

Jerald Silverman, DVM, Column Coordinator

Using privately owned animals in a study of human subjects

Julie Schnepps, a private-practice veterinarian in California, was interested in the human–animal bond, and an opportunity was emerging for her to further that interest. One of Schnepps’s clients, Dr. Lucas Roman, was a reconstructive surgeon on a sabbatical leave from Great Eastern University. He suggested to her that it might be of importance to determine if pet-assisted therapy could lower the level of anxiety that many of his teenage patients experienced after undergoing surgery for traumatic facial injuries. Schnepps jumped at the chance but didn’t know how or where to begin, so she recruited the help of Dr. Maria Torres, her friend and a laboratory animal veterinarian at Riverbank University, a nearby research university. Schnepps and Torres decided that measuring blood cortisol levels in adolescent patients that did or did not have pet dogs would provide the initial data they needed. As a favor to Torres, Riverbank’s clinical laboratory

agreed to carry out the cortisol analyses at a minimal cost, which Schnepps would pay using funds from her private practice. Torres did not think that IACUC approval was necessary for the study.

Roman was a faculty member at the Great Eastern University medical school, and his surgical practice was at the Great Eastern Hospital. The hospital and the university were legally separate entities, although medical school students used the hospital for part of their training. Roman received approval for the study from the hospital’s Human Research Subjects Committee (analogous to an IACUC) and its Infection Control Committee. Once his patients were postoperatively stable, healing well, yet still hospitalized, they would be brought to a special visiting room where they would be allowed a short, controlled interaction with their pet dog. Blood samples would be collected from the patients before and after the dog visits, and then, after their

discharge from the hospital, a blood sample would be collected every time they returned for a postsurgical visit.

The primary interest of Schnepps and Roman was patient stress, as reflected in cortisol levels. They hoped to demonstrate that the teenage patients who had dogs had significantly lower cortisol levels than those without dogs. Given the many variables present, this was meant to be a pilot study that might (or might not) provide a justification for moving forward with more involved research on pet-assisted therapy.

Because the dogs are such a critical part of the study, is IACUC approval needed? If so, which IACUC should review the protocol: Riverbank University’s or Great Eastern University’s? Roman is a faculty member at Great Eastern University’s medical school; as part of their training, medical school students might observe the planned patient–animal interaction on video monitors. Does this fact affect the need for IACUC approval?

RESPONSE

Patient–pet interactions

Barbara C. Hansen, PhD

The described scenario has several aspects. The first is the desire of a private veterinarian to measure cortisol levels in blood samples from pet owners and from people who don’t own pets. Though well-intentioned, this notion does not constitute a valid research study of stress levels in adolescent patients who have or do not have pets. There is no need for any IACUC review of this aspect.

The second aspect is the sampling of blood in adolescents before and after a short visit by their own pets in a special room in the hospital and during their

postoperative recovery period. Approval of this study by the university’s human use committee implies that all concerns related to the inclusion of humans in the study, such as infection risk, dander risk and room sanitation, were addressed to the committee’s satisfaction. In my opinion, this aspect of the scenario also does not constitute a well-designed research study of human stress (or even a well-designed pilot study), but if it satisfied the human use committee, then so be it. There is no need for IACUC review of this aspect.

The third aspect is the recording of patient interactions with their own pets (assumedly with the patients’ knowledge and consent) and the possibility that medical students might view the video. In my opinion, this does not require IACUC approval for multiple reasons. The patients

and their parents or legal guardians have presumably agreed to participate in the study with full knowledge of the patient–pet meeting conditions (including the video). There is no animal welfare issue of any sort involved in the scenario provided. There is no research done on the animals, nor will any conclusions regarding the animals be derived. Given the information provided, there is no abuse or risk to the pets themselves beyond normal human–pet interactions. The study is on patients’ responses to their own pets.

I see no reason for any IACUC involvement here. If there were an IACUC issue here, however, the only IACUC implicated is the one at Great Eastern University.

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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 guidance¹: “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

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 procedures¹. 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 PHS². 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 research³. 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 practice⁴. 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 institution⁵.

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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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

the activities involving animals occur should take precedence. In accordance with PHS guidelines on collaborations⁴, a memorandum of understanding or a service agreement should be used to clarify regulatory oversight and study and grant funding management responsibilities among the collaborating entities.

A confounding factor is Roman's sabbatical leave. Whether faculty members who are on leave are able to represent the institution and oversee research involving humans or animals is typically governed by institutional policy. Some institutions do not allow faculty members who are on sabbatical leave to be the responsible party for such research.

An additional confounding factor is the inclusion of medical student training as a potential option. We feel that this option would be considered animal use in medical training. Therefore, if this aspect is pursued, we feel that it requires IACUC protocol review, review of occupational health and understanding of the applicable regulations, regardless of who owns the animals.

Finally, we feel that the dogs that participate in this study should complete programs for certification as hospital therapy dogs before this study goes forward. It was prudent that the hospital's human subjects and infection control committees reviewed and approved this activity, but we believe that there may be other committees that should be consulted for approval as warranted by the institution's policies. These include the hospital's risk management office, board of directors, legal counsel and environmental health and safety office. We also suggest that the investigators confer with the institutional veterinarian and review the hospital health clearance guidelines used by national pet-assisted therapy organizations (e.g., <https://www.avma.org/KB/Policies/Pages/Guidelines-for-Animal-Assisted-Activity-Animal-Assisted-Therapy-and-Resident-Animal-Programs.aspx>).

1. 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).
2. Public Health Service. *Sample Animal Welfare Assurance for Domestic Institutions* (US Department of Health and Human Services, Washington, DC, 2012).
3. Public Health Service. *Obtaining an Assurance* (US Department of Health and Human Services, Washington, DC, 2012).

4. 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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RESPONSE

Better safe than sorry

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The dogs in this scenario would be involved in a human subjects research project. The only costs are those related to blood cortisol testing, which will be covered by private funding; therefore, the provisions of the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*¹ need not apply. If strict interpretations of the Animal Welfare Act (AWA) definitions² of 'animal' and 'research facility' are used, however, then IACUC approval of this project may be necessary. The AWA defines an animal as "any... warm-blooded animal... used for research." Great Eastern Hospital meets the AWA definition of a research facility in that it is using dogs as a study component and presumably receives some federal funding for the conduct of its institutional research program. In addition, the US Department of Agriculture holds research institutions accountable for review and approval of proposed activities related to the care and use of animals and delegates the authority for oversight of animal care to the IACUC³. Although the activities described seem to be innocuous, the animals are an integral part of the study, for without the dogs, there would be no patient data to collect. Even though the dogs are not experiencing pain or distress under the study conditions, they are being subjected to novel, potentially stressful activities outside their normal routine, under the auspices of Great Eastern Hospital. Injury or escape of an animal could draw negative publicity, and the lack of animal use committee oversight could further damage public perception of the Hospital and, by association, the University. For these reasons, we believe that having an animal use protocol is the best

course of action for protecting Great Eastern Hospital and the University against research risks associated with the use of animals in the conduct of the study.

If an animal use protocol is necessary, then which institution should hold the protocol and provide oversight of the animal-based portion of the work: Riverbank University, Great Eastern Hospital or Great Eastern University? In our opinion, Riverbank University has no oversight responsibility; its only role is the provision of laboratory analysis on a fee-for-service basis. If Great Eastern Hospital has its own animal care program, then Roman, as principal investigator, should submit the protocol through the hospital's IACUC; this would be the simplest solution given that this is the site of the patient-pet interactions. If the hospital doesn't have an animal research program (as seems likely), however, then Roman should submit a protocol through Great Eastern University's IACUC, in which the room where patient-pet interactions occur is designated as an off-site location. Because the hospital and university are legally separate entities, the shared responsibility for animal oversight should be clarified via a memorandum of understanding (MOU). Specific details that should be delineated in the MOU include on-site responsibility for care and handling of the dogs, assignment of responsibility for occupational health, veterinary care and requirements for site visits by the University's IACUC and other regulatory or accrediting agencies. Great Eastern's IACUC should also determine whether the activities at the hospital will be considered separate from its PHS-supported activities and should state this exception in its Assurance⁴.

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 as amended (7 USC 2132).
3. Animal Welfare Regulations (9 CFR, Part 2, Subpart C, 2.31).
4. 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).

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