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Is electronic approval appropriate?

Sometimes, a matter that appears to be trivial can initiate major disagreements. That is what happened after a monthly meeting of the Great Eastern University IACUC. Dr. Lawrence Covelli opened the meeting by asking for a motion to approve the minutes of the previous month's meeting. A motion was made and seconded, but Lana Phillippe, the IACUC administrator, whispered to Covelli that he had miscounted and there were not enough members present to make a quorum. "No problem," said Covelli, "we'll wait for a quorum and approve the minutes later on." When the quorum was present, Covelli began what turned out to be a long meeting, and by the time he remembered to ask for a vote on the minutes, members already were drifting out of the room, and once again, there was no quorum. Unbothered, Covelli said he would just poll the members by e-mail and get the minutes approved that way. That statement initiated his disagreement with Phillippe.

Phillippe was adamant that polling the committee for a vote on the minutes was unacceptable to both the US Department of Agriculture/Animal Care and the National Institutes of Health/Office of Laboratory Animal Welfare. Covelli was equally adamant that polling was only unacceptable under specific conditions, such as voting on the suspension of an animal activity or full committee review of a protocol. Covelli defended polling in other instances by using the Designated Member Review process as an example. Initially, the IACUC office would poll committee members to see if any person requested a full committee review. Phillippe disagreed with the comparison, saying that federal regulations did not require a full committee meeting to make that initial decision, because doing so would largely defeat the purpose of a Designated Member Review. She then reminded Covelli that both the Animal Welfare Act Regulations¹ and the Public Health Service *Policy on*

*Humane Care and Use of Laboratory Animals*² require the keeping of minutes of IACUC meetings and, therefore, any vote to approve, modify or disapprove the minutes should be made like any other IACUC vote: at a quorum of the full committee and not by polling members after the meeting ended. "Oh," said Covelli, now becoming sarcastic, "are you saying that I can't poll the committee to see if we should go ahead with an investigation of a complaint?" "That's right," countered Phillippe, "you cannot use polling as a means of getting an IACUC vote that is directly or indirectly mandated by federal regulations."

Who do you think is right: Covelli or Phillippe?

1. Animal Welfare Act Regulations, 9 CFR (Chapter 1).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

RESPONSE

Assurance should dictate

Ellen Teneriello, RVT, LATG, MA

Both the Animal Welfare Act Regulations (AWARs; section 2.35a-2.35f)¹ and Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*; section IV.E)² require institutions that use animals in research to keep certain types of records, including meeting minutes, attendance records, committee activities and deliberations, IACUC proposals and activities, semiannual reports and records of accrediting body determinations. The AWARs and PHS *Policy* do not include guidance on how the records should be created, but do specify that records

should be kept on file for at least 3 years. Additionally, the PHS *Policy* (section IV. A)² requires institutions who receive PHS funding to file an institutional Assurance with the Office of Laboratory Animal Welfare (OLAW), which should "fully describe the institution's program" for compliance with the PHS *Policy*, including "the procedures which the IACUC will follow to fulfill the requirements set forth in this *Policy*"². Similarly, each institution is left to establish its own procedures for voting on approval or disapproval of records such as meeting minutes; these should also be included in the Assurance.

The concern for Great Eastern University is the issue of polling. Representatives of OLAW wrote, "Polling is defined as sequential, one on one communication, either in person or via telephone, email, fax,

US mail or by other similar means. Polling is an appropriate mechanism for providing all committee members with the opportunity to call for full review of protocol review"³. They went on to indicate that polling does not satisfy the definition of a convened quorum³. Therefore, it is important that Great Eastern University's Assurance document includes a description about various forms of communication established and used by the IACUC, such as e-mail voting.

In my opinion, Covelli can call for an e-mail vote on the minutes as long as the e-mail is distributed to the entire IACUC and the records of that vote include any objections or minority views.

It is important to note that voting by e-mail cannot substitute for a convened meeting when it comes to matters such as a vote on animal use activity protocols. In

addition, if any IACUC member objected to the e-mail process of voting on meeting minutes, or if the process was not adequately described in Great Eastern University's Assurance, then Covelli would need to wait until the next fully convened meeting before the minutes could be approved.

1. US Department of Agriculture. Animal Welfare Act Regulations, 9 CFR (Chapter 1, Subchapter A, Parts 1, 2 and 3).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Garnett, N. & Potkay, S. Use of electronic communication for IACUC functions. *ILAR J.* 37, 190–192 (1995). <<http://grants.nih.gov/grants/olaw/references/ilar95.htm>>

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RESPONSE

Convened meeting for approval

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IACUC minutes are frequently inspected by US Department of Agriculture Veterinary Medical Officers during their unannounced visits and are also reviewed by site visitors from the Association for Assessment and Accreditation of Laboratory Animal Care as part of the accreditation process. Both Section 2.35 of the Animal Welfare Act (AWA)¹ and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*)² mandate that the IACUC maintain minutes (although neither document specifies that minutes must be reviewed and approved at convened meetings). The IACUC Meeting Minutes are thus an important regulatory document. Unlike the minutes of most ordinary societies, which record only the decisions taken at the meeting, the AWA and PHS *Policy* require that IACUC meeting minutes also record the deliberative process involved in reaching decisions² and document major issues discussed “in sufficient detail for an outsider to ascertain the nature of the discussion and the conclusions reached”³. It is therefore important that not only the facts but the nuances of the deliberations be recorded

accurately and in accordance with the recollections of a majority of the IACUC.

Covelli is correct in stating that both the AWA¹ and PHS *Policy*² specify only two IACUC actions that require a quorum at a convened meeting: full committee review and suspension of an activity. By convention, however, most IACUCs consider that all business with a regulatory mandate requires a quorum (e.g., conducting the semi-annual Program Review, categorizing deficiencies as major or minor, setting correction dates), as does all substantial business such as approving new policies. Reading and approval of the minutes is conventionally the first order of business at any meeting, according to Robert's Rules⁴; it is not an administrative activity but important official business of the Committee. It is unwise to begin a meeting without first reviewing and approving the minutes of the previous meeting, to remind IACUC members of the deliberations and decisions made at the preceding meeting that may have a bearing on the current meeting.

Covelli also draws an analogy to the polling process used for Designated Member Review. In the case of Designated Member Review (which is not used by all institutions), the IACUC must have made a decision in advance to adopt this procedure and to designate a Reviewer. In this case involving minutes, the IACUC has not previously discussed or adopted a formal policy authorizing approval of the minutes outside of a convened meeting. We believe that neither the AWA¹ nor the PHS *Policy*² would prohibit the IACUC from adopting such a policy but that in the absence of such a policy, minutes cannot be approved by this method. We also believe that it would be a bad idea to adopt the Designated Member Review polling model or a procedure of circulating and re-circulating drafts with iterative changes. In fact, if there is substantial debate about the content of the minutes, that discussion should be captured in the minutes of the subsequent meeting, per the AWA¹ and PHS *Policy*².

In sum, we believe that circulating meeting minutes ahead of time in order to collect feedback and comments to be discussed at the IACUC meetings is helpful and desirable but that the actual approval requires a majority vote of a quorum at a convened meeting. Polling outside of convened meetings, or in

the absence of a quorum, should be limited to Designated Member Review by previously approved IACUC policy or to non-business activities, such as eliciting feedback on meeting dates, times and lunch selections.

1. Animal Welfare Act Regulations, 9 CFR (Chapter 1).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions*. IACUC Composition, Functions and Authority, Question B-7. (US Department of Health and Human Services, Washington, DC, 2006; revised 2010). <<http://grants.nih.gov/grants/olaw/faqs.htm#b7>>
4. Robert, S.C., Robert III, H.M., Evans, W.J., Honemann, D.H. & Balch, T.J. *Robert's Rules of Order Newly Revised In Brief* p14 (Perseus Publishing, Cambridge, MA, 2004).

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RESPONSE

Quorum requires convened meeting

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Covelli is correct that there are only a few specified functions where a quorum is required by the Animal Welfare Act Regulations¹ or the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS *Policy*)²: full committee review of a research project (PHS *Policy* IV.C.2 and 9 CFR Part 2 subpart 2.31(d)(2)) and suspension of an activity (PHS *Policy* IV.C.6 and 9 CFR Part 2 subpart 2.31(d)(6)). However, it can be inferred from the regulations and communications by the regulatory bodies that approval of minutes by the IACUC requires a vote of a quorum at a convened meeting. This is because the IACUC is required to maintain “minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations” (PHS *Policy* IV.E and 9 CFR Part 2 subpart C 2.35 (a)(1)).

Ultimately, the question at hand goes back to what is considered acceptable electronic communication in order to meet

A word from OLAW and USDA

In response to the questions posed in this scenario, the Office of Laboratory Animal Welfare (OLAW) and United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offer the following clarification and guidance:

The Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) and the Animal Welfare Act and Regulations (AWARs) specifically require a convened meeting of a quorum of the IACUC to carry out full committee review and approval of a protocol and to review and vote to suspend an activity^{1,2}. The PHS Policy and the AWARs are silent on the steps required to approve IACUC meeting minutes. The PHS Policy and the AWARs state that the research facility shall maintain minutes of IACUC meetings, including records of attendance, activities of the committee and committee deliberations^{1,2}. OLAW and USDA expect IACUC members to be involved in assuring the accuracy of these documents, to correct identified errors and to certify that the records factually reference the discussions and outcomes regarding the proposals reviewed and the business conducted. IACUCs have latitude as to the steps taken to approve the final version of the meeting minutes. Some possible options include discussion at a convened meeting of a quorum, distribution by hard copy or electronically for concurrence or obtaining verbal concurrence by telephone after distribution of the document.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
2. Code of Federal Regulations, Title 9, Chapter 1, Subchapter A - Animal Welfare: Part 2 Regulations. (§2.31, 2.35).

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result of ‘full committee’ action” and “[t]hus, endorsement of final reports issued under the IACUC aegis should include the opportunity for full participation and the opportunity for minority views to be expressed and recorded. This function should normally occur at a meeting of a convened quorum of the IACUC”³. Therefore, although this is not specifically addressed in the PHS Policy, it is clear that the Office of Laboratory Animal Welfare has interpreted that it is important that all members have a chance to participate in the deliberative process for the final vote on committee reports, such as meeting minutes, so that accurate descriptions of the discussions and votes are reflected in the permanent record.

Therefore, in this case, it is my opinion that the IACUC administrator, Phillipe, is correct that activities by the committee that require a vote by a quorum must be done at a convened meeting and cannot be done by polling. As such, the minutes, because they are the official record of these activities, must also be approved at a convened meeting and not by e-mail polling.

1. Animal Welfare Act Regulations, 9 CFR (Chapter 1).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Garnett, N. & Potkay, S. Use of electronic communication for IACUC functions. *ILAR J.* **37**, 190–192 (1995).

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the requirement for a deliberative process. Garnett and Potkay, both formerly of the Office of Laboratory Animal Welfare, co-wrote an article on this subject in which they stated that the preferred method for meetings is to have all members present in the same room so that a full discussion could be conducted³. With the advent of technology, however, methods such as telephone or audio-visual conferencing may

be appropriate, provided that the institution’s Assurance allowed for this and that all members participating in the meeting are able to hear and interact with one another at the same time. What Covelli is suggesting, e-mail polling, is appropriate only for activities such as distributing and reviewing drafts of meeting minutes or reports. In addition, Garnett and Potkay also state that “all official IACUC reports are considered to be the