

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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