PACUC Policy on

Extralabel Treatment of Experimental Food Animals

PACUC will follow the recommendations from the Food Animal Residue Avoidance Databank (FARAD):

• A researcher (like a practitioner) may administer to a food animal any drug, or any other substance that produces a measurable physiologic change in the animal, that he or she can legally obtain and administer under the Animal Medicinal Drug Use Clarification Act (AMDUCA) and subsequently market the animals. This includes pain relievers, anesthetics, antibiotics, etc. Both practitioners and researchers administering extralabel treatment to food animals to be marketed must prescribe an extended withdrawal time based on adequate scientific data. If adequate scientific data does not exist, then the researcher/practitioner must insure that the treated animal does not enter the human food chain.

• AMDUCA does not allow practitioners or researchers to use extralabel drug administration for production purposes (oxytocin for milk production, hormones to regulate reproductive cycles).

• A researcher can give an unapproved, experimental drug to food animals that DO NOT enter the food chain. Researchers doing so are obligated to fulfill record-keeping requirements outlined under 21 CFR 511.1(a).*

• A researcher can give an unapproved experimental drug, or any other substance that produces a measurable physiologic change in the animal, to and market food animals ONLY if he or she has obtained an Investigational New Animal Drug (INAD) permit (with slaughter authorization) through the Food and Drug Administration's Center for Veterinary Medicine.

• None of these federal obligations address requirements that an individual research institution might have, such as protocol review by an Animal Care and Use Committee

*21 CFR 511.1(a) is from the Federal Food, Drug, and Cosmetic Act.