

Jerald Silverman, DVM, Column Coordinator

# Protocol amendment for an unrelated study

It always riled Sara Martin when an investigator amended a protocol to add another study that had no solid relationship to the existing one. Yet, as second-in-command of the Great Eastern University IACUC office, she was not able to overrule the IACUC director or the IACUC Chair. Both the director and the Chair believed that an amendment could be placed in almost any protocol for any reason as long as it was properly reviewed by the IACUC. Martin was as adamant as she dared to be, saying that any animal use activity that constituted a significant change to an existing protocol should be submitted as a new protocol.

An amendment request from Dr. John Baker caused Martin to bring her argument, once again, to the IACUC director and IACUC Chair. Baker, an orthopedic surgeon,

used New Zealand White rabbits for his research. As part of his approved study, he euthanized the rabbits while they were under terminal anesthesia. A colleague asked him if he would consider amending his protocol so that she could use the same rabbits, while still under anesthesia, to practice a totally unrelated terminal procedure. Baker agreed, as the unrelated procedure would neither impact his data nor increase the animal's pain or distress and it made good sense to obtain as much use as possible from any one animal.

Martin had no objection to gaining more data from the same animal prior to euthanasia, but she strongly objected to Baker submitting an amendment to his protocol for a totally unrelated study. This was, in her opinion, a significant change to an existing protocol that required a new

protocol submission from Baker's colleague. She said that the new protocol should include a statement that the anesthetized rabbits would be transferred from Baker's protocol to the new protocol. The IACUC would then have a substantial amount of detail in the new protocol to decide whether the proposed second use of the rabbits was justified, whether the surgeon was skilled at working with rabbits, whether the anesthetic was appropriate for the new procedure and so forth. In contrast, Martin's boss and the IACUC Chair considered it far easier to have the new surgeon added to Baker's protocol, along with a brief description of the work to be done.

Would you agree with Martin or with the IACUC director? Are there other ways to resolve this disagreement?

## RESPONSE

### IACUC should vote

**Mario C. Rodriguez, DVM, MS,  
RaShae Cook, MS, LATG, CMAR &  
Chanda B. Hill, BS**

An extremely important piece of information is missing from this scenario: who funds Baker's project? If it is federally funded, the addition of the proposed surgery could change the approved scope of the project, which would require prior approval by the NIH Grants Management Officer (GMO). The GMO's disapproval overrules any IACUC opinion. Not all significant changes constitute changes in scope, however<sup>1,2</sup>.

Both Martin and the IACUC director are partially mistaken. Baker's amendment should be reviewed by a duly constituted IACUC to determine whether it meets institutional and regulatory requirements and whether the changes require a new

protocol submission. The outcome of the IACUC's vote represents a fair decision of a majority of the committee that takes into account the opinions of both the IACUC Chair and Martin. Problem solved. If desired, dissenting members can submit a minority opinion following the IACUC vote.

On the other hand, the IACUC Chair's decision to approve a surgical procedure on the basis of a "brief description of the work to be done" is inappropriate. A well-written amendment includes sufficient justification and a detailed description of any new procedure. For this purpose, a separate surgical or procedural attachment is used by many institutions. Such attachments require detailed descriptions of surgical procedures, including the identity of each surgeon and his or her related experience. This information should satisfy Martin's well-intended need for details and might convince her that an amendment will suffice.

- NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).
- National Institutes of Health. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions*. IACUC Composition, Functions and Authority, Question No. B.13. (US Department of Health and Human Services, Washington, DC, 2006, revised 2014).

*Rodriguez is Attending Veterinarian and Cook is Project Manager at SoBran, Inc., Norfolk, VA, and Hill is Manager of Research Compliance at Eastern Virginia Medical School, Norfolk, VA.*

## RESPONSE

### Submit a new proposal

**Jennifer M. Mitchell, VMD &  
Lemnique N. Wafer, DVM**

In this scenario, the proposed change to Baker's protocol would be considered significant by NIH standards, namely because it not only changes the objectives of the original study but also might increase

1. National Institutes of Health. Guidance on significant changes to animal activities. Notice