occupational health program for all personnel involved with animals must also be included in the assurance statement. Rutgers must ensure that the laboratory animal facilities meet the requirements outlined in the Guide for the Care and Use of Laboratory Animals. At Rutgers, the function of the Institutional Animal Care and Use Committee is delegated to two committees, the Animal Care and Facilities Committee and the Institutional Review Board for the Use and Care of Animals.

Rutgers has an Animal Welfare Assurance on file with OPRR. The effective date is April 27, 1987. The Assurance Number is A-3262-01.

### 2. Institutional Animal Care and Use Committees

The centerpiece of each research facility's animal research program is the mandatory Institutional Animal Care and Use Committee (IACUC). At Rutgers, the functions of the IACUC are delegated to