

**RESPONSE**

**The buck stops where?**

**Patricia N. Coan, DVM, PhD, DACLAM & William A. Hill, DVM**

Schope was rightfully perturbed that the IACUC changed policies midstream, but changes routinely occur in biomedical studies. For this reason, protocol and program reviews are required to revisit, update, and refine procedures and policies.

Was Schope correct that there is no applicable regulatory guidance? No. The AWRs define PI as an employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving

animals<sup>1</sup>. Additionally, the Public Health Service (PHS) defines PI as the individual(s) designated by the applicant organization to direct the project or program. According to the PHS, the PI is responsible and accountable for the proper conduct of the project or program and must have the authority and responsibility for leading and directing the project, intellectually and logistically<sup>2</sup>.

If Schope became more involved with the studies, as a PI should, the work could continue. Alternately, Schope and an individual from the company could serve as co-PIs. In such an arrangement, Schope would be responsible and accountable for the study but could assign some of the specifics to her counterpart.

As the PI of record, Schope must become more involved in the studies. Additionally, collaborations could be explored. If neither option is acceptable, there may be a faculty member at Great Eastern that would agree to serve as PI on the projects. The studies could continue provided that the new PI was closely involved in the protocol. If there is no interest from the faculty, then the studies must be stopped and the start-up companies forced to find another way to perform their experiments. In this event, Great Eastern should, at a minimum, allow any ongoing studies on animals currently housed at the institution to be completed so as to not waste animal resources or cause future unnecessary duplication of the research.

1. 9 CFR, Chapter 1, Subchapter A—Animal Welfare.
2. US Department of Health and Human Services Public Health Service. Application for a Public Health Service Grant. [http://grants.nih.gov/grants/funding/phs398/instructions2/p3\\_definitions.htm](http://grants.nih.gov/grants/funding/phs398/instructions2/p3_definitions.htm).

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Organisation for Economic Co-operation and Development’s Principles of Good Laboratory Practice state that the PI is responsible for ensuring “that the delegated phases of the study are conducted in accordance with the applicable Principles of Good Laboratory Practice<sup>1</sup>.” The AWRs define the PI as “an employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals<sup>2</sup>,” and go on to summarize the PI’s responsibilities as (1) to “submit proposed activities and significant changes to activities to the [IACUC] for approval” and (2) to “provide acceptable written justification to the IACUC for areas of noncompliance with the [AWA]<sup>3</sup>.” These guidelines would indicate that the PI should be involved in monitoring the conduct of his/her studies at a level that goes beyond veterinary oversight.

By listing herself as the PI, Schope has taken on all regulatory responsibility for any studies being run by her ‘tenants.’ Schope can and will be held fully accountable for any cases of noncompliance under these studies, including of course non-compliance with the Animal Welfare Act. Without understanding exactly what Great Eastern’s IACUC Chair means by “intimately involved,” it appears that Schope is reluctant to have anything more than a cursory involvement in the research being conducted by her tenants. Schope should rethink her stance, consider assigning someone more involved as PI (probably requiring some modifications to the contracts), or consider terminating the contracts entirely.

It would likely behoove Great Eastern to provide an official (internal) document that clearly defines the role of a PI.

**RESPONSE**

**Increase PI involvement**

**Jem Scott-Emuakpor, DVM**

It is true that there is no clear regulatory guidance on this matter; however, the

1. Organisation for Economic Co-operation and Development. Principles of Good Laboratory Practice. <http://www.oecd.org/env/qlp>.
2. 9 CFR, Chapter 1, Subchapter A—Animal Welfare.
3. Crawford, R.L. Animal Welfare Act Interpretive Summaries. <http://www.nal.usda.gov/awic/legislat/awabrief.htm>.

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