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Rights of a Designated Member reviewer

Everybody at the school knew Ike, and everybody knew Ike’s favorite expression: “if I did things your way, we would both be wrong.” When Ike became a member of the IACUC, his penchant for doing things his way created a significant problem for the committee.

Isaiah Meriwether Clay—Ike—was one of three designated member reviewers of a protocol that proposed two survival surgical procedures on the same animal. Two of the reviewers believed that the second surgery was an important aspect of the study. Ike wholeheartedly disagreed, and because the reviewers could not resolve their differences, the protocol was referred to full committee review. At the full committee review, Ike vociferously

argued his case, but the committee sided with the Principal Investigator and the other two reviewers, voting to allow both survival surgical procedures. However, there were still some non-surgical aspects of the protocol that required additional consideration, and the committee voted to send the protocol back to designated member review to tie up the loose ends and secure final approval of the study. The vote to allow both surgeries did not sit well with Ike, and throughout the remainder of the meeting, he pondered his options. Then, in a flash of self-congratulatory brilliance, it came to him. He could still get his way.... or so he thought.

When the same three designated reviewers reviewed the protocol again to request the

minor modifications needed to secure final approval, Ike simply refused to agree with the need for the two survival surgeries.

“Ike, you’re out of line. The full committee already voted to allow both surgeries,” was the quick and expected response from the other reviewers.

“That means nothing now,” Ike replied. “We have to reopen the entire discussion about surgery because if I were to agree with you that the second surgery was needed, we would both be wrong.”

Ike may not be a team player, but he never claimed to be one. Is Ike overstepping federal regulations by ignoring the committee’s vote, or is he within his rights as a designated reviewer to restart the discussion about the two surgeries?

RESPONSE

Not very expedient

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In this scenario, neither the species of animal being used in the protocol nor the source of funding for the study is identified. The *Guide for the Care and Use of Laboratory Animals* (the *Guide*), which applies to essentially all research animals, indicates that “[m]ultiple major survival surgery procedures on a single animal are discouraged but may be permitted if scientifically justified by the user and approved by the IACUC”¹. The provisions of the Animal Welfare Act and Regulations (AWARs), which cover research animals “except birds, mice of the genus *Mus* or rats of the genus *Rattus*”² are in agreement with those of the *Guide*, provided the Principal Investigator provides justification in writing². With regard to funding, all projects that use animals covered by the USDA must abide by the AWARs regardless of funding

source. Institutions that accept NIH funding must abide by the PHS *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*)³. Even if a study does not use USDA-covered species and if the institution does not receive NIH funding, the facility might still be required to adhere to the *Guide* if it is accredited by AAALAC, International.

The purpose of the Designated Member Review (DMR) is to speed up the protocol review process and decrease the overall workload compared with Full Committee Review (FCR)⁴. In accordance with an OLAW Guidance on DMR subsequent to FCR, “the reviewers must be unanimous in any decision”⁵. If there is any disagreement among DMR reviewers, the protocol must be sent back to FCR.

In this scenario, even though the IACUC has already voted during FCR to allow both surgeries, the study proposal is still under review. Neither FCR nor DMR has resulted in a final decision regarding the proposed study. Both the AWARs and the PHS *Policy* similarly state that “[i]f full Committee review is not requested, at least one member

of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those activities”³. Only a FCR can withhold approval from a study^{2,4}. Since Ike does not have the power to withhold approval of the protocol and cannot agree with the other DMR reviewers, the proposal will inevitably be approved during a future FCR session, when all requested modifications have been made.

Ike’s attitude, “if I did things your way, we both would be wrong” lacks professionalism and tact and brings his credibility into question. Even though his behavior is not overstepping federal regulations, I think it is his responsibility to exercise his due diligence in the task he was asked to perform. He should help the other DMR reviewers with the request for minor modifications needed to secure final approval. In the end, if he still feels strongly about the two survival surgeries, he may file a minority view with the IACUC. A minority