

Wilson's failure to respond in a timely manner does not negate the fact that the protocol was approved with the justification of animal numbers. The AWRs³ and the PHS Policy² do not require that all members must respond, only that all members are given the opportunity to do so. Again, the designated reviewers were satisfied with Ross's justification, and no other members objected to her proposal.

IACUC members do not vote on proposals reviewed by designated member(s) but have the opportunity to request full committee review. In keeping with the objectives of the DMR process, which include decreasing the load of protocols that must be reviewed by the full committee, deadlines for member response must be set to maintain order. The deadline should be set for a time when all members will reasonably be able to review the proposal and voice their opinion on its designation (5–7 days). The burden of answering committee-related correspondence lies with the individual members.

The PHS Policy² states that "applications and proposals that have been approved by the IACUC may be subjected to further appropriate review and approval by officials of the institution." Neither Covelli, as chairman of the IACUC, nor the Institutional Official is required by the regulations to revisit an approved protocol in response to the complaints of an IACUC member. I believe that to do so, especially with the conflict of interest concerns between Wilson and Ross, would be inappropriate; hence, Covelli handled the situation within the expectations and allowance of governing regulations.

1. Russell, W.M.S. & Burch, R.L. *The Principles of Humane Experimental Technique* (Methuen, London, 1959).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV, C, 2 and IV, C, 8 (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Animal Welfare Regulations. Sections 2.31, e, 1; 2.31, e, 2; and 2.31, d, 2 (2005).
4. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 10 (National Academies Press, Washington, DC, 1996).
5. Public Health Service. *Principle II. US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (US Department of Health and Human Services, Washington, DC, 2002).

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RESPONSE

Re-review not required

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This scenario invites deliberation of core issues brought forth by Wilson in the three assertions that comprised his formal request to the IACUC: (i) the justification of animal numbers, (ii) the function of Designated Member Review (DMR) and (iii) the right of an IACUC member to demand the re-review of an approved protocol.

Wilson disputed the number of animals requested by Ross because she had a previous protocol that utilized a similar assay but required only half as many animals. Institutions using animals regulated by the Animal Welfare Act and Animal Welfare Regulations¹ and submitting applications to the Public Health Service (PHS) are obligated to assure that proposals contain a rationale for the number of animals to be used². The direct application of animal numbers or group sizes from one protocol to another is inappropriate without giving consideration to the specifics of study design and statistics. Perhaps Ross' earlier protocol was a pilot study designed to arrive at a variance for application to future projects. Armed with that information, Ross might have requested additional animals in the current protocol to achieve statistical significance using that assay. Regardless, the reviewers were satisfied that the justification for the number of animals was scientifically sound, and their approval should be upheld.

Regarding Wilson's challenge of DMR approval, we presume that the IACUC acted within the procedures outlined in Great Eastern University's Assurance and that all IACUC members were given sufficient time to receive materials and request a full committee review². The fact that Wilson's travel prevented him from responding in a timely manner is unfortunate, but his failure to respond within the consideration period given may be interpreted as approval to use DMR for review.

Wilson also requested a re-review of Ross' protocol, claiming that this was within his rights as an IACUC member. Indeed, the IACUC's involvement with a project does not end with protocol approval. Both the Animal Welfare Act and Animal Welfare

Regulations¹ and the PHS Policy on Humane Care and Use of Laboratory Animals³ require the IACUC to carry out continuing review of a protocol no less than annually¹. Under certain circumstances, such as in situations of protocol non-compliance, the IACUC is also obliged to conduct an investigation. If warranted, the IACUC may convene to re-review the protocol and take appropriate action¹. In this case, however, there is no such basis for Wilson's request for re-review of the protocol. Furthermore, granting his request would supplant the authority of the IACUC and DMR process. At the time of annual renewal, Wilson would be free to review Ross' progress report and express any reservations at that time.

In conclusion, we believe that Covelli acted within the word and spirit of existing federal regulations.

1. Animal Welfare Act and Animal Welfare Regulations.
2. Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* (CRC Press, New York, 2000).
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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RESPONSE

IACUC should discuss

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It is our opinion that Covelli did not act within the word or spirit of existing federal regulations. Once a concern regarding an approved protocol was reported, Covelli should have called for a convened meeting of the IACUC to review the complaint. The committee should then follow established procedures for initial evaluation and actions. It was stated that Great Eastern University's policy granted the authority to determine whether any complaint warranted further investigation to the IACUC chair. This policy may be in error. If decisions regarding animal use and welfare are mandated to be considered by a committee, then allowing a