

You know what happens when you assume...

A certain level of trust and understanding is required for an IACUC to support the use of animals in research while simultaneously

guarding animal welfare. Part of that trust includes when researchers are asked about their experience or the experience of their collaborators with a particular animal model.

In this instance, Schwartz may have answered the questions of the IACUC application truthfully but in a way that damaged the trust that the IACUC placed in him. His answers fulfilled the letter of the law but violated the spirit of the application questions.

With that in mind, the IACUC should not stand blameless, as they possessed prior knowledge of his lack of rodent cardiac experience. After all, *The Guide for the Care and Use of Laboratory Animals* states “The IACUC, together with the AV, is responsible for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures...”²¹. The committee’s knowledge of Schwartz’s apparent dearth of rodent surgical expertise should have prompted questions/concerns prior to the protocol ever being approved. In this case, the committee’s assumption may have inadvertently led to a waste of animal life.

While the outcome thus far in the scenario has been less than optimal, the potential for a teachable moment still exists for both the IACUC and Schwartz. First, Schwartz can be instructed by the IACUC that when unanticipated problems arise during a surgical procedure, he should stop and seek the opinion and guidance of other individuals with expertise. The death of 2-3 animals should’ve been enough to indicate he needed to consult with a veterinarian on the surgical technique. Reporting these types of problems (even once resolved) would build and strengthen trust among researchers, veterinarians, and the IACUC. It also serves to document and thus prevent similar problems from recurring in the future. Documentation of the problem and its resolution could be captured in a verbal report (for example, in the meeting minutes) to the IACUC or through an unanticipated problem report form provided to Schwartz. This report should include why Schwartz now feels that he can perform this procedure without any problems. It would be helpful to know from where Dr. Schwartz has gained this new found confidence when he has presumably not been performing this procedure since the time that the veterinarian asked him to halt his surgeries.

The IACUC should take steps to ensure that this type of mistake does not happen in the future. While the purpose of the question about experience in the IACUC application was designed to help determine Schwartz’s ability to successfully perform the cardiac procedure, it was not specific enough to do that. The IACUC might

A WORD FROM OLAW AND APHIS

In response to the issues posed in this scenario, the National Institutes of Health-Office of Laboratory Animal Welfare (NIH-OLAW) and the U.S. Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS) provides the following clarifications:

In this scenario, a surgeon skilled with cardiac procedures in humans, dogs, and swine is approved by the Institutional Animal Care and Use Committee (IACUC) to conduct similar procedures in mice. Without confirming his competency with the species, high mortality results. The IACUC must decide a course of action to remedy the issue and prevent further occurrences.

NIH-OLAW response

The first step to determine the cause of the mortalities is for the IACUC to thoroughly investigate how the surgeries were conducted. Complications resulting from the length of the surgeries and technique of the inexperienced surgeon may have contributed to the deaths, i.e., hypothermia, tissue dehydration, blood loss. Additionally, reviewing necropsy results and the anesthetic regimen may provide insight into the cause.

A further step toward correction is for the IACUC to modify the protocol form to ensure that a researcher’s experience with procedures are specific to the species proposed. The U.S. Government Principles¹, Health Research Extension Act of 1985² and the PHS Policy³ refer to appropriately trained personnel and required instruction and training by the institution⁴. The Guide requires institutions to ensure that research staff members performing experimental manipulation, including anesthesia and surgery, are qualified to accomplish such procedures humanely and in a scientifically acceptable fashion⁴.

The IACUC should require hands-on surgical training for the surgeon and monitor their competency. The IACUC should focus additional training for all researchers that emphasizes institutional expectations to minimize pain, distress, and (in this case) unnecessary mortality.

Training should also emphasize that when procedures do not go as expected the veterinary staff should be contacted promptly. Continuing IACUC oversight of animal activities through effective post approval monitoring is critical^{2,5}.

USDA-APHIS response

The Animal Welfare Act (AWA) excludes from the definition of animal, mice of the genus *Mus* that were bred for use in research⁶. As a result, the AWA regulations cannot be applied to the mice in this scenario. In light of this, the USDA defers to OLAW or any agency with the appropriate regulatory authority, in accordance with the requirement under the AWA to consult and cooperate with other Federal agencies concerned about the welfare of animals in research⁷. □

Patricia Brown^{1*} and Betty Goldentyer²

¹Director, Office of Laboratory Animal Welfare, OER, OD, NIH, HHS, Bethesda, USA.

²Acting Deputy Administrator, Animal Care, APHIS, USDA, Washington, USA.

*e-mail: brownp@od.nih.gov

Published online: 23 October 2019

<https://doi.org/10.1038/s41684-019-0422-7>

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- 7 U.S.C. Section 2132(g)
- 7 U.S.C. Section 2145(a)