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# Virtual IACUC Meetings: Compliant or Not?

Email and electronic communications, in general, are transforming the way the world does business. Therefore, it should come as no surprise that many IACUCs are using electronic communications for part or all of the protocol review process. The Great Eastern University IACUC was using email to expedite its work, but mostly to have a veterinarian ‘pre-review’ the protocol so as to find and correct significant problems before it went to the full Committee for general review at a convened meeting. That system worked well, but the continued increase in the number of protocols discussed at each meeting led the researchers on the IACUC to demand that the entire protocol review process be handled electronically. They were all on the same campus, but it seemed to them that they were spending too much time at IACUC meetings. The Chair of the IACUC was a researcher and saw a decreased workload for himself, so he strongly favored the idea. The veterinarian was skeptical, thinking that the entire process might become perfunctory, but he was willing to try it. The other members did not object.

The process they agreed upon was not to have Designated Member review, but to continue with the veterinarian’s pre-review, and then to have the corrected protocol sent electronically to all IACUC members. Two members would serve as the primary and secondary reviewers who had the obligation of reading all protocols and commenting on them, while other members were only encouraged to do so. Members sent any comments to the IACUC office, which in turn forwarded them to all the members. Thus, all members were able to see and respond to any other person’s comments if they chose to do so. The process continued until the primary reviewer considered that the

Committee had no further significant comments, and advised the IACUC office to collate any requested clarifications or modifications and send them directly to the investigator for final consideration and corrections. The full Committee then received the revised protocol from the investigator. They then voted electronically to approve, approve if specific modifications were made, or withhold approval. Committee members emailed their votes to the IACUC office, where they were tallied.

The process seemed to work reasonably well; nevertheless, it was questioned during an AAALAC site visit. The site visitors wanted to know how the IACUC complied with the PHS *Policy* and Animal Welfare Act (AWA) regulation, which called for approval “at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.” The Chair of the IACUC responded that all members had the opportunity to vote, and no approval could occur without the approval of a majority of all the IACUC members. That, he said, was comparable to having a quorum present. Still, it did not seem quite right to the site visitors, because they suspected that some, perhaps many protocols, were receiving little if any review by most of the IACUC members, who just arbitrarily voted to approve any protocol that the primary reviewer had concluded was ready for a vote. On the other hand, they reasoned, this situation wasn’t much different from what happens with many IACUC meetings attended by all members. However, the issue of needing a convened meeting was still bothersome.

Was Great Eastern University acting appropriately with the methods they chose to use for protocol review, or were the AAALAC site visitors on the right track with their concerns?

## Trying, But Failing



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The question about what constitutes proper IACUC review is a compelling one. Personally, I recall AAALAC presenting this question in a previous site visit at our facility. However, I think that the use of the AWA quote in the case involving Great Eastern does a disservice to the text and spirit of the section being quoted.

The quote cited by the AAALAC official, “at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present,” comes from section 2.31 (d)(2) of the AWA. While the wording is accurate, it is far from complete. The quotation taken in its entirety reads: “If a full committee review is requested for a proposed activity, approval for that activity may be granted only after a review at a convened meeting of a quorum of the IACUC and with approval of a majority of the quorum present.”

Section 2.31 (d)(2) states that “Prior to any IACUC review, all members of the committee must be provided with a list of proposed activities to be reviewed.” Great Eastern is certainly fulfilling this requirement. Section 2.31 (d)(2) goes on: “Any IACUC member may require a full committee review of any activity by requesting such. If a full committee review is not requested, at least one qualified member can be designated by the chairman to conduct the review. That person shall review the activities and has the authority to approve, require modification, or request a full committee review of the activities.” The case involving Great Eastern is not clear regarding a member’s ability to request a full IACUC review meeting with a quorum.

**A Word From USDA and OLAW**



For clarification on regulations and policy guidance related to 'virtual' protocol review, readers are advised to consult the following references:

- Garnett, N.L. & DeHaven, W.R. Innovative, but not compliant. *Lab Anim. (NY)* **30(3)**, 15 (2001). <http://www.labanimal.com/letters/garnett.html>.
- Garnett, N. & Gipson, C. Suggestions to bring electronic protocol system into compliance. *Contemp. Top. Lab. Anim. Sci.* **40(6)**, 8 (2001). [http://grants.nih.gov/grants/olaw/references/elec\\_protocol\\_sys.htm](http://grants.nih.gov/grants/olaw/references/elec_protocol_sys.htm).
- USDA APHIS. Electronic Communication. Animal Care Resource Guide. (April 2001). <http://www.aphis.usda.gov/ac/researchmanual/18-8ELEC.PDF>.
- Wolff, A. Correct conduct of full-committee and designated member protocol reviews. *Lab Anim. (NY)* **31(9)**, 28-31 (2002). <http://www.labanimal.com/iacuc/wolff1002.htm>.

While these passages from the AWA do not state that IACUC members must actually read the protocols, they do imply the necessity. Additionally, the AWA states that an IACUC consists of a minimum of three members, the attending veterinarian (AV), the Chair, and a layperson. Great Eastern is having the AV read the protocols but did not specify the identity of the primary and secondary reviewers.

While I believe that Great Eastern is attempting to satisfy the AWA requirements for protocol review, I am of the opinion that they are not fulfilling the spirit of the AWA. In my mind, the resolution of this matter would lie in my being assured that the primary reviewer was the IACUC Chair and the secondary reviewer was the designated layperson. Another option would be to have these two specific members read the protocols before subsequent review by the designated primary and secondary reviewers. In either case, I would also need to be assured that a full meeting with a 'quorum' of the IACUC members would take place if any member made such a request.

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vened meeting, but are still able to provide valuable contributions during discussions. I'd surmise that not only would these same variables reduce input from panel members during an electronic forum, but debate about issues would also be limited. One of the appeals of emails is that one can respond later when time allows. I side with the AAALAC visitors in being concerned that Committee members may not find the time to provide an adequate review.

One can argue that the IACUC panel members are dedicated and concerned individuals who would generally provide the same degree of review in either an electronic or face-to-face meeting. It would seem to me that, if this were the case, it would take less time to resolve an issue in a face-to-face meeting than awaiting, reading, and responding to a series of emails. By extending the review and discussion process over a prolonged period of time, as you would have in an electronic forum, you would expect a loss of focus and commitment—unless, of course, everyone agreed with the primary reviewer.

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## Out of Sight, Out of Mind?



Tyrrel de Langley DVM

The AAALAC site visitors were justified in their concerns. The combination of heavy workload and human nature is such that some IACUC members may not thoroughly review all protocols brought to a con-

## Flexibility and Focus



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Research institutions should be attempting to advance their animal care and use programs, not only through proper veterinary care and advanced housing facilities, but

also in other areas of animal research, including administrative oversight. Therefore, Great Eastern is doing the right thing by attempting to keep in step with advances in communication technology. However, while there should be support for flexibility and growth, the bottom line must remain clearly in focus, lest it be lost in an ever-changing atmosphere.

So, what is the bottom line as it applies to the scenario presented here? The AAALAC site visitors were concerned that Great Eastern's IACUC was not fully complying with federal regulations concerning protocol approval "at a convened meeting of a quorum of the IACUC...", because they suspected that protocols were "given little, if any, review by most of the IACUC members..." This is a serious concern, because it jeopardizes one of the principal reasons for mandating that an IACUC be in place at every institution. That is, every research animal deserves to have a thoughtful review of the procedures for which it will be used in research. Institutions can achieve an effective review if every protocol is provided the kind of environment that is most conducive to thoughtful deliberation and interaction<sup>1</sup>.

More specifically, the point of an interactive discussion may be lost in Great Eastern's new review method. Regardless of a person's skill as an editor, everyone can miss important details in the protocol that need to be clarified or justified further. Moreover, a drug or proposed procedure may be acceptable to one reviewer and not to another, and it is only within a real-time discussion that the problematic areas are articulated and discussed in full by both parties. Having scientists with different expertises, as well as community members, on an IACUC serves this purpose. Conversely, a proposed procedure may be so standard to one Committee member (from a similar research field) that he or she may not consider refinements or replacements of that procedure. For these reasons and others, a deliberative atmosphere is necessary to ensure proper animal care and use.

Finally, although the purpose of the

electronic review process at Great Eastern is to reduce the IACUC members' workload and save time. However, it seems that the process creates more work for everyone involved. For example, each member is required to (1) read the first version of the protocol, (2) send comments and questions to the IACUC office, (3) read everyone else's comments, (4) respond to any other member's comment, if necessary, (5) read the final version of the protocol, and (6) email a vote to the IACUC office. It seems that every member is submitting a kind of pre-review with every protocol. Therefore, all members actually do more reading—and certainly more writing—over a longer time period. In addition, it is possible that comments and questions regarding each protocol could get lost in the shuffle of ongoing emails between IACUC members because of the extended time period for review and subsequent communication.

Both OLAW and USDA APHIS have issued statements that clarify the differences between acceptable and unacceptable circumstances for IACUC protocol review<sup>1,2</sup>. According to these statements, the methodology used by Great Eastern is not in compliance, because the 'virtual meetings' obliterate the deliberative atmosphere, which is a crucial component of the IACUC review process in the attempt to decrease administrative burden. However, it is important to note that there may be totally acceptable, yet new and undefined, ways of achieving these important elements of peer review that each IACUC is mandated to uphold. Maintaining a strong focus on what the role of the IACUC is does not mean there is only one way to achieve it. We should not be hesitant to look for better ways to achieve these goals.

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#### References

1. Garnett, N. & Potkay, S. Use of electronic communication for IACUC functions. *ILAR J.* **37(4)**, 190–192 (1995).
2. USDA APHIS. Electronic Communication. Animal Care Resource Guide. (April 2001). <http://www.aphis.usda.gov/ac/research-manual/18-8ELEC.PDF>.

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