

Regulations, Policies, and Guidance

Regulatory Agencies and Regulations

Responsibilities for ensuring compliance with Animal Welfare regulations are shared among three federal entities: United States Department of Agriculture (USDA), Department of Health and Human Services (DHHS), and the Food and Drug Administration (FDA). Their respective responsibilities are described in a Memorandum of Understanding (2011).

- **United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)**

USDA APHIS is responsible for overseeing compliance with the Animal Welfare Act and Regulations which establish standards for the humane treatment of laboratory animals and registration/licensing procedures for institutions that breed, sell, transport, hold and use such animals. APHIS Veterinary medical officers or other suitably trained persons periodically inspect institutions for compliance. Serious incidents of noncompliance may result in civil penalties, "cease and desist orders," and confiscation of animals.

- **NIH's Office of Laboratory Animal Welfare (OLAW)**

OLAW implements the PHS Policy on Humane Care and Use of Laboratory Animals. The PHS policy implements the Health Research Extension Act of 1985 (Public Law 99-158) and is based on the U.S. Government Principles for the Utilization and Care of Vertebrate Animals in Testing, Research, and Training. Institutions receiving funding from PHS agencies must have an approved Animal Welfare Assurance on file with OLAW. The Assurance describes the institution's program for complying with the PHS policy. Potential sanctions for continued, uncorrected incidents of noncompliance can be found in the NIH Grants Policy Statement, Part II."

Currently, research performed at Lyon College does not involved warm-blooded animals and therefore the College is NOT require to follow the PHS Policy, but still uses it as guidelines.

- **Food and Drug Administration (FDA)**

The FDA enforces the Federal Food, Drug, and Cosmetic Act. 21 CFR 58, Good Laboratory Practice for Nonclinical Laboratory Studies, establishes standards for nonclinical studies involving the use of animals as follows:

- 58.43 Animal Care Facilities
- 58.45 Animal Supply Facilities
- 58.90 Animal Care

Compliance is assessed through an active program of periodic inspections carried out by trained inspectors. Serious incidents of noncompliance may result in consequences ranging from study rejection to laboratory disqualification.

The FDA also implements the Schedules of Controlled Substances.

Policies and Principles

- [Lyon College Animal Care and Use](#) - the policy of Lyon College regarding animal care and use. It applies to research, training, and teaching activities involving live, vertebrate animals conducted at the College, or by College faculty, staff, or students.
- [U. S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)
- [Guide for the Care and Use of Laboratory Animals, 8th ed.](#)
- [USDA Animal Care Policy Manual](#)
- [Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd Edition, 2010 \(FASS\)](#)
- *Field Studies: Currently only the animal types in bold are being used on campus. The other links are indicated for reference.*
 - For mammals: [Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research](#), American Society of Mammalogists, 2011
 - For birds: [Guidelines to the Use of Wild Birds in Research](#), The Ornithological Council, Washington, DC, 3rd ed., 2010
 - For **amphibians** and reptiles: [Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research](#). Joint publication of the American Society of Ichthyologists and Herpetologists, The Herpetologists' League, and Society for the Study of Amphibians and Reptiles. 2nd Ed., 2004.
 - For **fishes**: [Guidelines For the Use of Fishes in Research](#). Joint publication of the American Society of Ichthyologists and Herpetologists, American Fisheries Society, and American Institute of Fisheries Research Biologists. Fisheries, Vol. 13, No. 2, pp. 16-23, 1988
- [AVMA Guidelines for the Euthanasia of Animals: 2013 Edition](#)