

is technically not required by regulations to be included on the animal use protocol. But we see many benefits of adding Bryant to the protocol and no good reason not to do so.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
2. Animal Welfare Act Regulations. 9 CFR. Chapter 1, Part 2, Subpart C.

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**RESPONSE**

**Not in the protocol, not approved**

Austin Fritsch, BS, RLATG

As inter-institutional research collaborations become more common, this situation might arise more frequently in research protocols. In this case, there is an established collaborative relationship between Chambers and Bryant that was not represented in the protocol submitted to the IACUC. Chambers submitted a protocol for his work but did not add Bryant to the protocol under the assumption that Bryant would not be working with live animals. Though this may be true, Bryant will be collecting tissue for electron microscopy from animals that are being euthanized for experimental purposes. According to the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*, prior IACUC review and approval is required when an animal is specifically euthanized for the purpose of obtaining tissue<sup>1</sup>.

The veterinarian's concern is appropriate and might have identified a mishap before it turned into a noncompliance matter. In order for this research to proceed, Chambers should submit a modification for his protocol to the IACUC that includes the procedures carried out by Bryant and lists Bryant

on the protocol. It is the task of the IACUC to review all aspects of the proposed use of animals to fully comprehend the research and the contribution the rats will make<sup>2</sup>.

Most IACUCs and vivaria have policies that govern facility access; most of the time, access is granted to individuals listed on active protocols. Access control ensures the safety and security of the research animals and staff. In order for Bryant to have access to the necropsy room for tissue collection and experimentation, a protocol modification will need to be submitted and approved by the Great Eastern IACUC. With Bryant added, and all appropriate training completed, there would be no reason for access to be withheld.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions*. Question No. A.3. Does the PHS Policy apply to the use of animal tissue or materials obtained from dead animals? (US Department of Health and Human Services, Washington, DC, 2006, revised 2015).
2. Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 3rd edn. (CRC Press, Boca Raton, FL, 2014).

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**RESPONSE**

**Safety is the main concern**

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The veterinarian is right to be concerned. When entering the animal facility to collect tissues, Bryant will be exposed to possible health risks, including rodent allergens and toxic or uncharacterized chemicals. Any institution using animals in research is obligated to inform and protect animal users from research-related risks in compliance with federal, state and local regulations<sup>1</sup>. Although the IACUC oversees all aspects of research animal care and use, protection of researcher health and safety is typically the responsibility of an occupational health

and safety (OHS) department. This department usually requires all personnel working in the facilities or vivaria to complete, at minimum, a health questionnaire for clearance prior to beginning work.

Although we can relate to the veterinarian's concern about a person who is not listed on the IACUC protocol entering the animal facility, the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* overseen by the NIH Office for Laboratory Animal Welfare applies only to activities involving live vertebrate animals. Therefore, collection of tissues from dead animals in the research setting might not require formal IACUC approval. But it is within the purview of the Great Eastern University IACUC to require Chambers to add Bryant to the protocol with a description of his role, limiting it to the collection of animal tissues *post mortem*. In addition to OHS clearance, the Great Eastern University IACUC might require Bryant to receive training on vivarium entry requirements, biosecurity and use of specific areas such as necropsy rooms. Bryant should complete any required training before being allowed to enter the facility. We also recommend Bryant's access be limited to the designated areas in which he will be working and that he be escorted at all times.

Although there is no legal mandate for the IACUC to review the use of tissues from dead animals, review of this kind of research at the institutional level is considered best practice<sup>1</sup> in order to provide assurance that the institution has applied the appropriate standards to the acquisition, use and disposal of the animal tissues. Standardized review of this kind of research also serves the best interests of the institution for a variety of other regulatory and non-regulatory reasons (e.g., biosafety, liability and occupational health and safety).

1. Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 3rd edn. (CRC Press, Boca Raton, FL, 2014).

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