RESPONSE

Pet-assisted therapy

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At first review of this scenario, our impression was that it did not require IACUC approval. The scenario describes the use of privately owned pets for research on human subjects in a hospital setting. One must remember that the research subject of this study is the human patient—not the patient's pet dog. The pilot investigation does not include any animal research, teaching or testing, and neither institution (academic or hospital) has ownership of the animals. In addition, this study is not currently supported by funding from the Public Health Service (PHS). The scenario did not indicate whether any of the entities involved are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International.

Ownership and funding as related to the need for animal program oversight is addressed by AAALAC International (http://www.aaalac.org/accreditation/faq_landing.cfm#A1) and by PHS guidance[1]: "The PHS Policy covers live vertebrate animals used or intended for use in research, research training, and biological testing activities conducted or supported by the PHS. The PHS Policy and the Animal Welfare Act and Regulations (AWAR) do not distinguish between animals owned by the institution and privately owned animals. Pets used in research must be covered under an IACUC-approved protocol. The institution must have an OLAW-approved Animal Welfare Assurance covering all performance sites. The institution should ensure that the informed consent of the owner is obtained prior to the conduct of the research. The institution may want to involve their legal counsel in the development of informed consent documents."

Whether the proposed activities as described are covered may hinge on the Letter of Assurance for the institutions involved in this scenario. Some institutions have broad letters of assurance and state that all animal activity at that institution is covered. Therefore, IACUC involvement may be warranted[2,3]. Furthermore, if the goal of the study is to generate pilot data that may be used for PHS-funded projects in the future, as suggested in the scenario, then IACUC review might be necessary. If future studies involve institutionally owned animals, then oversight is absolutely required.

If IACUC protocol oversight is warranted, then which entity has ultimate authority? Our suggestion is that the site at which

A word from USDA and OLAW

In response to the questions posed in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) and the Office of Laboratory Animal Welfare (OLAW) offer the following guidance:

This scenario involves a study in which human surgical patients are allowed post-operative visits with their pets. Blood samples are collected from the patients before and after the visits to evaluate whether interactions with their pets reduce cortisol levels. This activity is not regulated by the Animal Welfare Act (AWA) because the pets are not the subjects and are not undergoing any manipulation for research or experimentation. Under §2143(a)(3)(A) of the AWA, the research facility is required to ensure that pain and distress are minimized during animal care, treatment and practices in experimental procedures[1]. Pets spending time with their owners is not an experimental procedure; therefore, regulating this type of activity was not the intent of the AWA, and the activity does not require IACUC approval. It is, however, recommended that the IACUC be kept apprised of all activities involving animals to ascertain whether they are under the purview of the AWA.

The Public Health Service (PHS) requires that the standards of the PHS *Policy on Humane Care and Use of Laboratory Animals* (*Policy*) be applied to research, testing and training funded by the PHS[2]. Although the animal activity described in the scenario is privately funded, it is being conducted as a part of a human-subjects study within the institutional research program, which presumably does receive PHS funds. Oversight of such activities by the IACUC ensures a uniform and consistent standard within the program and facilitates quality research[3]. If medical students are being trained through observation of an animal activity, IACUC oversight is also necessary.

Additionally, IACUC oversight may not only ensure animal and human safety but also limit liability to the institution should a patient's pet be injured accidentally or cause harm to other patients, visitors or staff members. Use of a consent agreement developed with legal counsel is a prudent practice[4]. The agreement should include an explanation of the purpose and the procedures involved in the study, the potential benefits and risks to the animals and the responsibilities and rights of the owner and the institution[5].

In this scenario, the faculty member is affiliated with both the hospital and the university. Such dual appointments are quite common at many medical research facilities. If the hospital does not have its own IACUC, then the university's IACUC would be the default oversight body and a formal written understanding between the institutions should be in place[6,7].

1. Animal Welfare Act as Amended (7 USC 2143).
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. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions.* Applicability of the PHS Policy, Question No. A1. (US Department of Health and Human Services, Washington, DC, 2006; revised 2013).
4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions.* Applicability of the PHS Policy, Question No. A7. (US Department of Health and Human Services, Washington, DC, 2006; revised 2013).
5. Brown, P. & Gipson, C. A word from OLAW and USDA. *Lab Anim. (NY)* **38**, 186 (2009).
6. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions.* Protocol Review, Question No. D8. (US Department of Health and Human Services, Washington, DC, 2006; revised 2013).
7. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

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