

Institutional Oversight of Animal Research

Wake Forest University Health Sciences (WFUHS) and Wake Forest University (WFU) are committed to the ethical principles and regulatory requirements for the use of animals and have established the WFU Animal Care and Use program to provide University-wide oversight responsibilities regarding adequacy of facilities, animal husbandry, health care and appropriate use of animals in educational programs and research.

The Principles for Assuring that the Rights and Welfare of Subjects are Protected

For all activities using live vertebrate animals, regardless of sponsorship, WFU applies the ethical principles and regulatory requirements of the three main agencies who oversee the use of animals in research: (1) the United States Department of Agriculture (USDA); (2) the Office of Laboratory Animal Welfare (OLAW), and (3) the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

The USDA ensures that all regulations of the Animal Welfare Act are followed. The Institution is inspected at least yearly by the USDA. The USDA inspector has the authority to conduct random, unannounced visits to any part of the school to observe and discuss adherence to USDA regulation and internal animal care and use protocols.

The OLAW is a branch of the Department of Health and Human Services (DHHS) and is housed at the National Institutes of Health (NIH). The OLAW issues each institution receiving federal research funds a Public Health Service (PHS) assurance number. OLAW has the authority to inspect schools but rarely does so without cause.

While accreditation by the private organization, AAALAC, is voluntary, it is strongly encouraged by OLAW as evidence a regulatory compliance, which is required in order to continue receiving federal funding.

Definition of Animal Research

WFU applies the regulations set forth in The Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions (1985, revised 1986) and the Animal Welfare Act (1966) and defines animal research as all proposed activities using live vertebrate animals.

Assurances

WFU has filed a written Animal Welfare Assurance Statement of Compliance with the Office of Laboratory Animal Welfare (OLAW).

The assurance has been signed by an individual with the legal authority to represent the institution. This individual is referred to as the Institutional Official (IO). The IO establishes an institutional culture of respect for animal subjects; ensures effective institution-wide communication and guidance on animal research issues; ensures that investigators fulfill their responsibilities; facilitates participation in animal research education activities; serves as a knowledgeable point of contact for OLAW, USDA, FDA and other regulatory agencies; provides the ACUC with necessary resources; and supports the authority and decisions of the ACUC.

WFU maintains a registration of facilities as required by the USDA.

The WFU animal care and use program is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

Designation of an Institutional Animal Care and Use Committee

WFU has established an Animal Care and Use Committee (ACUC) that complies with the regulations set forth in The Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions (1985, revised 1986) and the Animal Welfare Act (1966).

Authority of the ACUC

The ACUC has University-wide oversight responsibilities regarding adequacy of facilities, animal husbandry, health care and appropriate use of animals in educational programs and research. The responsibilities of the ACUC include:

1. Review the institution's program for humane care and use of animals. Inspect, at least semi-annually, all of the institution's animal facilities, including satellite facilities
2. Review concerns involving the care and use of animals at the institution
3. Make written recommendations to the IO regarding the institution's animal program, facilities or personnel training
4. Review and approve, require modifications in (to secure approval), withhold approval or propose significant changes regarding the use of animals in ongoing activities.
5. The ACUC may suspend a previously approved activity if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide or the institution's Memorandum of Understanding. The ACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the ACUC and with the vote of a majority of the quorum. If the ACUC suspends an activity involving animals, the institutional official in consultation with the ACUC shall review the reasons for suspension, take appropriate corrective action and report that action with a full explanation to the Office for Protection from Research Risks, other NIH offices or other agencies as required.

The ACUC will maintain and make available operational policies and procedures. Operational policies and procedures for the WFU ACUC can be found on the Office of Research web page.

WFU ACUC Jurisdiction

The use of animals for research, education, and all other activities, which in part involve animals, regardless of sponsorship, must be reviewed and approved by the WFU ACUC.

Regardless of sponsorship, activities involving animals must be reviewed by the WFU ACUC when:

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14. Employees or agents of WFU, in connection with their institutional responsibilities, used animals for research or educational purposes;
15. The animal research is conducted by or under the direction of employees or agents of WFU in connection with their institutional responsibilities;
16. The animal research involves the use of any property or services of WFU for research purposes;
17. WFU receives a direct HHS award to conduct animal research, even where all activities involving animals are carried out by a subcontractor or collaborator (e.g., a small business receives a HHS award to design a medical device at its own facility and contract with a medical clinic to test the device with animals; a foundation receives a HHS award on behalf of an affiliated institution that will actually conduct the animal research);
18. The animal research is sponsored by WFU;

Employees include individuals employed by either Wake Forest University Health Science or Wake Forest University. Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility for either Wake Forest University Health Science or Wake Forest University. Agents include students enrolled at Wake Forest University School of Medicine or Wake Forest University performing activities in connection with their roles and responsibilities as students.