

Public Health Service (PHS) and U.S. Department of Agriculture (USDA) Requirements for IACUC Review and Approval

What Species are covered under Public Health Service (PHS) Policy?

PHS policy defines an *Animal* as: Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

Animal Facility means any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

The Public Health Service (PHS) through the National Institutes of Health (NIH)/Office of Laboratory Animal Welfare (OLAW) requires an IACUC at any institution that conducts PHS-supported activities involving any live vertebrate animals. The contract DePaul has with PHS, called an assurance, indicates that we agree to apply our policies and procedure pertaining to the IACUC to all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals. In doing so, we promise the institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals, the institution will be guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and the institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide). The same policies and procedures will be applied to these activities whether or not they receive external funding.

PHS Policy and Field Studies

PHS policy does not distinguish between field and laboratory studies and, therefore, requires IACUC review and approval of all field studies covered under the DePaul assurance.

Guidance from the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) indicates: IACUCs must know where field studies will be located, what procedures will be involved, and be sufficiently familiar with the nature of the habitat to assess the potential impact on the animal subjects. If the activity alters or influences the activities of the animal(s) that are being studied, the activity must be reviewed and approved by the IACUC (e.g., capture and release, banding). If the activity does not alter or influence the activity of the animal(s), IACUC review and approval is not required (observational, photographs, collection of feces).

In addition, recent changes to the *Guide for the Care and Use of Laboratory Animals, 8th edition* (the *Guide*) indicates that field investigations may involve the observation or use of non-domesticated vertebrate species under field conditions (*Guide*, p 32). The *Guide* requires that the institutional occupational health and safety program must identify potential hazards in the work environment and conduct a critical assessment of the associated risks, including risks associated

with unusual experimental conditions such as those encountered in field studies or wildlife research (*Guide*, p. 18). The Occupational health and safety program should address safety issues, including zoonosis, and provide the IACUC with assurances that the field study will not compromise the health and safety of either animals or persons in the field (the *Guide*, p. 32). These changes mean that even though a study may be purely observational or behavioral, it may require IACUC oversight. For this reason, DePaul policy requires IACUC review and approval for all field study activities.

What Species are covered under USDA Regulations?

The current USDA regulations define an *Animal* as: any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes (1) birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes;

Research facility means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States or the purpose of carrying out research, tests, or experiments.

Based upon the USDA definition of animal, most warm-blooded animals are covered species. The regulations currently exclude birds, rats (of the genus *Rattus*), and mice (of the genus *Mus*) which are bred for use in research. This would mean that birds not bred for research would be covered species. However, the USDA has not published specific regulatory standards for birds. Since the PHS policy covers all vertebrates, any activity with birds must be reviewed and approved by the IACUC.

The USDA is currently working on revised regulations that will provide specific regulatory standard for birds, mice, and rats not bred for research. Once the final regulations are published, the DePaul Office of Research Services will announce the regulatory changes to DePaul faculty, staff, and students.

USDA Regulations and Field Studies

The USDA defines **Field study** as any study done on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study. The USDA specifically exempts these studies from IACUC review and approval. However, a field study on free-living wild USDA-covered species

that involves invasive procedures, harms or materially alters the behavior of an animal under study is covered by USDA animal welfare regulations and requires IACUC review and approval.

Although the USDA regulations exempt some field studies from IACUC review and approval, the DePaul IACUC must comply with the PHS Policy and the terms of our assurance with OLAW, so DePaul policy requires IACUC review and approval for all field study activities.