

of the activity are required to be reviewed by or overseen by the IACUC, and (3) if there are related topics that the institution may want to consider.

The PHS Policy and the Animal Welfare Act and Regulations (AWARs) do not distinguish between animals owned by the institution and privately owned animals. Privately owned animals used in research supported by the PHS must be covered under an IACUC-approved protocol². An important distinction between conventional biomedical research projects and research involving pets is the presence of a veterinarian-client-patient relationship (VCPR). In the context of a valid VCPR, standard veterinary care of a privately owned

animal is not a research activity and does not require IACUC approval or compliance with the PHS Policy or AWAR^{3,4}. As part of the VCPR, if the animal undergoes procedures that are medically justified and are the standard of care, even if the results are used for research purposes (e.g., limb amputation), those procedures are not subject to oversight³. Dr. McCrae has confirmed that the limb amputation procedure is the standard of care for this disease; therefore, that surgical procedure is not subject to IACUC oversight and should not be included in the review. Conversely, the experimental drug, E-2400, is not the standard of care; therefore, details about this drug should be reviewed by the IACUC.

It would be prudent for the institution to review the informed consent received from clients enrolling their pets in a clinical study. Legal counsel or the risk management group would likely be involved with this documentation, perhaps even public affairs and communication. Though not part of this scenario, if Dr. McCrae decides to include referral practices to increase the patient population in this PHS-supported study, these practices must be listed as performance sites in the GEU's Animal Welfare Assurance².

It should be noted that in a biomedical research setting, it is standard for an IACUC to ask for an appropriate description of a major survival surgery (or any procedure). Considering Dr. McCrae has a long-standing record of being a good citizen, when she objected the reviewers should have consulted with subject matter experts (e.g. IACUC office staff) whether they were overstepping their authority. The GEU IACUC may consider being [re-]trained on the limits of IACUC oversight of clinical studies. Dr. McCrae would surely oblige. □

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A WORD FROM OLAW

In response to the issues posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) provides the following clarifications:

In this scenario, a PI proposes to test a drug to treat osteosarcoma in canines in an NIH-funded study. The study proposal describes in detail all aspects of the experiment that will be conducted after amputation of the affected limb. However, it does not describe the amputation procedure. When asked to include the amputation procedure during administrative pre-review by the IACUC office, the investigator declines, replying that this request exceeds IACUC authority, as the standard of care SOP will be followed. The scenario asks, “How should the IACUC handle the situation?” However, the key question is whether the amputation procedure must be included in the protocol.

The IACUC is responsible for the welfare of each animal in the research study.¹ Amputation is an integral part of the study and the IACUC must have all the information on procedures to be performed on the animal to evaluate animal welfare. Additionally, it would

be necessary to know which anesthetics, analgesics, and fluids were used as well as physiological parameters assessed during surgery, if unexpected complications occur during the research study.

The PI may provide details of the amputation procedure within the protocol or may simply reference the veterinary school SOP for details of the procedure. As described by reviewers, this “helps reduce regulatory burden for investigators, while providing the IACUC the necessary details of the procedures performed.” The IACUC may review and accept the established written standard of veterinary care for the surgery and incorporate it in the protocol. □

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Complete details for a complete review

The IACUC did not exceed its authority, and is within reason to request additional information from the PI to complete a thorough protocol review as mandated by both PHS Policy¹ and Animal Welfare Act and Regulations². These federal regulations do not differentiate between institution- and client-owned animals, and

because the work described in the scenario is PHS-funded research, the institution must maintain an OLAW-approved Animal Welfare Assurance covering all performance sites.

As written, the scenario indicates that the ‘proposed plan was for the dog’s affected limb to be totally amputated’, indicating that the surgery is clearly being

conducted for the purpose of the research, therefore it cannot be solely considered veterinary clinical care of a privately owned animal. If amputation is included in the pre-treatment regimen for the effective use of the study drugs, then the procedure should be described in the protocol for IACUC review.