

A word from OLAW

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) offers the following guidance:

This column poses several questions: Should the IACUC consider the cost of using a particular species in its discussion of a protocol? Should the rationale for the development of a new model be based on fiscal factors? Is having a second model for a particular disease or condition a sufficient rationale?

Although financial considerations are a necessary step in the pursuit of a scientific inquiry, decisions involving costs of research are made by bodies other than the IACUC. The peer review of grant applications evaluates the proposed model; if it is found meritorious, an award is made. Department heads at research institutions often make decisions on support for research models funded locally. A separation between the fiscal decision-makers and the body that oversees animal welfare relieves the IACUC from this responsibility and focuses the committee's efforts on considering US Government Principle III and the appropriateness of the species to obtain valid results¹. OLAW has provided similar guidance on the choice of species in stating, "It is the IACUC's responsibility to review and confirm that a sound, objective and logical reason has been provided... prior to approving the use of animals for the research proposal"^{2,3}.

Although cost must not be the primary reason for proposing a new model, it certainly may influence the investigator's practical considerations, as does the availability or complexity of a given model. Likewise, alternative model development is fundamental to innovation and the creative scientific pursuit. Although the investigator neglected to include important scientific considerations in his proposal to justify his new model, a request for a modification addressing the committee's concerns should easily rectify the situation, as highlighted by the scenario reviewers.

1. Interagency Research Animal Committee. US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (US Department of Health and Human Services, Washington, DC, 1985).
2. Gipson, C., Holt, M.A. & Brown, P.A. A word from USDA, FDA and OLAW. Deciding which animals to use. *Lab Anim. (NY)* 37, 295 (2008).
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals—Frequently Asked Questions*. Protocol Review, Question No. D7. (US Department of Health and Human Services, Washington, DC, 2006; revised 2013).

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Eastern University to fund creation of the appropriate vivarium for rabbits? The dichotomy becomes exceptionally stark when one considers the use of expensive species (nonhuman primates, canines or ruminants) or animal modeling instrumentation such as advanced imaging or telemetry. Surely many IACUC protocols are approved with the often unspoken knowledge that the most scientifically accurate and strictly 3Rs-conformant animal model may not be the most economically practical, reasonable or even achievable. In a nod to the concept that money factors into decisions on animal welfare, the Office of Laboratory Animal Welfare³ has recently approved the use of non-pharmaceutical-grade pentobarbital, ruling, "Recent exorbitant cost increases of pentobarbital have placed it logistically into the unavailable category." Though perhaps not routinely recognized or consciously considered, the economy of research is a consistent underlying feature of animal use protocol management.

Despite the financial realities of research, the focus should shift from speculations on fiscal conservatism to the specific scientific and animal welfare benefits of the protocol at hand. In this scenario, we feel there is much sound scientific reasoning and valid animal welfare motivations to pursue the rat model: greater accuracy owing to increased bone density in the rat⁴; greater versatility for future genetic manipulation; reduced regulatory oversight and greater accessibility as the rat is not covered by the USDA; and greater amenability to advanced imaging techniques owing to smaller body size. Such justification is what the protocol reviewer, Burke, hints at when he asserts, "...a new animal model is always a welcome addition to the research armamentarium." Therefore, we suggest that although economics may be a factor in the decision to pursue the new animal model, it is not the sole focus. Because the endeavor has strong scientific merit and holds up well under scrutiny of animal welfare concerns, the IACUC should feel justified to approve the pilot study.

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

addresses economic considerations, and the *Guide for the Care and Use of Laboratory Animals*² tackles the issue only tangentially: "cost savings alone is not an adequate reason for performing multiple major survival surgical procedures." It seems IACUCs are largely left to their own discretion in making decisions in this regard and, in general, have taken the position to avoid using financial considerations as the sole or a primary factor in approving protocols.

Nevertheless, IACUCs should appreciate that financial considerations are intimately intertwined and often inseparable from the protocol approval process. The truth of this is found in the realization that research time, equipment and husbandry costs are

economic parameters and play a large part in driving development of animal models. In fact, one could argue that the explosion in the use of rodent models over the last few decades is driven by the motivation to reduce costs: rodents require less space and less food and have shorter lifespans than some larger animals.

Let us suppose for a moment that Hampton is a new investigator on a limited budget and that his facility does not have the space, expertise or capability to properly house and care for rabbits. Assuming that a well-established rabbit model suitable for his research does exist, should the IACUC disapprove development of the new rat model and require Hampton or Great