

# 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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### References

- Office of Laboratory Animal Welfare, National Institutes of Health. Public Health Service Policy on Humane Care and Use of Laboratory Animals. (US Department of Health and Human Services, Bethesda, Maryland, USA, 2015). <https://olaw.nih.gov/policies-laws/phs-policy.htm>
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A — Animal Welfare: Part 2 Regulations. §2.31.
- Office of Laboratory Animal Welfare. Institutional Animal Care and Use Committee Guidebook 2nd edn. 15 (US Department of Health and Human Services, Bethesda, MD, 2002).