

RESPONSE

A bridge too far

Scott Gamble, DVM

Aminit's discomfort with the protocol is justified. No protocol, however loosely written, can cover all of the potential animal use concerns that could present themselves in a university setting. The examples provided in this scenario include new surgical procedures, new anesthetic regimens, and a change in species; most institutions would consider all of these to be major changes.

I can imagine the IACUC deliberations, all intended to provide more expedient service to the research staff, that somehow create a distinction among 'real' research, 'pilot studies', and a third category that the Committee created for feasibility studies. I believe that is the point at which the IACUC made their critical mistake. The approach adopted in the training and feasibility protocol does not conform to current standards of protocol review. The Animal Welfare Act Regulations (AWARs) and PHS *Policy* do not mention differing categories of review requirements. In fact, they require the same review process for new and ongoing activities^{1,2}.

In the examples given, the AV is acting as the Principal Investigator (PI) and *de facto* Designated Reviewer. Also, there is no opportunity for other IACUC members to review changes to the study before the use of the animals. Using the AV as a PI is probably a bad idea, unless another qualified veterinarian is available to provide consultation during protocol development, to avoid conflict of interest. Appointing the AV to discharge all of the duties of the PI and IACUC, with a

report of animal use after the fact, is simply beyond any reasonable interpretation of the regulations.

Both the AWARs and PHS *Policy* require that the IACUC review and approve proposed significant modifications to ongoing activities using animals before initiation³. As a member of the Great Eastern IACUC, I would want assurance that the study of frog anesthetics was not a duplication of research and that the rat was a suitable substitute for the dog, given the objective of the original protocol.

The IACUC might salvage some of their hard work by narrowing the focus of the protocol. A training protocol that approves using animals for procedures described in university standard operating procedures leaves no open-ended questions and creates a training system that can be responsive to short-notice requests for training. I am sure that there are other situations beyond the current discussion that can be addressed using a similar approach. The IACUC obviously is searching for a means to respond quickly to research staff needs. They could consider adding more members to the Designated Reviewer pool to reduce the workload on each individual, and make the review process flow as quickly as possible.

1. 9 CFR 2.31 (d) (2).
2. Public Health Service. *Public Health Service Policy on Humane Care and Use of Laboratory Animals* IV.C.2 (US Department of Health and Human Services, Washington, DC, 1986).
3. Gaertner, D.J. & Moody, K.D. in *The IACUC Handbook* (eds. Silverman, J., Suckow, M.A. & Murthy, S.) 10.2 (CRC Press, Boca Raton, FL, 2000).

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