

transfer had been carried out through appropriate channels, the IACUC or the veterinary staff could have verified that these animals had not previously undergone a procedure. Overall, the IACUC was not given the opportunity to fulfill its responsibilities of oversight, and Rosen and Chen were therefore not in compliance.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*, Section IV.C.1 (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th ed. (National Academies Press, Washington, DC, 2011).

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RESPONSE

An IACUC reviews much more than training

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The principal investigators make a common sense argument: since the specific rabbit surgery was approved by the IACUC in a current protocol under Chen, and Rosen was recognized as being adequately trained to do this same surgery in a previous protocol, Rosen’s surgery in the current protocol should also be okay with the IACUC.

This argument fails for a few reasons. First, the IACUC did not approve the use or relevance of Rosen’s latest animal work, which is a part of any IACUC’s basic charge. Rosen added a proof-of-concept study, which the IACUC must confirm as appropriate. Second, the IACUC reviews personnel for more qualities than just their training. For example, it also assesses a project’s risk to occupational health and the current status of personnel. Finally, this scenario hints about other problematic conditions that are managed, at least in part, by the IACUC.

The appropriate way to handle this small add-on project would be to acknowledge that it is not within the approved

protocol and to obtain approval from the IACUC either through a formal modification to Chen’s protocol or through a new protocol. Relevance could be confirmed by the IACUC at that time. In addition, the IACUC could coordinate with other administrative units to ensure the proper use of grant funding, which might not apply to the costs of the add-on project.

The requirement to assess relevance is set by U.S. Government Principle II of the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*: “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”¹. This is also upheld by other US regulations^{2,3}. It is a matter of debate, however, just how an IACUC should assess relevance or the related concepts of scientific merit and harm-benefit analysis^{4,5}. Nonetheless, it is clear that the IACUC must confirm that the overall use of animals is relevant, rather than merely approve the surgical component of the protocol, as claimed by the investigators. Chen and Rosen failed to understand that IACUC approval considers more than the question of how animal activities are conducted. Investigators should receive sufficient training so that they can readily spot when IACUC review is required.

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. Animal Welfare Act regulations. 9 CFR. Chapter I, Subchapter A, Part 2, Subpart C.
3. The Public Health Service Responds to Commonly Asked Questions, *ILAR J* 33, 68–70 (1991).
4. Vieira de Castro, A.C. & Ollson, I.A.S. Does the goal justify the methods? Harm and benefit in neuroscience research using animals. in *Current Topics in Behavioral Neuroscience*, Vol. 19 (eds. Lee, G., Illes, J. & Ohl, F.) 47–78 (Springer, Berlin, 2014).
5. Carbone, L. In *The IACUC Handbook* 3rd edn. (eds. Silverman, J., Suckow, M. & Murthy, S.) 215–217 (Taylor and Francis, Boca Raton, 2014).

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RESPONSE

Stitching together multiple protocols creates confusion

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This is a thought-provoking scenario with a number of underlying issues and questions that need to be addressed. Does Rosen have IACUC approval to use the animals—in this case rabbits—on her approved protocol? Does Chen have the authority to allow Rosen to ‘borrow’ two of his animals to conduct her research? Although the procedures described are parts of different approved protocols, ultimately the answer to both of these questions is ‘no’.

Chen and Rosen should not be permitted to continue their research without additional IACUC approvals. At any point during the experimental process there can be a need to amend or revise a protocol to reflect changes in the intended research plan, such as a change in species¹. In this instance, Rosen determined that she needed to use a larger animal model than that for which she was currently approved, in order to satisfy the requirements of a proof-of-concept study.

While the surgical procedure and work had been previously approved by the IACUC, it was only approved for Chen’s protocol. While Rosen historically worked with Chen and had surgically manipulated rabbits, it appears she now has a stand-alone approved protocol on which she performs her procedures solely on mice. Based on the information provided, one can reasonably infer that Rosen’s protocol is not approved for use of rabbits. Given the need to use a USDA covered species, this changes the scope of the project and qualifies as a significant change to the protocol, thereby requiring notification of the IACUC².

The Animal Welfare Act (§2.31(c)(7); ref. 3) requires that investigators receive IACUC approval for all significant changes to approved animal research protocols, and the PHS *Policy on Humane Care and Use of Laboratory Animals* requires PIs to seek IACUC approval for protocol modifications. As such, it is Rosen’s responsibility to