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Amendment submitted; protocol reviewed?

Dr. Jan White submitted a protocol amendment to the Great Eastern University IACUC and patiently waited—seemingly forever—for feedback from the committee. Eventually she e-mailed the IACUC office and asked for an update. What she heard upset her and led to a series of less-than-pleasant interactions with the IACUC.

White's amendment proposed adding an open-field exploration test to an already long list of behavioral tests that were commonly done in her field of research. In the open-field test, a mouse is placed in the center of an enclosed area, and various observations are made without disturbing the animal. Unfortunately for White, the reviewer decided to review her entire protocol, not just the amendment, and was disturbed about how some of the other behavioral tests, such as the forced swim test, were being performed. When White learned of the

reason for the review's delay, she immediately complained to Dr. Larry Covelli, the IACUC chairman, saying that all of her other behavioral tests had been recently approved by the IACUC and that she hadn't asked for them to be reviewed again.

"I'm sorry," said Covelli, "but it's the prerogative of the reviewers to review any or all parts of the protocol in addition to your amendment. Sometimes they find important items that other reviewers have missed, and it's to the benefit of animal welfare and good research to have any perceived problems fully explored."

"And is it to the benefit of animal welfare and good science to have this drag on forever? You had a veterinary pre-review of my protocol, changes made by me in response to the pre-review, and then you had a full committee discussion about my protocol in which nobody found anything else that

needed changes. How many times does my protocol have to be reviewed and approved before I can get on with the science? Where in your rules and regulations book does it say that a protocol can be re-reviewed every time a person puts in an amendment?"

Covelli knew that during an initial full committee or designated member review, any member of the committee could request additional information or raise concerns about any aspect of a study. He also knew that at any time, any person could request that the IACUC consider re-reviewing all or part of an already approved protocol, but he wasn't entirely sure how to respond to White's question. When an amendment to a protocol is submitted by an investigator, does the reviewer have the authority under federal regulations to re-review sections of the protocol, in addition to the amendment? What is your opinion?

RESPONSE

Unnecessary delays!

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It is unfortunate that White had to endure what many researchers face when dealing with their IACUCs: unnecessary delays. The amendment submitted was for a non-invasive behavioral observation procedure. For many IACUCs, a minor amendment like this could be reviewed through the designated member review (DMR) process. In most cases, the DMR process is faster than waiting for a full committee review. In this scenario, it appears that White's amendment was being reviewed by the DMR process.

Regardless of which process is used, the reviewers have the right to assess the amendment and how it fits with the procedures in the rest of the protocol. This may lead to concerns with parts of the

protocol that were already approved, and the IACUC should require the investigator to address those concerns. However, the IACUC should not require the investigator to wait "seemingly forever" or to contact the committee for a status report.

IACUCs should have deadlines for their reviewers to respond, just as they have deadlines for researchers to submit materials. The IACUC could inform the investigator of the review deadline, so that he or she would know when to expect a response. This would make the review process more objective and ensure a timely response to the investigator. If problems had been found in already-approved procedures and the reviewer had provided that information quickly, then White likely would not have had the same response for Covelli.

The designated member reviewer should also be questioned as to why he or she was not already comfortable with the recently approved protocol. Perhaps the reviewer did not attend the meeting where the protocol was initially discussed and was unable to review it and provide feedback

before that meeting, meaning that he or she is seeing the full protocol for the first time. In this situation, the reviewer can certainly raise concerns and ask for clarification regarding the approved procedures. Assuming there were no problems with this amendment, the IACUC, through the DMR process, could approve this amendment, allowing the researcher to collect data using the new procedure while addressing any concerns about the previously approved procedures.

IACUCs should adhere to the same standards that they expect from researchers. As the group responsible for the animal care program, the IACUC may become frustrated when researchers are delayed in responding to concerns. Likewise, IACUCs should be frustrated when their own processes cause delays in getting responses back to researchers.

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