IACUC POLICIES, PROCEDURES, and GUIDELINES

Definition of Animal and Approved Animal Numbers

101.1 Purpose

This document establishes the Institutional Animal Care and Use Committee (IACUC) definition of animal as it relates to regulatory oversight and establishes policies related to the number of animals approved for use in research, education, and testing.

101.2 Responsibilities

The IACUC is responsible for the oversight of the University of Kentucky’s animal program, facilities, and procedures. Part of this responsibility includes the review and approval of all vertebrate animal activities involving research, education, and testing.

101.3 Background

The Animal Welfare Regulations (AWRs) (8), Public Health Service Policy (PHS Policy) (3), the Guide for the Care and Use of Laboratory Animals (ILAR Guide) (2), and the Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide) (7) all require that each institution establish a process for the management and oversight of animal care and use activities. A component of this oversight process is the review and approval of all “animal” activities including the appropriateness of the species used and the number of animals to be used. Depending upon the specific agency, however, the definition of what constitutes an “animal” and the “number of animals” changes.

For example, the AWRs define “animal” as any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research; horses not used for research purposes; and 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.” Additionally, the AWRs require that the IACUC review and approve “the approximate number of animals to be used.”

The PHS Policy, in contrast, defines "animal" much more broadly as "Any live, vertebrate animal used or intended for use in research, research training,
experimentation, or biological testing or for related purposes.” Also, the ILAR Guide and the Ag Guide both require the IACUC to review and approve “the number of animals proposed.”

101.4 Definition of Animal

The Institutional Animal Care and Use Committee has reviewed the multiple variations in the regulations and offers the following definitions and clarifications to be used in determination of which animals are under the oversight of the IACUC and require IACUC approval for use in research, education, and testing.

**Animal** – The term animal, for the purpose of IACUC oversight at the University of Kentucky, shall include all independent live vertebrate members of the Phylum Chordata, Class Vertebrata (all vertebrates) used in research, education, or testing. The determination of when a developing embryonic or neonatal animal is considered an independent live vertebrate is largely dependent upon the class of the animal. Neonatal mammals are considered animals for the purpose of IACUC oversight from the time of live birth, avians when they reach 85% of their required incubation (e.g. 18 days for chickens, 15 days for Japanese quail, 24 days for ducks and turkeys, etc.), and from the time of hatching for reptiles, amphibians, and fish. Any use of an animal in research, education, or testing at the University of Kentucky requires IACUC review and approval.

As part of responsible care and use of animals in research, the National Institutes of Health/Office of Laboratory Animal Welfare (NIH/OLAW) has stated an expectation that the number of animals used in support of research be tracked, including those produced in excess of the number or type needed. This means that animals euthanized before weaning must also be counted and subtracted from approved animal numbers in the IACUC protocol.

**Covered Species (Regulated Species)** – Covered or Regulated species are those species specifically included under the Animal Welfare Regulations (definition above). Covered species are a subset of animals for which the IACUC is responsible for oversight. This term excludes birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research (those not bred for use in research are not excluded) and farm animals.

**Farm Animal** – includes any domestic species of cattle, sheep, swine, goats, llamas, horses, rabbits, mink, chinchilla, etc. which are normally and have historically been kept and raised on farms in the United States and used solely as work and pack animals or used or intended for use as food or fiber, or for improving animal nutrition, breeding management, or production efficiency. This definition includes (6):
• Farm animals used to manufacture or test veterinary biological products intended for use in the diagnosis, treatment, or prevention of diseases in agricultural animals.
• Farm animals used in agricultural teaching, such as farm or ranch management procedures (e.g., hoof trimming, shearing), handling practices and breeding techniques.
• Farm animal exhibits intended to advance the agricultural arts and sciences.
• Agricultural animals in livestock shows, fairs, FFA or 4-H venues, or rodeos.
• Incidental exhibition of farm animals, such as public access (viewing) of a working bison farm, where people driving by can see the animals. They are not being kept for the intent of exhibition, nor are they advertised for viewing purposes.
• Historic farm parks that are accurate representations of the farm setting and are intended to educate the public as to that way of life.

**Regulated Agricultural Animal** – Agricultural species not specifically used solely as work and pack animals or used or intended for use as food or fiber, or for improving animal nutrition, breeding management, or production efficiency are regulated by the AWRs. Examples of regulated agricultural animal use include:

• Agricultural animals used to manufacture or test biologics for nonagricultural or nonproduction animals, or humans. This includes biologics that are produced or tested for possible use in either agricultural or nonagricultural species, such as multispecies rabies vaccines.
• Agricultural animals that are used as models for human subjects or nonagricultural animals (e.g., using calves to develop an artificial heart for humans). Public health service funding nearly always indicates a biomedical use that is regulated.
• Agricultural animals used for biomedical teaching; that is, the training of human or veterinary medical personnel in medical methods and procedures, such as surgery, diagnostic techniques, anesthesia and analgesia.

**101. 5 Animal Numbers**

As a component of the animal use protocol review and approval process, the IACUC is tasked with reviewing and approving the number of animals used in the proposed research, education, or testing proposal. Principle III of the *U.S. Government Principles of the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (1) states that “the animals selected for a
procedure should be of an appropriate species and quality and the minimum number required to obtain valid results."

The AWRs require that a proposal to conduct an animal activity contain an “identification of the species and the approximate number of animals to be used” in addition to a “rationale for the appropriateness of the species and numbers of animals to be used.” Both the Ag Guide and the ILAR Guide require that the approved animal use protocol contain a “justification for the species and number of animals proposed” with the caveat that the numbers should be statistically justified whenever possible.
While not explicitly stated, the requirements of the AWRs, PHS Policy, ILAR Guide, and Ag Guide “implicitly require that institutions establish mechanisms to monitor and document the number of animals acquired and used in approved activities.” (5) Fortunately, the IACUC is permitted some latitude in establishing what is considered a significant change from what has been approved by the IACUC in the protocol as long as the decision is compliant with “the PHS Policy requirement that the number of animals used be limited to the appropriate number necessary to obtain valid results.” (4)

The IACUC also realizes that commercial animal suppliers (rodents, amphibians, fish, etc.) frequently ship animals additional to those ordered in anticipation of potential health issues related to the shipment. Investigators frequently wish to use these animals in their animal activity rather than have the animals euthanized or transferred to other protocols. These additional animals, if used by the investigator, must be accounted and tracked as animal use on the protocol in spite of the fact that they were not intentionally ordered by the investigator.

The IACUC has determined that in animal use protocols using rodents (mice, rats, hamsters, and gerbils), guinea pigs, chinchillas, quail, chickens, frogs, axolotls, and fish animal use up to 110% of the number approved by the IACUC is within the acceptable range of the approximate number approved by the IACUC. For all other animals, the actual number approved by the IACUC is considered the maximum approved number. Animal use exceeding the maximum approved number is considered the performance of an activity not approved by the IACUC and is a violation of the approved animal use protocol and reportable to the Office of Laboratory Animal Welfare.

The number of animals to be used must be appropriately justified. Further, the number of animals used must be the minimum required to meet the objectives of the work. In this regard, experiments should not unnecessarily duplicate previous work. Investigators should recognize that replicates of experiments are a form of duplication. In contrast, the overall calculation of animal numbers should be appropriately powered, such that the group sizes are likely to detect a statistically significant difference in the variable of interest.

References:


Approved and Adopted by the Institutional Animal Care and Use Committee
September 21, 2011

Approved and Adopted by the Institutional Animal Care and Use Committee
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Approved and Adopted by the Institutional Animal Care and Use Committee
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