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Dogs as Sculpture Models: Is IACUC Review Needed?

There are times when a complicated problem arises from what seems to be a simple issue. This is what happened to the Institutional Review Board (IRB) at Great Eastern University. (The IRB is roughly the equivalent of the IACUC for research using human subjects.)

Dr. Sandra Gershowitz planned to study the effect of a novel art therapy on clinically depressed persons who also had a significant visual disability. The crux of the concept was to use the person's guide dog as a tactile sculpture model. Gershowitz, a faculty member of the University, was highly respected in the field. She planned to conduct the study in the art therapy room of Great Eastern University Hospital. The hospital was a separate corporation from the University although they were in adjoining buildings. The study was funded by the National Institute of Mental Health.

No significant issues arose at the IRB meeting, except that Dr. Sherry Smith, who was also an IACUC member, suggested that IACUC approval would also be required because of the guide dog. Her comment elicited a chorus of laughs and disbelieving stares from other IRB members, almost none of whom had ever had any interaction with an IACUC. They could not believe that an approval of any kind was needed for a dog that was specifically trained to help a human being and was to do nothing more than sit still and be gently touched while being a model for an art therapy project. The dog was not to be evaluated in any way whatsoever. Furthermore, they said, this therapy was to occur at a hospital that had no formal affiliation with Great Eastern University and its IACUC. Dr. James Stark, who did have some IACUC experience, likened the use of the guide dogs to a study in which snakes were the object of the research, and live neonatal mice were fed to the snakes. He said, "no

IACUC would ever require a protocol and approval for the use of neonatal mice as feed, and the analogy holds true in this study. The dogs are not the object of the study ... the people are the objects. The dogs are totally and completely of no concern."

Was Smith or Stark right in their assertions? Must an IACUC have to approve the use of the guide dogs in Gershowitz's study?

IACUC-IRB Cooperation Needed

Harry Fyke, DVM

This question seems to evoke one of those 'gray zone' cases that compliance boards often encounter. Whether or not it should require IACUC approval may not be as important as ensuring that steps are taken to assure the health and welfare of both the animals and humans involved.

If Great Eastern University has an NIH/OLAW Assurance, the IRB should

consult it, because some institutions require approval by the IACUC for all uses of vertebrate animals.

That the research is to take place at an off-site facility is certainly not as important as the fact that this is a PHS-supported project that receives funding through the University. This makes it subject to the oversight of the University. The bottom line here is that this is an NIH-funded research project that involves a USDA-covered species¹.

The IACUC in collaboration with the IRB, should decide whether the oversight is handled by the IRB or requires IACUC involvement. The discussion may be limited to the respective Chairs and the Attending Veterinarian.

There are certainly occupational health and safety issues that need to be addressed. Service animals are generally screened for health problems, including disposition, while they are being trained, but there are no requirements for the maintenance of their health by private owners. Therefore the potential exists for them to harbor and transmit diseases and/or parasites to other animals, as well as humans. A veterinarian

A Word From OLAW

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) offers the following clarification and guidance:

This month's scenario describes unusual animal use in a nontraditional research setting. The National Institute of Mental Health is a component of the National Institutes of Health (NIH), a Public Health Service (PHS) agency. As was stated by some of the reviewers this is, by definition, a PHS-supported activity involving live vertebrate animals; therefore, as a condition of funding, the awardee institution and all performance sites must be covered under one or more Assurances on file with OLAW and verification of IACUC approval must be submitted prior to award. The IACUC review criteria and oversight requirements should be specially tailored to address those practical issues (e.g., health and welfare of animals and humans involved) already raised in the responses above.

The scenario also mentions, as a proposed analogy for consideration of the issues involved in the dog study, the practice of feeding live mice to snakes. It should be noted that in situations where the PHS Policy is applicable, the feeding of live vertebrate animals to other animals is also subject to IACUC oversight either as a part of the protocol review process or as a covered component of the institutional program of animal care and use.

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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.

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IACUC Review Needed

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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).

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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.

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