

## Regulations in Animal Research

### 1 Animal Welfare vs. Animal Rights: Historical Perspective

#### 1.1 Animal Welfare vs. Animal Rights: Definitions

**Animal Welfare:** The obligation of human kind to provide proper stewardship when utilizing animals (i.e., to care for them and to ensure their well-being; humane care and use)

**Animal Rights:** The belief that animals have legal standing (i.e., are individuals with legal rights) and are not property. As such, animals cannot be "owned" by humans, and claims that an individual animal's legal rights have been violated can be addressed through the court system; human rights equal animal rights

#### 1.2 General Ethical Principles

Questions regarding the ethical use of animals in biomedical research have understandably received much attention recently. The tenets of these considerations were well stated by Marshall Hall in 1831 and are outlined below:

1. We should never have recourse to experiment in cases in which observation can afford us the information required.
2. It must be assumed that no experiment should be performed without a distinct and definite object, and without persuasion, after the maturest consideration, that the object will be attained by the experiment in the form of a real and uncomplicated result.
3. We should not needlessly repeat experiments that have already been performed by individuals of reputation. If a doubt with respect to their accuracy, or the accuracy of the deductions drawn from them, arises, it then indeed becomes highly important that they should be corrected or confirmed by repetition. This principle implies the necessity of due knowledge of what has been done.
4. A given experiment should be instituted with the least possible infliction of suffering.
5. Every experiment should be performed under such circumstances as will secure a due observation and attention of its results, and so obviate, as much as possible, the necessity for its repetition.

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### 1.3 Brief Background History

Humane legislation, not passed in the United States until 1958, was related to the humane care of livestock. The legislation was termed the "Humane Slaughter Act" and was thought to be fueled by Upton Sinclair's book, "*The Jungle*".

During the 1960s, the issue of animal welfare/animal rights came to the forefront as a result of two events that received widespread public attention.

In 1965, a pet Dalmatian owned by a New York family was missing. The owner thought he recognized his dog in a news photograph of a group of dogs being transported by a commercial dog dealer to a holding facility for eventual resale to biomedical research institutions. The dog dealer refused to consider the pleadings by either the owner or his representative in the U.S. Congress, Rep. Joseph Resnick, to return the animal.

Frustrated by this situation, Resnick introduced a bill to regulate the trade of dogs. A similar bill was introduced simultaneously in the Senate. Both bills had only marginal support and might have died in committee, had it not been for the second supporting event.

### 1.4 The Life Magazine Article of 1966



- A 1966 photo in *Life* magazine exposed the abuse of dogs at the hands of animal dealers, including those dealers that sold animals to laboratories and universities.
- This article stimulated Congress to pass two laws that regulate the use of animals in research, testing, and teaching: the Animal Welfare Act of 1966 and the Public Health Service Policy of 1985.

## 2 Regulations Mandating Animal Welfare Practice

### 2.1 The Animal Welfare Act

Public Law 89-544 originally enacted on August 24, 1966, and amended by Public Law 91-579 (1970), Public Law 94-279 (1976), Public Law 91-198 (1985) and Public Law 101-624 (1990)

Implemented and Regulated by The United States Department of Agriculture (USDA)

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## Details of the Animal Welfare Act:

- Covers warm-blooded animals. By current regulation, birds, rats of the genus *Rattus*, and mice of the genus *Mus* are not covered
- Requires registration with the USDA every 3 years
- Involves regular unannounced inspections by USDA

Provisions are defined more thoroughly by a series of policies enacted by the USDA. These policies are available at the following website:

<http://www.aphis.usda.gov/ac/polmanpdf.html>. The most important USDA policies include:

- Policy 3, Veterinary Care of Animals
- Policy 11, Painful/Distressful Procedures
- Policy 12, Written Narrative for Alternatives to Painful Procedures
- Policy 14, Multiple Survival Surgery

## 2.2 The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals

The Health Research Extension Act of 1985, Public Law 99-158, Animals In Research

Passed by the U.S. Congress on November 20, 1985, this law provides the statutory mandate for the PHS Policy. It allows the Secretary of the U. S. Department of Health and Human Services, acting through the Director of NIH, to establish guidelines for the following:

- The proper care of animals to be used in biomedical and behavioral research;
- The proper treatment of animals while being used in such research;
- The organization and operation of animal care committees.

The Office of Laboratory Animal Welfare (OLAW, formerly Office for Protection from Research Risks, Division of Animal Welfare) at the National Institutes of Health has responsibility for the general administration and coordination of the Policy on behalf of the PHS. (<http://grants.nih.gov/grants/olaw/references/phspol.htm#1985>)

The main tenets of the PHS Policy on the Humane Care and Use of Laboratory animals are as follows:

- Governs ALL animal use at institutions that receive funding from the Public Health Service (PHS), including research not directly funded by the Federal Government;

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- Covers ANY live vertebrate animals used or intended for use in research, research training, experimentation, biological testing, or for related purposes;
- Requires a written assurance to NIH that the institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The assurance must include information on the institutional program for animal care and use, record keeping, and reporting. Assurances must be renewed at 4 year intervals;
- Depends on the IACUC for enforcement.

### **2.3 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training**

These Principles were promulgated in 1985 by the Interagency Research Animal Committee and were adopted by U.S. Government agencies that either develop requirements for, or sponsor procedures involving, the use of vertebrate animals. The Principles were incorporated into the 1986 PHS Policy and provide a framework for research conducted in accordance with the Policy.

The following Principles must be adhered to at all institutions that receive funding from the U.S. Federal Government for the use of animals in research:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.<sup>1</sup>
- II. 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.
- III. The animals selected for a procedure should be of an appropriate species and quality, and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
- IV. 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 assume that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain, or 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.
- VI. 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.

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VII. 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.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for in-service training, including the proper and humane care and use of laboratory animals.

IX. 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.

1. For guidance with these Principles, the reader is referred to the [Guide for the Care and Use of Laboratory Animals](#) prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences. This important source of information is referred to as the "Guide" throughout this training module. It is highly recommended that all users of animals at the University of Pittsburgh be familiar with this handbook

### 2.4 Comparing the Animal Welfare Act and NIH Policy

	USDA Regulations/Animal Welfare Act	NIH Policy
<b>Species Covered</b>	Warm-blooded animals except mice, rats, & birds	All live vertebrate animals
<b>Oversight</b>	Unannounced inspections by USDA	Self-monitoring and reporting by IACUC
<b>Sanctions</b>	Fines, revocation of USDA registration, imprisonment	Restriction or withdrawal of grant funding
<b>Implementing Documents</b>	Animal Welfare Act and USDA Policies	NIH Policy on the Humane Care and Use of Laboratory Animals and Guide for the Care and Use of Laboratory Animals

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PLEASE NOTE: Since the University of Pittsburgh receives grant monies from PHS, all users of vertebrate species must comply with NIH policies regarding the use of animals. Users of warm-blooded species other than birds, rats, and mice also must comply with USDA regulations.

### **3 Requirements of Funding Agencies**

#### **Funding Agencies and Foundations**

Each funding agency and research foundation has its own set of guidelines regarding the use of animals. Nonetheless, the NIH Guide (Guide for the Care and Use of Laboratory Animals, 1996 edition) is the standard for laboratory animal research, and all funding sources insist on compliance with both the Animal Welfare Act and the NIH Policy.

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

- The AAALAC is a private, nonprofit body that accredits laboratory animal facilities and animal care programs through peer review, based on the tenets of the NIH Guide and USDA Policies.
- Every three years a team visits the institution and evaluates both its facilities and policies regarding the use of animals.
- Accreditation by AAALAC is recognized internationally, and is deemed the best means of demonstrating compliance with the NIH Guide and Federal regulations concerning the use of animals.

### **4 Summary**

#### **1 Animal Welfare vs. Animal Rights: Historical Perspective**

The animal rights and the anti-vivisection movements contributed to passage of two major pieces of Federal legislation regulating the use of animals in research, testing, and education.

#### **2 Regulations Mandating Animal Welfare Practices**

The most important pieces of legislation regulating the use of animals in research, testing, and education are the Animal Welfare Act of 1966 and the Health Research Extension Act of 1985. The later legislation established current NIH Policy.

#### **3 Requirements of Funding Agencies**

Each funding agency has unique requirements regarding the use of animals in research. However, in general all require compliance with NIH Policies and the Animal Welfare

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Act. In addition, most funding agencies consider accreditation by AAALAC as being the "gold standard" for affirming that an institution maintains high standards with respect to the use of animals.