

# A late notice & personal conflict—was suspension warranted?

**D**r. 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?

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## Perception, deception, distrust – Oh My!

**I**n 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.

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# Bad blood: retraining in professional behavior needed for everyone

The official role of an IACUC is to oversee the Animal Care and Use Program at its Institution<sup>1</sup>.

In practical terms, this means the IACUC is responsible for helping the Institution's faculty perform research in compliance with all regulatory bodies and agencies. In this scenario, all participants engaged in a series of missteps, fueled by personal resentment and acrimony, and the committee let personal animosity influence decisions that hindered the progress of research at Great Eastern University.

Although Monteverde incorrectly assumed that a phone call was an official approval notice<sup>2</sup>, the IACUC also was at fault for not sending the IACUC approval letter the next day "per the standard policy of the IACUC." While PHS Policy

specifically states that "[t]he IACUC shall notify investigators and the institution in writing of its decision"<sup>3</sup>, the scenario does not indicate whether the IACUC office phone contact and/or investigator training materials clearly state that an animal study may only start after an official written approval letter is received by the investigator. Since Monteverde was new to animal use, its regulations, and IACUC policies, it is understandable that he believed that a phone call from the IACUC office was a valid mean of communicating approval of his protocol. In addition, the IACUC office told Monteverde that the approval letter would be emailed the next day, so his timeline to start his project a few days after the phone call seems reasonable. Further protocol noncompliance occurred when

Monteverde started using mice on another approved protocol without transferring them to his new IACUC protocol<sup>4</sup>. This assumes that this IACUC allows transfers and as a part of the process requires new cage cards to be printed with the appropriate protocol number<sup>4</sup>.

The IACUC was correct to respond to Monteverde's noncompliance but their response was far from collegial or helpful, nor was not in congruence with the PHS Policy that prohibits IACUC members with a conflict of interest (COI) from contributing to a quorum<sup>5</sup>. One way in which COI can manifest is through "personal bias against an investigator's research"<sup>6</sup>; according to the scenario, the member who made the motion to permanently suspend the protocol "had a contentious relationship with Monteverde." As that member made the motion, we assume that this person was a part of the quorum. While members with COI may provide information as requested by the IACUC<sup>5,6</sup>, this member should have recused himself from the final discussion and vote. Additionally, the vote to permanently suspend the protocol is out of proportion to the policy violation<sup>7</sup>. The reporting IACUC member's personal hostility towards Monteverde of the IACUC clearly influenced the rest of the committee. Although the members of the IACUC can take past faculty actions and infractions into consideration, each incident is best evaluated as a separate event. This noncompliance resulted in no known animal welfare concerns and would have been easily avoided if the IACUC office had not made a mistake.

We would advise the IACUC Chair to re-evaluate the committee's deliberation and decision regarding Monteverde's protocol suspension and include "corrective actions to help prevent future problems"<sup>7,8</sup> for not only all parties involved. Corrective actions for Monteverde could include re-training, provided by the Institution, on the procedures for animal research<sup>9</sup>. For the IACUC office, corrective actions could include assessing methods to reduce confusion when communicating with investigators, assess the policy on the timeline for sending written approval letters, and making certain that investigators receive proper training. For the IACUC committee, the policy discussing COI and protocol suspensions should be reviewed and updated to prevent similar issues in the future. Overall, the IACUC Chair and committee

## A WORD FROM OLAW

In response to the issues posed in this scenario, the National Institutes of Health - Office of Laboratory Animal Welfare (NIH-OLAW) provides the following clarification:

In this scenario, the IACUC voted to permanently suspend a protocol because the investigator mistakenly began his research without waiting for receipt of an approval letter that was delayed by an IACUC office oversight. The investigator indicated it was not their intent to violate the IACUC policy and thought that a verbal approval was equivalent. At issue is the undue influence of a committee member with a conflict of interest that compelled the IACUC's decision to suspend.

The PHS Policy and the AWARs 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 requested by the IACUC"<sup>1,2</sup>. Conflict of interest must be mitigated by the IACUC Chair whenever a member's personal biases may interfere with his or her impartial judgment, a member is involved in a competing research program, or access to funding or intellectual information may provide an unfair competitive advantage<sup>3</sup>. To address the current situation, the IACUC Chair at Great

Eastern should consider convening an IACUC meeting and require the member with the conflict to recuse from the vote and any discussion, except to provide information requested by the IACUC. For the vote to be valid without the recused member, a quorum (>50% of the voting members) must be maintained<sup>1,3</sup>. OLAW would also encourage the IACUC to take corrective measures to reinforce clear communication with research staff and review the existing IACUC policies on member recusal and approval notification. In OLAW's observations, when an IACUC has a mutually respectful relationship with investigators, the cooperative environment results in reduced noncompliance. □

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should work to assist and help research at the institution, not be a hindrance. □

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## Conflicts of interest: Lack of policy and/or of common sense?

While the rules governing animal research can always be applied to the proverbial “letter” by IACUCs, some common sense and pragmatic dialogue is required to maintain a productive partnership between the regulators and scientists and ensure both compliance and research progress. This case is a disappointing application of the rules for addressing a member’s or committee’s personal agenda against Monteverde. In the absence of such conflicts of interest (COIs), this situation could have been resolved without fanfare or drama as Monteverde had every intent to comply with established procedures. This scenario highlights a need for guidance on eliminating detrimental COIs from interfering with a research-IACUC partnership that was intended to further the biomedical research enterprise.

According to the scenario, Monteverde was informed verbally by IACUC administration that the protocol was approved and that he could begin the work. It was later discovered that the IACUC erred in not sending a written letter within the next day, as the local IACUC’s own policy states. Monteverde relied on the “word” of the committee and had no intention to circumvent any federal guidelines. A critical aspect is that animal safety was assured and not in jeopardy. The subsequent actions and sanctions from the IACUC are then quite problematic. The actions were initiated by an IACUC member, denoted IACUC member Y, who has had personal conflicts with Monteverde. At its worse, this is a manipulation of the rules structure and a recruitment of other committee members to satisfy IACUC member Y’s personal agenda.

A simple self-recusal on all matters by IACUC member Y would have removed the spectacle of tainting the proceedings with personal issues. Monteverde had all intention to comply with the protocol and IACUC rules. The personal conflict by an IACUC member created a more devastating situation that resulted in excessive punishment and sanction. Yes, the rules can always be applied in this way by the letter of the rules, but such use is also contrary to the spirit on which the rules were devised.

In the end, this is a case of miscommunication and of a personal agenda by IACUC member Y. The sanctions on Monteverde are overly harsh. The IACUC committee wields considerable power over an investigator’s research. Some common sense judgment should be exercised in wielding those powers, which should never be subverted to satisfy a personal agenda against an individual investigator. A flaw is that the IACUC proceedings do not have sufficient language or guidance on the basis for recusals on a wide range of COIs. Thus, such overreach of possible powers and of sanctions are technically possible, but should they be used? This is akin to enacting a life imprisonment for a traffic violation. This overly harsh application then victimizes investigators such as Monteverde, who submitted the protocols and acted in good faith on the communications that he received. A good dose of ethical behavior, common sense, and adequate communication by the IACUC would have avoided this entire debacle.

**Recommendation:** Specific guidance on recusal of IACUC members is required to avoid a subversion of the process for

personal and institutional agendas not related to the protocol at hand. While most guidance should be simple common sense, this scenario and the practice of levying disproportionately harsh sanctions are detrimental to the partnership of IACUCs and research programs. It is unconscionable that a simple miscommunication and bureaucratic snafu can lead to a suspension and interference with a PI’s research. Judicious and common sense exercise of IACUC committee rules should be the objective of every committee. Not all powers should be wielded to the utmost degree. But, the gap in specific guidance on COI provides a loophole to subvert the process for personal agendas by a specific member. This member then swayed his fellow committee members—IACUC member Y should not have participated at all. Specific guidance on conflicts of interest and for member recusals is necessary. We must close this loophole with thoughtful new policies at the institutional and federal level. The IACUC and research programs should be a partnership to advance our biomedical research enterprise. The IACUC should never be used as a vehicle for personal agendas and should be exceptionally mindful of the spirit in which the rules were devised. □

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