

have valid application to the scientific questions under investigation. However, if there are less invasive methods that are equally or more appropriate, then the investigator should have the obligation to alter the approach accordingly. The comments provided are worthy of consideration by the IACUC but do not necessarily make the correct decision clear.

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**RESPONSE**

**Contrary to the 3 Rs**

**Pierre Freeman, RLAT & Jayma A. Moore, DVM, MS**

Clearly, officials at Great Eastern are within their charge to refuse to approve the protocol if scientific merit is lacking. It is more difficult, however, actually to evaluate scientific merit.

The IACUC’s merit review and approval of animal use, which is mandated by public policy, differs from merit studies done by funding agencies. One key consideration in IACUC review is whether or not the proposed work has sufficient scientific merit so that its cost in terms of animal use is outweighed by the value of knowledge potentially gained. The IACUC must remain cognizant of principles of humane animal use known as the 3 Rs<sup>1</sup>: replacement, reduction, and refinement. Furthermore, the Committee must evaluate each proposal reasonably on its own, without being unduly biased by a researcher’s past successes or failures.

Does Vogelman’s work have merit? Experts in the field have concluded that his research does not justify external funding and that it is not of publishable quality. Although he may be asking pertinent scientific questions, his methods cannot, according to colleagues and journal editors, provide any useful answer to those questions. Therefore, he has wasted the animals that he has used, even though he has been careful, flawless, humane, and meticulous. Because his work is not published, any results that he might obtain will not be disseminated to

others in the field—necessitating repetition of the work that would violate the principle of reduction.

Does Vogelman’s work have any redeeming value? His work could be significantly useful in training students on research models, experimental design, techniques, and animal care. However, the issue of using passé techniques then arises. Outmoded methods may not be accurate or sensitive enough to obtain reliable, reproducible data. It is the investigator’s responsibility to seek current procedures that improve or replace those that are outdated, always with the goal of refinement. If students are trained with passé techniques, they then have the disadvantage of that limitation; this subverts the credibility of the training argument and detracts from the benefit side of the cost-to-benefit ratio.

Is it time for Vogelman’s experiments to end? Because Vogelman’s colleagues consider his techniques to be outmoded and because his research is not being published, the work does not seem to have adequate merit to justify continued IACUC approval for animal use. His questions about drug dependency may be scientifically valid, but if there is no realistic expectation that he will obtain answers to that question, then the costs of his work seem to outweigh the benefits.

The IACUC has a duty to end its sanction of Vogelman’s work because of insufficient refinement as well as the lack of merit.

1. Russell, W.M.S. & Burch, R.L. *The Principles of Humane Experimental Technique* (Methuen and Company, London, 1959).

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**RESPONSE**

**Cut the funds**

**William Allen Hill, DVM**

Should IACUCs evaluate animal use protocols for scientific merit? In many cases, the answer is “yes.” Yet in others, such as Vogelman’s case, the answer is more obscure

and quite debatable. U.S. Government Principle II states that “procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society<sup>1</sup>.” In stark contradiction, the Animal Welfare Act Regulations (AWARs) state that “nothing in this part shall be deemed to permit the IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility<sup>2</sup>.” Fuel for the “merit” debate arises from this regulatory paradox.

Many would agree that IACUCs have a responsibility to review and evaluate the scientific merit of animal use proposals subject to the requirements of PHS *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*). However, opponents may raise yet another valid question: Are the terms ‘relevance’ and ‘merit’ synonymous? It seems that the AWARs relieve IACUCs from questioning either relevance or merit. Yet, as stewards of animal welfare, IACUCs should bear an ethical responsibility to ask the pertinent question: “Is the use of animals in this proposal justifiable?” Certainly, the PHS *Policy* gives voice to this question. In the case of Vogelman, whose work is funded by internal mechanisms, the question remains valid, but the regulatory protection to refuse approval is lacking.

Great Eastern’s IACUC has fulfilled its obligation to ask these important questions. Vogelman’s departmental colleagues should ask themselves an equally probing question: “Does Vogelman’s ‘gentle demeanor and generosity toward students’ justify animal sacrifices?” Although agreeable character traits are commendable, they do not constitute valid standards by which to measure scientific justification. Vogelman’s department should laud his contributions to Great Eastern but discontinue funding research that they themselves describe as “passé” at best.

1. Research Animal Committee. *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training II* (Office of Science and Technology Policy, Washington, DC, 1985).  
2. 9 CFR 2.31 (a).

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