Institutional Animal Care and Use Committee (IACUC)

ST. GEORGE'S UNIVERSITY POLICY ON THE USE AND CARE OF ANIMALS IN RESEARCH, EDUCATION AND TESTING

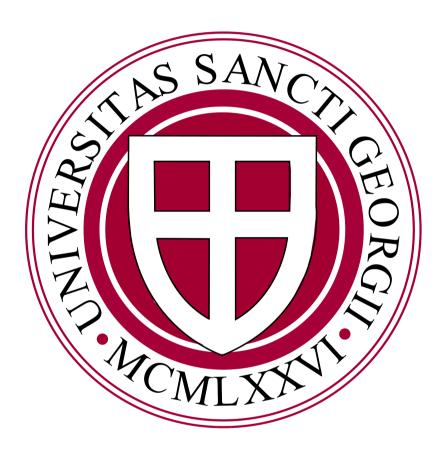


Table of Contents

Summary		4
	I. Preface	4
	II. Introduction (Purpose and Intent)	5
	III. Institutional Official	5
	IV. Institutional Animal Care and Use Committee	6
Policy on Use and Care of Animals in Research, Education and T		7
	Preamble	7
	Article I. General Regulatory Guidelines	7
	Article II. Guidelines for Studies of Wild Animals	7
	Article III. Four "R" Tenets	7
	Article IV. University Responsibilities	8
	Section 1.	8
	Section 2.	8
	Article V. Investigator Responsibilities	9
	Article VI. Institutional Official	9
	Article VII. Institutional Animal Care and Use Committee (IACUC)	9
	Section 1. Basic Functions	9
	Section 2. Composition	10
	Article VIII. Centre for Animal Resources and Education (CARE)	10
	Section 1. The Attending Veterinarian	10
	Section 2. Responsibilities of the Attending Veterinarian	10
	Section 3. New IACUC Members	10

St. George's University

IACUC polic

Section 4. IACUC Members and Meetings	11
Section 5. Application Submission to IACUC	11
Article IX. Occupational Health and Safety in Animal Care and Use Program	
Section 1. Identify Hazards	12
Section 2. Risk Assessment Program	13
Article X. Euthanasia of Research Animals	
Euthanasia Policy	13
References	
Regulatory Information	
Governmental Regulations, Policies, and Guidelines	16
Additional Reference Resources	16
Office of Laboratory Animal Welfare (OLAW)	16
Research Facilities	17

Summary

I. Preface

Research using animals has made, and continues to make, a vital contribution to the understanding, treatment and cure of major human and animal health problems; including cancer, heart disease, polio, diabetes and neurological diseases and disorders. While new methods have enabled scientists and medical researchers to reduce studies involving animals, some work must continue for further fundamental advances to be made.

St. George's University only uses animals in teaching and research where there are no alternatives. In fact, international law demands that where a non-animal approach exists, it should be used. The principles of reduction, refinement and replacement of animals in research (the '3Rs') underpin all related work carried out at the University, ensuring that the number of animals used is minimized and that procedures, care routines and husbandry are refined and regularly reviewed to maximize welfare.

Until satisfactory alternatives have been developed, the processes of discovery, enquiry and teaching require procedures that involve animals in order to gain knowledge and understanding of structure, physiological and pathological processes, and in order to pass on knowledge to students.

Teachers and scientists at St. George's University are seeking ways to reduce the number of animals needed for their research and for teaching. However, 'alternative' tests and models have yet to be developed that can properly reproduce the complex biological characteristics of man and animals, and studies of wild animals in their natural environment will always require the involvement of the animals themselves.

In the international community, research and teaching activities involving animals considered to be sentient are governed by a range of legislation and guidelines. All members of the University carrying out procedures on animals, or use animals for teaching purposes, must have prior training and relevant experience. All projects and teaching courses affecting animals are subject to prior formal ethical review within the University.

In any work involving animals of protected species, the policy of St. George's University is to adhere to high standards of humane care and treatment of those animals. The University has procedures to meet these requirements and complies with relevant laws and guidelines.

The over-riding considerations are that:

- Research on animals is conducted only when it will contribute to the advancement of knowledge that is likely to lead to improvement of the health and welfare of animals or human beings, or provide a better understanding of the animals themselves.
- The University conducts studies involving animals on the basis of well-defined scientific objectives and the advancement of knowledge, giving due consideration to the welfare of the animals, minimizing the number of animals employed in each test, and avoiding unnecessary duplication.
- Where animals are used in teaching, either to demonstrate fundamental principles or to provide practical training to veterinary students, the same principles of minimizing numbers and maximizing animal welfare are practiced.
- The University actively supports the development, validation and adoption of appropriate alternatives to the use of animals, in order to eliminate the need for animals in both research

and teaching. In-vitro studies are used as substitutes for whole-animal studies whenever such tests are feasible, and cadavers, audio-visual technology and simulations are used in teaching.

Animals are transported, housed and cared for by dedicated and trained staff under professional supervision in a manner designed to ensure the best health and wellbeing of the animal, with provisions for environmental enrichment.

Principal investigators and a designated veterinary surgeon are available at all times for consultation, care and attendance.

St. George's University is committed to the responsible use of animals in its research and teaching activities. All University personnel who supervise or undertake activities involving animals are trained to carry out their duties in a responsible and humane manner.

II. Introduction (Purpose and Intent)

St. George's University (SGU) affirms the following:

- Respect for all forms of life is an inherent characteristic of scientists who conduct research involving animals and lecturers who's teaching involves animals
- Respectful treatment, care, and use of animals involved in research and teaching is an ethical, didactic and scientific necessity
- The use of animals in research and teaching contributes to the advancement of knowledge and understanding.

Accordingly, SGU has established and provides resources for an Animal Care and Use Program that is managed in accordance with the United States of America Animal Welfare Act and the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

All research and teaching activities involving vertebrate and invertebrate animals must be conducted in accordance with the SGU Policy on Use and Care of Animals in Research, Education and Testing (SGU Policies), available in the designated IACUC section of the University Web site: www.sgu.edu/iacuc

III. Institutional Official

The Institutional Official is appointed by the Chair of the Panel on Research and Scholarly activities and is the administrative official responsible for the Animal Care and Use Program. The Institutional Official will be appointed for a period of three (3) years. There is an option to renew the appointment; no time limit has been set. The institutional official has appointed an Institutional Animal Care and Use Committee (IACUC) that is responsible for the oversight and evaluation of the animal care and use program, procedures, and facilities.

IV. Institutional Animal Care and Use Committee

All vertebrate and invertebrate animal use, including field studies conducted by SGU faculty, students, staff, or visiting scientists conducting vertebrate and invertebrate animal research or teaching, which may or may not require clearance by relevant Government Agencies, must be reviewed and approved by IACUC pursuant to SGU policies.

The IACUC has authority to:

- Review, approve, require modification, or withhold approval of proposed research or teaching using animals
- Review the facilities and program for animal care and use, including laboratories outside of animal facilities where procedures are performed
- Review and, if warranted, investigate concerns involving the care and use of animals

- Prepare written reports of its evaluations Make recommendations to the Institutional Official concerning any aspect of the animal
- care and use program
 Suspend any activity involving animals that does not conform to SGU policies or Grenadian or U.S. federal regulations.

Policy on Use and Care of Animals in Research, Education and Testing

Preamble

St. George's University, recognizes that animals play a central and essential role in research, testing, and education for continued improvement in the health and welfare of human beings and animals. SGU also recognizes that humane care of animals used in research, testing, and education is an integral part of those activities.

St. George's University affirms that respect for all forms of life is an inherent characteristic of biological and medical scientists who conduct research involving animals, that the respectful treatment, care and use of animals involved in research is an ethical and scientific necessity, and that the use of animals in research and teaching contributes to the advancement of knowledge and the acquisition of understanding.

Article I. General Regulatory Guidelines

To the extent of the above, St. George's University has established and provides resources for an Animal Care and Use Program that is managed by an Institutional Animal Care and Use Committee that is a self-regulatory body appointed by the Institutional Official in accordance with the following:

- Guide for the Care and Use of Laboratory Animals (Guide), (http://www.nap.edu/openbook.php?record_id=5140&page=1)
- United States of America Animal Welfare Act (http://www.aphis.usda.gov/animal_welfare/awa_info.shtml)
- Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), (http://grants.nih.gov/grants/olaw/references/phspol.htm)
- All applicable Grenadian laws and regulations
- St. George's University Policy
- IACUC Policy and Procedure Guide Book
 These written IACUC Principles and Procedures and all associated relevant documents are
 reviewed and updated semiannually by a quorum of the regular members of the IACUC.

Article II. Guidelines for Studies of Wild Animals

Studies of wild animals in or derived from natural settings are conducted in accordance with the following:

- Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research http://www.mammalsociety.org/uploads/Sikes%20et%20al%202011.pdf
- *Guidelines for Use of Fishes in Field Research* http://www.nal.usda.gov/awic/pubs/Fishwelfare/ASIH.pdf
- Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research http://www.asih.org/files/hacc-final.pdf
- *Guidelines to the Use of Wild Birds in Research*http://www.nmnh.si.edu/BIRDNET/documents/guidlines/Guidelines/August2010.pdf
- Any other published guidelines that may be relevant to the protocol being reviewed

Article III. Four "R" Tenets

In keeping with these concerns, the SGU endorses the principles embodied in the "Three R" tenet of Russell and Burch (1959), and have added a fourth. These principles are:

- Refinement of experimental methods to eliminate or reduce animal pain and distress
- Reduction of the number of animals consistent with sound experimental design

- *Replacement* of animals with non-animal methods wherever feasible
- *Respect* for Animals

The use of animals in research, testing, and education is a privilege carrying with it unique professional, scientific, and moral obligations, and ethical responsibilities. The SGU encourages proper stewardship of all animals, but defends and promotes the use of animals in meaningful research, testing, and education programs.

The SGU condemns all acts of violence, vandalism, or intimidation directed toward individuals, facilities, or tertiary organizations affiliated with the use of animals in research, testing, or education.

Article IV. University Responsibilities

Section 1.

It is the responsibility of St. George's University to provide suitable orientation, appropriate materials, adequate resources, and training to enable research faculty and staff and IACUC members to carry out their respective duties consistent with the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy), and the *Animal Welfare Act* (*AWA*) and *Animal Welfare Regulations* (AWRs), regular updates are available from the *Animal Welfare Information Centre*.

Section 2.

Local institutional policies and procedures need to be a part of the training and education program. Frequently, researchers, and IACUC members find it confusing to understand the differences between the governmental policies (such as the Animal Welfare Act and the Animal Welfare Regulations as mentioned in article I and section 1) and requirements and institutional policies and procedures. The Institution is responsible for informing researchers and IACUC members of their responsibilities, providing training relative to their respective roles, and ensuring information to fulfill their duties is available.

Article V. Investigator Responsibilities

This Policy requires that all investigators (faculty members, staff members, graduate students, undergraduate students, or similar persons from other institutions) comply with both internal and United States of America governmental regulations regarding the care and use of animals in research and teaching, and the appropriate administration of protocol activities. Additionally, investigators have the responsibility of staying abreast of policies to remain within compliance. Failure to do so will result in the investigators losing their capability to perform as the individual responsible for the administration of the research protocol. The *IACUC Policy and Procedure Guidebook* provides information about these responsibilities.

Article VI. Institutional Official

The Institutional Official is appointed by the Chair of the Panel on Research and Scholarly Activities and is the administrative official responsible for the Animal Care and Use Program. The Institutional Official has appointed an Institutional Animal Care and Use Committee (IACUC) and alternates, whose members are responsible for oversight and evaluation of the animal care and use program, its procedures, and facilities to ensure that they are consistent with the recommendations of the Guide, AWA, ASPA, SGU Policy on Use and Care of Animals in Research, Education, and Testing, and the IACUC Principles and Procedures.

Article VII. Institutional Animal Care and Use Committee (IACUC)

The mission of the Institutional Animal Care and Use Committee (IACUC) is to oversee the provisions for the care and well-being of animals used for research, educational and testing purposes at St. George's University. The IACUC is also committed to serving the public by ensuring conformance to all legal and ethical standards regarding the use of animals in research. In addition, the IACUC is engaged in assisting animal research investigators with their animal-related needs.

Section 1. Basic Functions

The IACUC is composed of veterinarians, biological and nonbiological scientists, and local community representatives. The members are appointed to the committee, after recommendations by the committee chair, by the Institutional Official on behalf of the Panel on Research and Scholarly Activities.

The responsibilities of the IACUC include, but are not limited to the following list. The IACUC will:

- 1. Inspect all of the animal facilities, including animal study areas and satellite facilities at least once every six months.
- 2. Review the animal resource center's program for the utilization of animals in research and teaching at least once every six months.
- 3. Review and approve, require modifications to, or withhold approval to animal care and use protocols.
- 4. Review and investigate legitimate concerns involving the care and use of laboratory animals resulting from public, employee, or student complaints. Serious or continuing noncompliance will be reported to the appropriate University body.
- 5. Suspend an activity involving animals if noncompliance is verified; take corrective action and report noncompliance to funding agencies.
- 6. Ascertains that all protocols are in compliance with above mentioned legislation (article I) and that government approval is obtained (through the Research Oversight Committee).

Section 2. Composition

The IACUC consists of not less than six members, and includes a Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine who has direct or delegated program responsibility for activities involving animals at the institution, a practicing scientist experienced in research involving animals, a member who is not affiliated with the University other than as a member of the IACUC and is not a member of the immediate family of a person who is affiliated with University, and a member whose primary concerns are in a nonscientific area and who represent general community interests. IACUC membership includes at least one representative from the School of Medicine, the School of Arts and Sciences, and the School of Veterinary Medicine. IACUC membership includes a member who can provide the IACUC with an understanding of the nature and impact of proposed field investigations, the housing and care of the species to be studied, and the risks associated with maintaining wild vertebrates in captivity.

Article VIII. Centre for Animal Resources and Education (CARE)

The St. George's University Center for Animal Resources and Education (CARE) is a service and a resource to the SGU research and teaching community. CARE implements, and administers the Animal Care and Use Program, provides high quality animal care and veterinary services, and advises and educates researchers, staff and students on animal experimentation issues while promoting best practices for the responsible use of animals. These actions result in quality science merging with animal welfare. This office is headed by the Attending Veterinarian (AV).

Section 1. The Attending Veterinarian

The university has an attending veterinarian (AV), who must be qualified by virtue of appropriate postgraduate training and/or experience in laboratory animal science and medicine. The AV is a voting member of the IACUC. The AV has the authority to execute the duties inherent in assuring the adequacy of veterinary care and overseeing other aspects of animal care and use. The AV clinical veterinary care responsibility is delegated to clinical veterinarians and veterinary technologists who are part of the veterinary staff. Where there are concerns about animal welfare or imminent danger to animals or human health, if the clinical veterinarian is not available, or if agreement cannot be reached, the AV has authority to act to protect the health and well-being of institutional animals and will make the final decision regarding the disposition of the animal.

Section 2. Responsibilities of the Attending Veterinarian

- Ensure that the university's Animal Care and Use program meets at a minimum, the standards of care required by the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (2002) ("*PHS Policy*") and Animal Welfare Act and Regulations (AWAR).
- Participate in the planning and design of any construction or renovation involving animal facilities. Review and approve all final plans for animal housing and procedure spaces.
- Participate in the oversight of all renovations to and construction of animal housing and procedure spaces.
- Oversee all animal facilities.
- Keep supervisors and department chairs and/or program directors informed of problems or concerns relating to the management of animal facilities in their respective areas of responsibility.
- Participate in selecting and hiring staff for any nonacademic position whose responsibilities will include managing an animal facility.
- Serve as an ex-officio voting member of the IACUC.
- Responsible for the process to obtain accreditation for SGU's animal program through the Association for Assessment and Accreditation of Laboratory Animal Care International.

Section 3. New IACUC Members

New IACUC members are required to complete two web-based training modules (CITI) viewable at (https://www.citiprogram.org) entitled, "Essentials for IACUC Members" and "Working with the IACUC." New IACUC members are required to attend a formal session of orientation and training by the IACUC administrative staff regarding the functions of the IACUC, and the regulations, principles and procedures that govern the University's Animal Care and Use Program.

IACUC members or alternates that do not comply with training requirements are provided written notification from the IACUC Chairperson that training requirements must be completed within thirty days. Failure to comply after said written notification can result in dismissal from the IACUC by the Institutional Official.

Section 4. IACUC Members and Meetings

IACUC members and alternates are appointed by the Institutional Official. A specific one-to-one designation of IACUC members and alternates is made to ensure that the committee is properly constituted at all times. An alternate may not contribute to the formation of a quorum or vote unless the member for whom they substitute is not available. Alternates receive the same training and orientation as IACUC members, and are expected to "vote their conscience" as opposed to representing the position of the regular member. IACUC members must attend each regular monthly meeting or send their alternate. IACUC members must notify the IACUC administrative staff of planned absences prior to protocol review assignments. When both an IACUC member and their alternate are unable to attend a meeting after protocol review assignments have been made, the IACUC member must submit a *Primary Review of an IACUC Application* for each assigned protocol to the IACUC administrative staff prior to the monthly meeting. The Institutional Official can dismiss IACUC members and alternates absent from more than three regular monthly meetings in a calendar year.

Section 5. Application Submission to IACUC

- a. All live vertebrate and invertebrate animal use, including field studies, conducted by University or visiting faculty, students, staff, or others involved in research or teaching, or supported by University funds, must be described in a IACUC application form and submitted to the IACUC for full committee consideration by attaching an *electronic-version* of it to an e-mail addressed to the IACUC Administrator, prior to the initiation of that activity, regardless of where it will be performed.
- b. The research plan must address five primary points on the planned use of vertebrate and invertebrate animals. [Vertebrate animals, as covered by this policy, are defined as live, nonhuman vertebrate mammalian embryos or fetuses, tadpoles, bird and reptile eggs within three days (72 hours) of hatching, and all other nonhuman vertebrates (including fish) at hatching or birth].
- b. Lack of complete information will negatively affect the evaluation of the application and absence of the information will result in the application not being reviewed. Although no specific page limitation applies to this section of the application, please be succinct.
 - Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
 - Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
 - Provide information on the veterinary care of the animals involved.
 - Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
 - Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on

Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

- d. Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. Alternatives include the following "4 R's":
 - Replace vertebrate animals with invertebrates, lower life forms, tissue/cell cultures, or computer simulations
 - Reduce the number of animals without compromising statistical validity
 - Refine the experimental protocol to lessen pain or distress to the animals
 - Respect for Animals
- e. The Principle Investigator must seek Governmental approval (Research Oversight Committee) for projects involving animals not owned by the University. The necessary forms can be obtained from the St. George's University Office of Research.

Article IX. Occupational Health and Safety in Animal Care and Use Program

"An occupational health and safety program must be part of the overall animal care and use program" as stated in the Guide for the Care and Use of Laboratory Animals.

The Occupational Health and Safety in Animal Use and Care (OHSAUC) program is composed of several components, all of which are critical to maintain a safe environment for personnel working with or around (laboratory) animals. The program involves utilizing correct personal hygiene techniques; provision of protective clothing/equipment, and utilizing the services of the St. George's University Health Clinic Services.

Section 1. Identify Hazards

The IACUC holds monthly meetings to evaluate all Protocol Review and Amendment Forms submitted for IACUC approval to identify occupational health and safety concerns. Animal facility inspections are conducted by facility managers and IACUC members on a semiannual basis. IACUC reviews incident reports submitted by individuals working with animals.

Section 2. Risk Assessment Program

All personnel working with animals must participate in the SGU Animal Hazard program. The Occupational Health and Safety (OHS) Information Form must be completed by all faculty, staff, students, visiting scholars, contractors, and volunteers who have direct or indirect exposure to SGU research, testing, and training animals. This program is designed to prevent unnecessary occupational hazards in the work environment, including the potential risks which are incurred due to contact with laboratory animals. The University Health Clinic Services is located in Building Z. A copy of the signed OHS Information Form MUST be on file in the IACUC office. This is a mandatory requirement for all personnel submitting an application involving use of animals at St. George's University.

Article X. Euthanasia of Research Animals

Euthanasia is the act of inducing humane death in an animal by a method that induces rapid loss of consciousness and death with a minimum of pain, discomfort, or distress.

Euthanasia Policy

Animal welfare regulations require that the Institutional Animal Care and Use Committee (IACUC) approve the euthanasia method for research animals. The proposed method of euthanasia and the criteria used to assess pain and distress in animals must be described in detail in the IACUC form. Additionally, the protocol must include contact information for all members of the research group, so that Veterinary Services can always reach someone with authority to deal with sick or injured animals.

The Lead Researcher (Principal Investigator) is responsible for assuring the committee that each member of the study team is prepared and familiar with an established course of action in the event that an animal must be euthanized to alleviate pain or distress. At least one member of the study team must be available locally at all times to euthanize any animal exhibiting symptoms of pain or distress. These members should be defined in the original protocol. Lead Researchers are ultimately responsible for the euthanasia of all animals purchased or bred under their approved protocols.

The method by which death will be confirmed in euthanized animals must be described in the approved protocol. Since rodents can be particularly resistant to euthanasia by standard methods, IACUC policy requires that an approved secondary physical method of euthanasia be employed prior to carcass disposal in ALL rodent species.

NOTE: Unintended recovery of animals after apparent death from CO₂ or other euthanasia agents constitutes serious noncompliance. All incidents involving unintended recovery of euthanized animals are reported to the Office of Laboratory Animal Welfare at NIH.

IACUC is guided and will accept humane euthanasia in accordance with the American Veterinary Medical Association's (AVMA) recommendations on humane euthanasia methods (<u>AVMA Guidelines on Euthanasia</u>). Personnel must be adequately trained in performing the approved techniques and in confirming death.

Authorized by
Signature of the Chair of the Panel on Research and Scholarly Activities
This day of 2013

References

- 1. Guide for the Care and Use of Laboratory Animals, 8th Edition
- 2. 2007 AVMA guidelines on euthanasia
- 3. International Guiding Principles for Biomedical Research Involving Animals of the Council for International Organizations of Medical Sciences (CIOMS)

1. Regulatory Information

1.1. Governmental Regulations, Policies, and Guidelines

Animal Welfare Act

United States of America Animal Welfare Act

<u>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training</u>

http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

These principles were developed specifically for U.S. Government agencies to follow when conducting testing, research, or training procedures involving vertebrate animals.

Guide for the Care and Use of Laboratory Animals

http://www.nap.edu/openbook.php?record_id=5140

The Guide is used "to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. It also serves to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles."

Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research

Expanding on the "Guide for the Care and Use of Laboratory Animals," this publication provides current best practices for animal care and use and discusses how applicable regulations and guidelines can be applied to neuroscience and behavioral research. It encourages the use of professional judgment and careful interpretation of regulations and guidelines to develop performance standards that ensure animal well-being and high-quality research.

American Veterinary Medical Association (AVMA) Guidelines on Euthanasia (formerly the 2000 Report of the AVMA Panel on Euthanasia) [2013]

This document provides guidance on euthanasia methods and agents to ensure that animals are relieved from unnecessary pain and suffering.

1.2. Additional Reference Resources

<u>Applied Research Ethics National Association (ARENA) / Office of Laboratory Animal Welfare</u> (OLAW) Institutional Animal Care and Use Committee Guidebook

Laboratory Animal Management: Rodents (National Research Council)

Biosafety in Microbiological and Biomedical Laboratories

Guidelines for Research Involving Recombinant DNA Molecules

2. Office of Laboratory Animal Welfare (OLAW)

The Office of Laboratory Animal Welfare (OLAW) implements PHS Policy. While OLAW is located organizationally at the National Institutes of Health (NIH) in Bethesda, Maryland, OLAW's responsibility for laboratory animal welfare extends beyond NIH to all PHS-supported activities involving animals. From time to time, OLAW issues policy guidance, interpretation, or general

notices regarding PHS Policy, and cosponsors animal welfare workshops that are held in different locations across the country.

Specific OLAW responsibilities include:

- Implementation of the PHS Policy
- Interpretation of the PHS Policy
- Negotiation of Animal Welfare Assurances
- Evaluation of Compliance with the PHS Policy
- Education of institutions and investigators receiving PHS support

1.3. Animal Welfare Assurance

Before the PHS may award a grant or contract that involves the use of animals, the recipient institution and all performance sites involving or using animals must have on file with OLAW an approved Animal Welfare Assurance (Assurance). The Assurance is the cornerstone of a trust relationship between the institution and the PHS. Included in the Assurance are:

- Designation of the Institutional Official Responsible for Compliance
- Commitment That the Institution Will Comply With the PHS Policy, With the *Guide*, and With the AWA and the Animal Welfare Regulations
- Description of the Institution's Program for Animal Care and Use

The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the Public Health Service (PHS). PHS agencies include:

- Agency for Healthcare Research and Quality
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control and Prevention
- Food and Drug Administration
- Health Resources and Services Administration
- Indian Health Service
- National Institutes of Health
- Office of Public Health and Safety
- Office of the Secretary
- Program Support Center
- Substance Abuse and Mental Health Services Administration
- Office of the Assistant Secretary for Preparedness and Response

3. Research Facilities

In addition to providing the required standards of veterinary care and animal husbandry, regulated research facilities must provide dogs with the opportunity for exercise and promote the psychological well-being of primates used in laboratories. Researchers must also give regulated animals anesthesia or pain-relieving medication to minimize the pain or distress caused by research if the experiment allows. The AWA also forbids the unnecessary duplication of a specific experiment using regulated animals.

Research facilities must establish an Institutional Animal Care and Use Committee (IACUC) to oversee the use of animals in experiments. The IACUC is responsible for ensuring that the facility remains in compliance with the AWA and for providing documentation of all areas of compliance to the USDA/APHIS. The AWA also does not permit APHIS to interfere with research procedures or experimentation. To ensure that all licensed and registered facilities continue to comply with the AWA, APHIS inspectors make unannounced inspections at least once annually.

If an inspection reveals deficiencies in meeting the AWA standards and regulations, the inspector instructs the facility to correct the problems within a given time frame. If deficiencies remain uncorrected at the unannounced follow-up inspection, APHIS documents the facility's deficiencies and considers possible legal action.

APHIS also conducts reviews and investigates alleged violations. Some cases are resolved with Official Notices of Warning or agency stipulation letters, which set civil penalties for the infrac-

tions. Civil penalties include cease-and-desist orders, fines, and license suspensions or revocations. If APHIS officials determine that an alleged AWA violation warrants additional action, APHIS submits all evidence to the USDA for further legal review.

In addition to conducting regular inspections, APHIS will perform inspections in response to public input about the conditions of regulated facilities. Concerned individuals also are encouraged to inform APHIS about facilities that should be licensed or registered.