and housed at the university, however, then AAALAC International would look at them⁴. The clients maintain ownership of the dogs who participate in Archer's study, and the Great Eastern College of Veterinary Medicine does not at any point possess ownership of the animals. These dogs are treated as client-owned animals. The USDA monitors only those animals owned by licensed dealers and exhibitors or registered research facilities. Because the dogs are privately owned and housed, they are not covered by the USDA regulation³.

Over the years, the Great Eastern College of Veterinary Medicine has decided to refer these types of studies to the CRC for approval. A client consent form is signed to help address issues of liability and public relations. Consent forms are not required but are recommended⁵. Archer has approval from the CRC to conduct her study. Archer has received funding for her study from the National Institutes of Health, confirming that an IACUC-approved protocol is not needed for this study. The National Institutes of Health requires documentation of IACUC approval for studies involving animals in research². In conclusion, I believe Archer is following the appropriate channels for approval of her study.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Animal Welfare Act and Animal Welfare Regulations.
4. AAALAC International. *Contracts, Collaborations and Co-Ownership: Roles and Responsibilities of the Institution* (2005). <https://www.aaalac.org/resources/Contracts_Collaborations_Co-Ownership.ppt>
5. Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 2nd edn. (CRC Press, Boca Raton, FL, 2007).

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RESPONSE

Don't rock the boat!

Kari Koszdin, MS, DVM DACLAM

Archer does not need IACUC approval for this study, because she is harvesting the mast cell tumors that she is studying in the course of providing clinical care for patients. Because she does not collect any extra tissue or samples from the animals whose owners consent to the use of the tumor tissue, she is not doing any research on the dogs; rather, she is using only the tissues she collects from them in her research. According to the Public Health Service, the use of parts of animals for research purposes is not a regulated activity, unless animals are killed for the purpose of obtaining the tissues or project-specific antemortem manipulations are done on the animals¹. Even though the Animal Welfare Act defines an animal as "any live or dead dog"², it does not specifically address the issue of research carried out on animal tissues. Additionally, the USDA does not regulate veterinary care for dogs in a private-practice setting.

Her client is correct that a medical school's Institutional Review Board would be required to review this study. According to the Office for Human Research Protections³, the study would be exempt from review by the Institutional Review Board only if the samples had been collected before the initiation of the research and if the information about the subjects was recorded such that there was no possible way to link the tissue sample to the patient. Archer's research seems to comply with the second part of this requirement but clearly does not comply with the first part. However, her study does not involve any human research subjects, and one must only peruse the sections of the Code of Federal Regulations that pertain to the protection of human research subjects to realize that the regulations governing research on human subjects are quite different than those governing research on animals.

In the end, it is strictly Great Eastern University's decision whether or not to require IACUC review for this study. There are a few good reasons that an institution may decide to require IACUC review for studies using tissues collected from dead animals or in a clinical setting. Tissues from wild animals, nonhuman primates and unconditioned pets may contain zoonotic pathogens, and so the institution must have some mechanism in place to address potential occupational health and safety issues that may arise in research that utilizes animal tissues. The IACUC review process is often a good means to address these types of issues, as the veterinarian on the committee has the expertise needed to evaluate them. Tissue studies may involve collection of tissues from sources that could lead to public relations problems for the institution's animal research program, and so the institution must have some oversight for these studies. Finally, the IACUC review process would ensure that the study parameters are clearly defined and that the investigator understands exactly which animal activities are approved (and which are not approved) in advance of the study. If the institution can assure that all of these issues can be addressed by its CRC, then IACUC review would be redundant, as it is not required by any regulations. If no CRC exists at an institution that conducts research on animal tissues collected from dead animals or in a clinical setting, then IACUC review would be a good idea.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Animal Welfare Act and Animal Welfare Regulations. 9 CFR.
3. Public Welfare (Title 45) and Protection of Human Subjects (Title 46). CFR. Department of Health and Human Services. 2005. <<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>>

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