

for some justification for the assertion that a certain number of replications is required to publish in this field. This justification could be provided by citing a major publication or two in the relevant area or an editorial statement.

My bottom line is that the replications are probably appropriate, and good science, but the IACUC would still be well advised to ask for some support of this methodology, rather than taking a researcher's word for it.

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### RESPONSE

## Replication should be independent

**Kathleen Parton, BS, MS, DVM**

Knight's approval should be withheld unless he is able to provide an editorial policy stating that repeated studies are required for publication. Although certain journals may indeed require repetition for publication, the information given here is not enough to justify the use of additional animals in these circumstances. Because the biostatistician is satisfied with the proposed research, it would be unnecessary for the committee to approve repetition. When a committee considers a research proposal, it should measure the work against the 3Rs to see if replacement, reduction or refinement has been implemented. A well-planned and well-executed study with an appropriate number of animals as determined by a power analysis should give journal editors and reviewers, as well as Knight, confidence in the results.

The number of animals necessary to attain a high level of confidence (power) can be calculated if the standard deviation, expected effect and error are known. Knight seems to have provided satisfactory proof of such to the IACUC. Using more animals increases power up to a point, but surpassing the required number of animals is a waste of resources and time.

Knight's argument that he must repeat his studies twice to show that the results are reproducible is a mistake that might be made by many researchers who are not

confident about statistics. A lack of understanding or a distrust of statistical methodology may negatively influence research design. Although Knight may object to the biostatistician's confidence in the size of his study groups and questioning of his need for repetition, he should understand that the biostatistician is better qualified to advise him on the appropriate design of the study. Proof that his work is repeatable should be undertaken independently. The purpose of publication is to promulgate the methods and results to the scientific community, allowing other researchers to independently replicate the results, which adds to the validity of the findings.

*Parton is Senior Lecturer at the Institute of Veterinary, Animal & Biomedical Sciences, Massey University, New Zealand.*

### RESPONSE

## A question of power or an abuse of power?

**James B. Turpen, PhD**

Knight is correct in his justification of the need to repeat his experiments. In the absence of other concerns, the IACUC should approve his protocol as submitted.

As Knight suggested, a cornerstone of scientific research is the concept of reproducibility. In order for data to become knowledge, the scientific community must show that the data are reproducible. This includes reproducibility by the investigator prior to submission of a manuscript and reproducibility by independent confirmation of the experiments and the data by other laboratories. Reproducibility is one of the key aspects of scientific reviews of merit, both at the level of publication and the level of grant review, and a key aspect of consensus-building in every discipline. It is not about editorial policy from specific journals in the field.

This scenario does have animal welfare implications related to the 3Rs. Based on the power analysis, the IACUC may reduce the number of animals that were requested. If the IACUC does reduce the requested number of animals, however, and the subsequent experiments as conducted are not of publishable quality in the investigator's discipline, the approved number of animals will have been wasted and valuable time will have been lost because of an inflexible statistical argument. Good science is essential for animal welfare.

The Code of Federal Regulations<sup>1</sup> specifically indicates that "[e]xcept as specifically authorized by law or these regulations, nothing in this part shall

### A word from USDA

*In response to the issues raised in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offers the following clarification and guidance:*

While the US Congress recognizes that the use of animals is instrumental in biomedical research, it also requires that researchers ensure minimum standards of care and treatment for these animals. If this scenario involved animals covered under the Animal Welfare Act regulations, the IACUC would be required to review the appropriateness of the numbers of animals to be used, and, in addition, 9 CFR Section 2.31 (d)(1)(iii) would require the Principal Investigator to provide written assurance to the IACUC that the animal research activities do not "unnecessarily duplicate previous experiments." This requirement helps to ensure that procedures involving animals will avoid or minimize discomfort, distress and pain to the animals, with the understanding that deliberate duplication of research can be deemed necessary if approved by the Committee. The IACUC must be satisfied that a good faith effort was made by the investigator in determining that a proposed experiment is not unnecessarily duplicative. The level of detail needed to provide this assurance is left to the discretion of the IACUC.

**Chester Gipson, DVM**

*Deputy Administrator  
USDA, APHIS, AC*