



Activities Involving Vertebrate Animals Guidance Document

Purpose

The purpose of this document is to provide guidance on the federal regulations that govern research involving vertebrate. If proposing activities with vertebrate animals, all activities must comply with the Laboratory Animal Welfare Act of 1966 (7 U.S.C. § 2131 et seq and the final rules as implemented in 9 C.F.R. Parts 1, 2 and 3), and all other applicable statutes pertaining to the care, handling, and treatment of warm-blooded animals held for research, teaching, or other activities, including, if appropriate, the Good Laboratory Practice for Non-clinical Laboratory Studies (21 C.F.R. Part 58). In addition, the activities should be in compliance with the “U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.”

NIIMBL members who involve vertebrate in their research activities must seek appropriate approvals prior to initiating their projects.

Types

These regulations apply to projects involving live warm-blooded animals that are being cared for, euthanized, or used by NIIMBL members in the execution of the projects. Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, are excluded from these regulations.

These requirements do not apply to proposed research using preexisting images of animals or to research plans that do not include live animals. These regulations also do not apply to obtaining stock items from animal material suppliers (e.g., tissue banks), such as cell lines and tissue samples, or from commercial food processors, where the vertebrate animal was euthanized for food purposes and not for the purpose of sample collection.

Custom Collections Harvested from Live Vertebrate Animals: NIIMBL requires documentation for obtaining custom samples from live vertebrate animals from animal material suppliers and other organizations (i.e., universities, companies, and government laboratories, etc.). Custom samples includes samples from animal material suppliers, such as when a catalog item indicates that the researcher is to specify the characteristics of the live vertebrate animal to be used, or how a sample is to be collected from the live vertebrate animal.

Field Studies of Animals: Some field studies of animals may be exempt under the Animal Welfare Act from full review and approval by an animal care and use committee, as determined by each institution. Field study is defined as “...*a study conducted on free-living wild animals in their natural habitat.*” However, this term excludes any study that involves an invasive procedure or that harms or materially alters the behavior of an animal under study. Field studies, with or without invasive procedures, may also require obtaining appropriate federal or local government permits (e.g., marine mammals, endangered species etc.). If the applicant’s institution requires review and approval by an animal care and use committee, NIIMBL will require that documentation be provided.



Review and Approval of Vertebrate Animals Activities

NIIMBL members who involve vertebrate in their research activities at their organization must seek appropriate approvals prior to initiating their projects. The organization undertaking the research activities must have an Institutional Animal Care and Use Committee (IACUC) where the research activity is located. The IACUC must hold one or more of the following assurances:

1. Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) indicated by the OLAW assurance number, *i.e.*, A-1234
2. USDA Animal Welfare Act certification indicated by the certification number, *i.e.*, 12-R-3456
3. Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) indicated by providing the organization name accredited by AAALAC as listed in the AAALAC Directory of Accredited Organizations

If your organization does not have an assurance on file from one or more of these certifying bodies, please contact your NIIMBL Program Manager for more guidance.

All assurance documentation and documentation of the IACUC approval must be made available to NIIMBL and will be submitted to NIST for approval prior to the start of any work. Work cannot be initiated on any NIIMBL project that involves vertebrate animals without written authorization.