Have a heart, think before you stop research

The question raised by this scenario is whether Dr. Martinelli's research with heart tissue collected from privately owned dogs is subject to IACUC oversight or the licensing requirements of the Animal Welfare Act¹. And if subject to these requirements, should the IACUC prevent Martinelli from obtaining tissue until an approved IACUC protocol and/or evidence of proper licensing is established?

A WORD FROM USDA

Under the Animal Welfare Act regulations (AWA), the definition of an animal includes any live or dead dog being used or intended to be used in research, teaching, testing, experimentation, or as a pet¹. In addition, the regulatory definition for a dealer includes any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of any dog whether alive or dead (including organs, limbs, blood, serum, or other parts) for research, teaching, testing, experimentation, exhibition, or use as a pet².

In this scenario, an investigator had an arrangement with a local not-for-profit shelter and the institution's veterinary school to obtain canine hearts at no charge from animals that either died or were euthanized there. The protocol was not under Institutional Animal Care and Use Committee (IACUC) oversight because no live animals were used. The veterinary school and the shelter decided to charge for harvesting the hearts to recoup costs and as a result, the IACUC felt it necessary to oversee the study to ensure compliance with the regulatory requirements for storage/disposal of animal parts, and not allow any further work to be performed until the shelter and the veterinary school obtained a USDA license as dealers.

The harvesting of organs by the veterinary school and charging the lab for this service is not an AWA covered activity because animals were not euthanized for research purposes and animal death was unrelated to experimentation. As a result, a dealer's license is not required. In regards to the shelter, the scenario does not provide any specifics other than it is not-for-profit. Government (city, state) owned or operated pounds and shelters are excluded/exempt from the definition of a dealer and

therefore do not require a license. Entities with questions about licensing can use the Licensing and Registration Assistant, a tool available online to help determine whether an activity requires a license or registration. The tool can be accessed at <https://efile.aphis.usda.gov/LRAssistant/s/>. Policy 20 on the sale of dead animals is no longer available for guidance because it was inactivated and removed from the website in 2018.

The AWA defines a Dealer as one who, "in commerce, for compensation

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There is no requirement under the AWA regulations for a research facility to obtain dead animals or parts (limbs, organs, blood, tissues, etc.) from a licensed dealer. Other regulatory requirements (State, Federal) or Institutional policies may apply depending on the species and material obtained.

Institutions registered with the USDA are required to meet the regulatory requirements for storage and disposal of dead animals and parts³. There is no regulatory requirement for IACUC oversight of this study because no live animals are being obtained or used; however, the IACUC has the regulatory authority to determine the best means to conduct program and facility evaluations and as a result⁴, it can require a written protocol to ensure storage and disposal are in compliance with the AWA regulations. □

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References

1. Title 9 Chapter 1 Subchapter A § 1.1-Animal
2. Title 9 Chapter 1 Subchapter A § 1.1-Dealer
3. Title 9 Chapter 1 Subchapter A § 3.1 (f)
4. Title 9 Chapter 1 Subchapter A § 2.31 (c)(3)

or profit" buys or sells "any dog or other animal, whether alive or dead for research," including their parts, unless exempted. If the university already has a Dealer's license (as many registered facilities do) then the veterinary school may already be covered. This can be determined by looking up the institution's status on the USDA website³. If there is a license in place, but the veterinary school is not covered, this can be corrected by making an administrative update to the locations covered by the license.

The "Licensing and Registration Guidelines" published by the USDA³ explain the agency's interpretation of the regulations in regard to various types of businesses. If the shelter's status is unclear, this can be addressed by asking Martinelli for an explanation if the shelter isn't listed on the USDA website.

This brings us to the question of whether the IACUC has oversight of Martinelli's research, and if so, can the IACUC prevent him from obtaining the tissues needed for his research.

There is no regulatory basis for the IACUC to require that Martinelli have an IACUC protocol for tissues obtained from client-owned animals if they are treated as routine patients⁴. The IACUC's oversight of regulatory compliance regarding semiannual program and facility review is broad, so the IACUC does evaluate supporting processes that apply to Martinelli's research, such as licensing, biohazardous waste disposal, or memorandums of understanding. But the IACUC does not have the authority to determine the correction to a deficiency⁵. Therefore, it would be beyond the IACUC's authority to prevent Martinelli from continuing with his research. Great Eastern University may have other mechanisms in place to ensure compliance, such as requiring a Material Transfer Agreement (MTA) for the receipt of biological materials and a biohazardous waste management plan.

We support the IACUC for re-evaluating the compliance requirements when the research experienced a change (in this scenario, regarding funding). But we think the IACUC has a responsibility to confirm the regulatory requirements and follow-up with Martinelli to ask for more information before taking the extreme and unsupported action of putting his research on hold. □

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