

A late notice & personal conflict—was suspension warranted?

Dr. Felix Monteverde was a long-time member of the Great Eastern University faculty, but until recently his research had never required the use of laboratory animals. Because of his relative newness to working with the IACUC, and in part due to his loathing of anybody or anything that might put constraints on his research, he had earned himself a reputation of being somewhat of a troublemaker for the IACUC.

Monteverde submitted a protocol for a mouse study and it was reviewed at a full committee meeting. After the meeting, he called the IACUC office and was told that the protocol was approved and a formal approval letter would be sent by email the next day, as per the standard policy of the IACUC. Monteverde was delighted that for the first time one of his protocols was approved without a need for revisions, and a few days later he began his study, using previously printed cage cards and mice that had been bred on a different IACUC-approved protocol. But there was no

approval letter and Monteverde soon found himself in trouble with the committee.

Monteverde learned from a friend in the IACUC office that his new experiment was noticed by an IACUC member who had a contentious relationship with Monteverde. This person thought it strange that Monteverde's study was able to start so soon after the IACUC meeting and reported this to the IACUC chairman. The chairman discovered that the approval letter was never sent due to a mistake by the IACUC office. He contacted Monteverde, who explained that he thought the study was approved and the approval letter was just a formality. He said he did not intentionally try to circumvent any federal regulation or IACUC policy.

At a hastily convened full committee meeting, the member who had reported the incident reminded the committee members that this was not their first run-in with Monteverde and that all investigators had been given written information that included the need to have a written approval from the IACUC

office before beginning any research. He then moved to permanently suspend Monteverde's protocol, and after some discussion, the motion passed unanimously. Monteverde was furious when he learned of the committee's action and that the vote to suspend his protocol was unanimous. He wrote a scathing letter to the IACUC chairman and the Institutional Official, claiming that the committee's action was illegal because it violated its own policy by not sending the approval letter the next day and by allowing a member with a clear conflict of interest to participate in the discussion and vote to suspend his protocol.

What is your opinion about the committee's actions and how would you act on Monteverde's complaint?

Jerald Silverman

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

e-mail: Jerald.Silverman@umassmed.edu

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Perception, deception, distrust – Oh My!

In the case of Monteverde's protocol, the Greater Eastern University IACUC had a golden opportunity to improve relations with a troublesome investigator and paint themselves in a positive light as a partner and resource. Frankly, they blew it. The suspension of Monteverde's protocol seems to be a harsh, unnecessary penalty for what amounts to a policy violation that they are also guilty of. The IACUC's first responsibility is to animal welfare and in this case, there does not appear to be any animal welfare concerns as the animal work had been approved without revisions at a full committee meeting.

The actions of the IACUC to permanently suspend Monteverde's protocol highlight the importance of training and communication in an institutional setting. There were internal breakdowns of IACUC policy about how and when approvals are communicated to investigators. Monteverde's approval letter was not sent as required; rather, someone in the IACUC Office reported the approval verbally. Current policy dictates that an investigator must wait for written approval prior to beginning research. Monteverde did not seem to recognize the difference between

verbal and written approval, but the fact that he was given a verbal confirmation over the phone might be an indication that the IACUC Office does not understand this difference either. Re-training of the IACUC Office staff and investigators should be considered.

Regarding Monteverde's complaint, there are a few things to consider. The accusations against the IACUC member raising the concerns must be investigated. It is interesting that one IACUC member holds enough power to convene an unscheduled meeting and convince the committee to unanimously suspend Monteverde's protocol. Is he railroading the committee? Is he harassing Monteverde? At this point, another meeting should be called, and the suspended protocol should be reviewed again. Since the work had already started, what will happen to the animals? The IACUC should also evaluate the process of cage card management and animal transfers as his use of previously printed cage cards and transferred animals may have contributed to this issue. At most, we would consider a written warning issued to Monteverde for starting his work prior to having written

confirmation of the protocol approval and for potentially using incorrect cage cards.

While there are things Monteverde could have done better and should be re-trained on, and while the committee is within its rights, the suspension of this protocol was not warranted. IACUCs are frequently seen as bureaucratic groups that hinder and slow research. The actions of the IACUC in this case show why investigators believe this! The policy violation was committed by both the IACUC Office and Monteverde and could have been addressed in less severe ways that all parties could learn from. The incident could have sparked discussions about training and communication across various groups. In the end, Monteverde was working under an approved protocol and there were no serious animal welfare concerns. This should have been an easy win for the IACUC.

Erin Straley* and Shameen Afif-Rider

AstraZeneca, Gaithersburg, MD, USA.

**e-mail: erin.straley@astrazeneca.com*

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