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Electronic (Mis)Communication in IACUC Procedures

The foibles of ‘electronic IACUCs’ never seem to stop. Perhaps they result from the relative novelty of the concept or because there are no definitive guidelines on what is or is not acceptable. Consider what happened to the Great Eastern University IACUC during an evaluation of the procedures necessary to approve or request modifications to a protocol that was sent for Designated Member review. At Great Eastern, each Designated Reviewer (DR) received an electronic copy of the protocol along with a request to evaluate it. The DRs could communicate with each other, if they chose to, by any means they preferred. The reviewers emailed written comments to a previously selected ‘primary reviewer’ (PR), who would ensure that all the other reviewers were speaking with unanimity to the Principal Investigator (PI). For example, if all reviewers agreed to approve the study, they would then email this information to the PR. In turn, the PR emailed the IACUC office and informed the IACUC administrator that all reviewers were in agreement to approve the protocol. If there was no agreement to approve the study, then the PR would synthesize the comments of the other reviewers and email the PI (via the IACUC office) with the requested modifications to help secure approval. The other reviewers received a copy of all emails. If, after two interactions with the PI, no agreement could be reached for approving the protocol, then it was automatically sent for Full-Committee review at the next scheduled meeting. Of course, any DR could request Full-Committee review at any point in the process.

The problem facing Great Eastern was not the general process but the specific means of indicating approval. The IACUC Administrator was cautious about any process in which the PR claimed that all

DRs approved a protocol, yet there was no documentation from the other reviewers to prove that. After a discussion at an IACUC meeting, one member suggested that the easiest solution was to use the voting feature on the email program. Unfortunately, the school had more than one email program, not all reviewers had the voting feature, and, in any case, they could not agree on the details. Someone then suggested that the PR continue to copy all other DRs on the approval email that he or she sent to the IACUC office. With this approach, members reasoned, any reviewer who believed that he or she did not truly approve a protocol could immediately raise objections. The IACUC Administrator was not happy with that suggestion, because it was the same system they were currently using. Furthermore, because the approval would have already been recorded and any dissent would require that it be negated, it was a process that she did not want to incur. Her preference, under the circumstances, was to have each reviewer send her an email signifying approval. Nevertheless, the Committee voted to maintain the status quo. The rationale was that, not only was it easy to do, but there was also nothing to suggest that it was not in compliance with any existing federal regulation for approving an IACUC protocol by the Designated Member review process.

Do you agree with the actions and logic of the Great Eastern University IACUC?

No Vote

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Though not stated in the scenario, we are to assume that the protocol going to the DRs has been previously sent to all members of

the IACUC, any of whom have the right to call for a Full-Committee review. Given that no member calls for a Full-Committee review, it seems that the process that Great Eastern University’s IACUC has been using to review protocols, by use of the DR method, complies with the Animal Welfare Act Regulation and is consistent with guidance provided by the Office of Laboratory Animal Welfare and the United States Department of Agriculture¹. The Chair of the IACUC may appoint an individual to be the PR and grant him or her the authority to convey the final approval decision. DRs do not have the authority to disapprove a protocol. They can only “...approve, require modifications in (to secure approval), or request full Committee review...².” Therefore, in effect, they do not vote. If, in the end, all DRs are not in agreement, then the protocol must go before the convened IACUC for a Full-Committee review. The suggested use of the voting feature on the email program would seem to give the erroneous impression that the DRs were voting.

If the Chair has appointed a PR and granted him or her the authority to convey the final approval decision, then there is no need for the IACUC Administrator to have on record documentation from all DRs indicating so. It is incumbent upon the PR to ensure that the process is complete before notifying the IACUC Administrator of a decision. All DRs must see the final product as changes are made and give agreement for approval before the PR conveys such approval. If the other reviewers are receiving email of all correspondence and interactions as indicated, then there should be sufficient communication to make an informed and appropriate decision.

References

1. Garnett, N. & Gipson, C. Suggestions to bring electronic protocol system into com-