

## COURSE 13, TUTORIAL 4

# ANIMAL SUBJECT PROTECTION



In previous tutorials, the focus was on human test subject protection. By contrast, this tutorial covers animal test subject protections. In the U.S., there are a large number of government principles, statutes, agency policies, directives and reference manuals that protect animal test subjects from abuse and poor care. Each Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) funding agency follows any number of these rules to address its own particular concerns. As a result, the animal test subject information requested from a Phase I SBIR/STTR applicant will vary from agency to agency. A complete listing of Federal oversights of research involving animals can be found in the useful Links section of this tutorial. In spite of the variety of agency to agency animal test subject protections, two are common to all SBIR/STTR funding agencies - the Animal Welfare Act (AWA) and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. A third, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, is utilized by most SBIR/STTR funding agencies.

### **ANIMAL WELFARE ACT (AWA)**

The implementation of regulations for the AWA are administered by the U.S. Department of Agriculture (USDA). The AWA was originally enacted in 1966 to codify protections for animals being used for laboratory testing. While the original intent was to “regulate the care and use of animals in the laboratory, it has become the only Federal law in the United States that regulates the treatment of animals in research, exhibition, transport, and by dealers. Other laws, policies, and guidelines may include additional species coverage or specifications for animal care and use, *but all refer to the Animal Welfare Act as the minimum acceptable standard*”. The AWA has been amended seven times since its enactment and can be found in the *United States Code*, Title 7, Sections 2131 to 2156.

The AWA designates the USDA as the regulatory and enforcement authority. The USDA uses its Animal and Plant Health Inspection Service (APHIS), Center for Animal Welfare to carry out licensing, inspection and enforcement activities.

### **AWA SUMMARY**

A summary of AWA protections is below:

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» *Permits are required to buy and sell listed animals or register for their use by dealers of animals, exhibitors of animals, and research facilities that use listed animals, but pet owners, agricultural use and retail pet stores are exempted from the provisions of this federal law.*



## There are three common Federal oversights of research involving animals in the SBIR/STTR space:

1. Animal Welfare Act
2. The Principles
3. PHS Policy

- » *There are limitations/regulations on how animals may enter the controlled chain of commerce, to eliminate the use of stolen animals.*
- » *There are limitations/regulations on the environmental conditions under which the animals must be kept.*
- » *Research facilities may purchase listed animals only from licensed dealers.*
- » *Those who transport the listed animals must comply with published regulations governing the well-being of the animals.*
- » *Research facilities must create an Animal Care Committee to review the use of animals by the facility and inspect the animal housing facilities.*
- » *Research facilities must abide by legal restrictions on the imposition of pain during research.*
- » *Research facilities must comply with extensive regulations concerning the housing and care of animals used in research.*
- » *In a separate provision, it made it illegal for any person to knowingly sponsor or exhibit an animal in any animal fighting venture to which any animal was moved in interstate or foreign commerce.”<sup>1</sup>*

<sup>1</sup> National Anti-Vivisection Society, <https://www.navs.org/what-we-do/keep-you-informed/legal-arena/research/explanation-of-the-animal-welfare-act-awa/#.Wbl49ciGOUk>

Relevant to the types of animals that could be research subjects in an SBIR/STTR project, **not every type of animal used in every type of activity is covered.** According to the USDA, the following animals are not covered: “farm animals used for food or fiber (fur, hide, etc.); coldblooded species (amphibians and reptiles); horses not used for research purposes; fish; invertebrates (crustaceans, insects, etc.); or rats of the genus *Rattus* and mice of the genus *Mus* that are bred for use in research. Birds are covered under the AWA but the regulatory standards have not yet been established.”<sup>2</sup> Remember, other federal laws and regulations do cover all vertebrate animals, including rats and mice. These will be discussed later.

Additional information on AWA can be gleaned from the [US-DA's Animal Welfare Information Center](#).

### THE PRINCIPLES

The next document which grants protection to animals is the United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (Principles) which was developed by the Interagency Research and Animal Committee in 1985. **These Principles are to be used as the basis for all federal agency animal test subjects.** Like the AWA, the Principles should be regarded as a minimum protective standard. The Principles are:

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1. *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>2</sup> United States Department of Agriculture, Animal and Plant Health Inspection Service, [https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA\\_AWA](https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA_AWA)



- 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 consider 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.
- 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 their 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.”<sup>3</sup>

For guidance on these Principles, one can refer to the [Guide for the Care and Use of Laboratory Animals](#) prepared by the Institute for Laboratory Animal Research, National Academy of Sciences .

### **PUBLIC HEALTH SERVICE POLICY**

A third, more research oriented set of animal subject protections can be found in the Public Health Service (PHS) – a division of the Department of Health and Human Services (HHS) – Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Although this is a HHS policy, the following SBIR/STTR funding agencies have chosen to observe and enforce the Policy as well. They are the Department of Defense, the National Science Foundation, the National Aeronautics and Space Administration, the National Institute of Standards and Technology (a division of the Department of Commerce), and the Department of Homeland Security.

The PHS Policy is administered by the National Institutes of Health’s (NIH) Office of Laboratory Animal Welfare (OLAW). The latest version has incorporated the content of [Guide for the Care and Use of Laboratory Animals \(Eighth Edition\)](#). The purpose of the Guide is to “assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate.” The PHS Policy incorporates all protections codified in the AWA and the Principles and enhances them with stronger protections. An important thing to note is that **the PHS Policy covers the use of all vertebrate animal subjects**, including mice and rats bred for research purposes.

## **The United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training is commonly known as The Principles.**

<sup>3</sup> National Institutes of Health, <https://grants.nih.gov/grants/olaw/tutorial/relevant.htm#2b>