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Should 'duplicative research' still be reviewed?

The Central Intelligence Agency could have taken lessons from Dr. Phil Finster. He chaired his IACUC with an iron hand and told members only what he thought they had to know. Everything else was considered to be a state secret. He had the IACUC convinced that he, as Chairman, could decide which protocols were to be reviewed by the committee, and in the past, he had rejected from IACUC consideration protocols that, in his opinion, had no scientific value.

Finster's throne was finally challenged by Sara Newsome, a new and plucky assistant professor whose research, like Finster's, involved glucose clamping of mice for various diabetes-related studies. Finster had served on the search committee that recommended hiring Newsome, but he never dreamed that Newsome would be

given a larger lab and a nicer office than he had. Finster was outwardly cordial to Newsome, but he was seething within and often tried unsuccessfully to bully her. So Finster took a different route. When Newsome submitted her first IACUC protocol, Finster, without Newsome's knowledge, withheld sending it to the committee until after he had submitted and gotten approval via designated member review for a protocol of his own that was nearly identical to Newsome's protocol. Then, with malice in his heart, he calmly told Newsome that her study would be nearly identical to his and that federal regulations and guidelines did not allow for unnecessary duplication of research. "I'm sorry, Sara," he said, "but we will not be able to review this study."

Newsome was equally calm as she told Finster it was her understanding that the IACUC had to review her study whether or not he thought it was duplicative research. But Finster held firm. So with a sweet tone to her voice, Sara Newsome said, "No problem, Phil, I'll go to our Institutional Official and see what he has to say, and if I get the same answer, I'll ask the NIH why I can't use the money they gave me for my research. I'm sure they'll look into the matter."

Although Finster was not acting in a mature or professional manner, the question remains: are there any circumstances in which Finster would be within his rights as an IACUC Chairperson to reject apparently duplicative research before the protocol reached the full committee?

RESPONSE

Is 'duplicative' really duplication?

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There are no circumstances under which Finster would be in his rights as an IACUC Chairperson to reject any proposed research before it reaches full committee. Legally, the Chair is given no different rights in protocol review than any other member of the IACUC, and only the IACUC can withhold approval for proposed use of animals. If designated member review (DMR) was the standard process used at this institution, Finster did not forward the protocol to the IACUC and hence did not meet the legal requirement of DMR. Reviewers participating in the DMR process are not allowed to withhold approval of protocols.

The Animal Welfare Act Regulations¹ (AWARs; section 2.31 (a)) indicate that the IACUC is responsible to determine that investigators have provided "written assurance that their research activities do not unnecessarily duplicate previous experiments." For concerns regarding the possible duplicative nature of a particular protocol, referral to the full committee for discussion by a wider audience, possibly including the principal investigator, is necessary.

As Finster recently received approval for his own protocol and has not yet published the results, his contention that the studies are nearly identical and that federal regulations and guidelines do not allow unnecessary duplication of research is unsupported. Duplicative research may not be the same as duplication of research. Mandrell stated that carrying out a published research protocol (duplicative research) in order to ensure comparable results and technical competency is not considered unnecessary duplication of research². In addition, Morgan introduced the term replication as the

repetition of experiments or tests to increase the reliability and generality of the findings³. It becomes unnecessary duplication only when an experiment has been replicated several times with the same findings such that the results are predictable and further repetition of the experiment is pointless. Therefore, apparently duplicative protocols may simply be replicative and should be reviewed by the IACUC with this in mind.

Furthermore, both the AWARs¹ and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*⁴ state that no IACUC member "may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity) except to provide information." Conflicting interests could also entail competing research programs, monetary rewards and personal biases that may interfere with an impartial protocol review.

In this scenario, Finster has shown a conflict of interest. He is working in the same area as Newsome, and even though there is no personal involvement or