

should ensure the animal's general health status.

Whereas the Americans with Disabilities Act requires that service animals have access to public facilities, it specifically states that such a facility has no responsibility to supervise or care for the animal². Depending on the length of time the animals will be spending at the facility, provisions should be made to provide access to drinking water and an appropriate site for urination and defecation.

This study clearly does not need its protocol to be reviewed and approved by the IRB and the IACUC. There are certain issues that need to be addressed by one or the other committee. Consultation and oversight by the veterinarian may be all that is needed to ensure the safety of both species included in this project.

References

1. Institute of Laboratory Animal Resources, National Research Council. *Guide for the Care and Use of Laboratory Animals*, (National Academy Press, Washington, DC, 1996).
2. Americans with Disabilities Act (ADA); Title III, 28 Code of Federal Regulations (CFR) Part 36, Nondiscrimination on the basis of disability by public accommodations and in commercial facilities; Section 36.302(c), Modifications in policies and procedure, Washington, DC, 1994.

Fyke is University Veterinarian, University of Mississippi, University, MS.

IACUC Review Needed

Stephen I. Levin, DVM and Kathryn M. Wiklanski, MPA

Although this situation may seem laughable to an IRB, the primary issue of concern is whether animals used in research, although not the objects of the research, are subject to regulations that would require a protocol review by an IACUC. Because Gershowitz's study is funded by the National Institute of Mental Health, one needs to consult both the Animal Welfare Act (AWA) and Public Health Service (PHS) *Policy* for the answer to this

question.

The AWA defines animals as "any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes¹", whereas PHS *Policy* states that an animal is "any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes²". Clearly, dogs used in research are covered by the AWA and PHS *Policy*. Although neither document specifically addresses the use of dogs in research when they are not the objects of the research, broad interpretation of the AWA and PHS *Policy* definitions suggests that an IACUC review and approval of this protocol is necessary.

A secondary issue that arises in this scenario is whether Great Eastern's IACUC can review the protocol given that the research is being performed at the unaffiliated Great Eastern University Hospital. Because Gershowitz is the awardee of the grant and a faculty member of Great Eastern University, the protocol should be reviewed by Great Eastern University's IACUC. Furthermore, both OLAW and APHIS have determined that a duplicate protocol review by the hospital's IACUC would not be necessary³. In the event that the hospital is not a registered research facility, Great Eastern University would need to designate the art therapy room of the hospital as part of its animal facility and assume the responsibility of inspecting the room, either semi-annually or as deemed necessary by the IACUC.

Although this all may seem excessive to a member of an IRB, the reality is that institutions that are registered with APHIS as research facilities and have a PHS Assurance on file are responsible for all institutionally sanctioned activities involving animals.

References

1. Code of Federal Regulations, Title 9, Subchapter A—Animal Welfare, Parts 1–3.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* III.A

(US Department of Health and Human Services, Washington, DC, 1986).

3. National Institutes of Health. Office of Extramural Research guidance regarding administrative IACUC issues and efforts to reduce regulatory burden. NOTICE: NOT-OD-01-017 (12 February 2001).

Levin is Postdoctoral Research Fellow, Unit for Laboratory Animal Medicine, and Wiklanski is Coordinator of Research Animal Standards and Staff Development, University of Michigan, Ann Arbor, MI.

More Info Needed

Erin Hutteman, LVT, RLATG and E. Jean Defendorf

We agree with Stark's position that the use of dogs as therapy models would not require IACUC review and approval. The dog's presence would be as a 'working' guide dog rather than a 'research subject'.

The use of guide dogs as art therapy models could generate conflicting views from the Great Eastern University's IACUC. On the one hand, the use of a species regulated by the USDA through the AWA is occurring in conjunction with research conducted using federal funds. The AWA clearly defines terms such as animal, research facility, and handling. On the other hand, the dog is privately owned and does not come under the umbrella of the PHS *Policy*, which includes all activities involving use of animals in research, testing, and teaching.

Adequate assessment of the need for an IACUC protocol requires the consideration of two key elements. First, we do not know if Great Eastern's PHS Assurance excludes non-PHS-funded activities. Second, one should examine state laws pertaining to allowing animals in a hospital setting. Gershowitz should check the regulations of the county or state and the hospital's policy about the presence of animals in that facility.

Hutteman is Research & Training Coordinator and Defendorf is UCAR Administrator, University Committee on Animal Resources, University of Rochester, Rochester, NY.