

# Declining permission for unproductive studies

Professor Harry Harrison had been a major federal grant recipient for research on neurofibrillary tangles in the mouse brain, but his federal funding had disappeared years ago and the little research he continued to do was supported by private funding from a longtime friend of his. Harrison continued to publish review articles but none of his own research had been published for many years. Nevertheless, he continued to submit IACUC protocols for pilot studies using genetically modified mouse strains. Harrison followed his protocols to the letter.

After years of approving Harrison's studies, Dr. Larry Covelli, the chairman of the Great Eastern University IACUC, politely suggested to Harrison that he should either

expand his pilot studies into publishable research or stop performing them, as they appeared to be a waste of space, money, and animal lives. But, Harrison contended that his research was important and he politely thanked the chairman for his opinion, adding that he would be continuing his studies that focused on the role of tau proteins and neurofibrillary pathology. Covelli then met with Harrison's department chair but the latter supported Harrison. Covelli's next stop was the institutional official, but that conversation was fruitless. Likewise, when Covelli discussed the matter with the attending veterinarian and the IACUC vice-chair, no helpful suggestions arose other than to bring the issue to the full committee. Covelli did just that but

the only recommendations were to allow Harrison to continue his studies or for the IACUC to simply refuse to approve Harrison's protocols.

What do you think? Should (and can) the IACUC refuse to approve further animal studies by Harrison, is he entitled as a faculty member to continue his apparently non-publishable research, or are there other paths to be considered? □

Jerald Silverman

University of Massachusetts Medical School,  
Worcester, Massachusetts, USA.

e-mail: [Jerald.Silverman@umassmed.edu](mailto:Jerald.Silverman@umassmed.edu)

Published online: 24 August 2018

<https://doi.org/10.1038/s41684-018-0130-8>

## Time for another look

Dr. Covelli, Great Eastern's IACUC Chair, has serious questions about the scientific merit of Dr. Harrison's work, citing Harrison's lack of recent published research and funding. We do not have crucial information in this scenario. Is he unfunded and unpublishable because his experiments are not working technically? Are his novel hypotheses, though possibly worth exploring, not supported by his pilot work while he keeps moving on to others? Are his methods obsolete? Is he losing animals rather than deriving important data from them?

Since it's not clear why Harrison as principal investigator (PI) lost federal funding and hasn't published, these factors alone don't substantiate Covelli's claim. The fact that Harrison's work is privately funded by a longtime friend, however, does raise concern as to whether it has undergone any recent, independent scientific merit review. Dr. Covelli is therefore right to raise these questions. Unfortunately, the way he attempts to address the issue is problematic. Covelli takes it upon himself to personally deliver an ultimatum to Harrison: either expand his pilot studies into publishable research or stop his work. Since the criteria to stop the protocol is implicit in the ultimatum, Covelli acts as the sole authority in possibly suspending an IACUC protocol.

As committee chair, Covelli should know that such a decision can only be made by a quorum of the IACUC at a convened meeting.

Fortunately, when Covelli seeks further input from his team (institutional official, vice-chair, and attending veterinarian), he follows their advice to bring the matter to the full committee. Although no one reminds Covelli that scientific merit evaluation typically lies outside of the IACUC's purview, one would assume that an institution of Great Eastern's size has a formal scientific merit review board or other process to which Dr. Harrison could submit his protocol.

The scenario indicates that the committee immediately put Harrison's protocol to a vote, bypassing any discussion. An alternative approach would be to review and discuss all of the pertinent details before voting so that members may make carefully informed decisions. If Harrison can secure scientific merit approval via the established process at Great Eastern, the IACUC can focus on the "scientific elements of the protocol as they relate specifically to the welfare and use of animals."<sup>1</sup>

The protocol must clearly explain how the proposed work will advance science and medicine. The committee should then consider whether the proposed benefits

justify the use of animals as well as any pain or distress from the procedures described. Additionally, the IACUC should look closely at the PI's literature search for alternatives to assure he's not unnecessarily duplicating research and that his experimental design and procedure refinements are informed by current published standards. The PI should be asked to include an update on progress made in the past three years and explain how the protocol's continuation will further advance its stated objectives. If Harrison's proposed sample size, group numbers, experimental design, readouts, and procedures appear sufficient to accomplish stated objectives, this strengthens the IACUC's decision to approve his protocol. If not, the IACUC can, and should refuse to approve further studies. □

Alison Cowell and Larry Carbone\*

University of California San Francisco, San Francisco, California, USA.

\*e-mail: [larry.carbone@ucsf.edu](mailto:larry.carbone@ucsf.edu)

Published online: 24 August 2018

<https://doi.org/10.1038/s41684-018-0131-7>

### References

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