

Jerald Silverman, DVM, Column Coordinator

Should the chairperson control IACUC meeting minutes?

Dr. Richard Cornish was the new chairperson of the Great Eastern University IACUC. Cornish believed that his primary responsibilities were to get protocols approved and support the school's faculty. He was always looking for shortcuts to approve protocols and ways to sidestep regulations he believed to be potentially deleterious to the faculty. Therefore, it did not surprise anybody on the committee that Cornish wanted to suppress the dissemination of information about a faculty member who received a written rebuke from the IACUC for telling his staff to ignore any critiques originating from the IACUC pre-review process and just submit the protocol as it was originally written. Cornish did

not support the reprimand but it was nevertheless approved by the committee.

To prevent further harm to the faculty member, Cornish waited until the next IACUC meeting and then made a suggestion that seemed reasonable to some members. He proposed a policy that stated, "Minutes of IACUC meetings, including records of attendance, activities of the committee and committee deliberations shall be maintained by the IACUC. The chairperson shall review the minutes and append or redact any information therein judged to be omitted or superfluous." He explained that it was a federal requirement to maintain meeting minutes but there was no policy requiring the minutes to be approved by the IACUC, which had been

the previous procedure. Therefore, he said, his suggested policy would save time and effort for the committee.

The IACUC administrator and one other member spoke up against the proposal, arguing that everybody should be privy to the minutes and only the full committee should be allowed to approve any alteration of the minutes. Cornish forcefully defended his position, noting that the minutes are posted on a secure internet site where anybody on the committee could read them. He quickly called for a vote and the new policy was approved.

Do you think that the new policy would be acceptable to the appropriate federal regulatory and oversight agencies? How would you approach this situation?

RESPONSE

Flawed logic

Regina Correa-Murphy, BS, RLATG, CMAR

Cornish seriously erred in thinking his primary responsibility as the IACUC chairperson was to get protocols approved. Although supporting the faculty seems noble at first glance, looking for shortcuts to approve protocols and ways to sidestep regulations might cause more harm than good to Great Eastern University's research program. If left unchecked, this behavior has the potential to draw intense scrutiny by regulatory oversight agencies and animal rights groups and might also attract negative publicity. The negative attention could ultimately result in the closure of or withdrawal of support for the animal program, hindering faculty members' research projects and their ability to obtain federal government funding.

Furthermore, Cornish's suppression of the information about a faculty member's

reprimand was obstructive, especially if it involved a whistle-blower. This is a cause for concern for Great Eastern's leadership.

Cornish's policy allows him to use his personal and somewhat subjective view to determine what should be omitted or considered superfluous; this goes against the IACUC's primary responsibility: the assessment and oversight of the institution's animal program components and facilities^{1,2}. Cornish's use of his position as the chairperson of the IACUC to alter policy that was approved by the duly composed IACUC by intimidation is coercive, and the forcing of a vote without allowing dissenting opinions to be acknowledged or even recorded can be considered an abuse of his role. Both the Animal Welfare Act² and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*³ state that the IACUC minutes require records of attendance, activities of the committee and committee deliberations. Those minutes should provide sufficient detail, including

dissenting opinions. Most institutions keep these records confidential by limiting access to IACUC members and oversight agencies that need to review and assess the animal care and use program.

Once this policy is reviewed by federal regulatory and other oversight agencies, Cornish and Great Eastern will have to answer some very difficult questions. Why are the minutes not reflective of the discussion including any dissenting IACUC members' views? What other shortcuts have been taken by investigators?

1. Institution for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
2. Animal Welfare Act. 9 CFR.
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV, E, 1, b (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

Correa-Murphy is Administrative Officer, Research and Development, Providence Veterans Affairs Medical Center, Providence, RI.

RESPONSE

Consider a compromise

Mary E. Martin, DVM, MPH, DACLAM & Christine A. Bellezza, DVM

Cornish is correct that federal regulations do not specify that meeting minutes must be approved by the full IACUC. He is also correct that the Animal Welfare Act Regulations (2.35 (a)(2))¹ and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (IV, E.1.b)² do specify that minutes of IACUC meetings, including records of attendance, activities of the committee and committee deliberations, shall be maintained by the IACUC. We presume that the decision to send a written rebuke to a faculty member from the IACUC for ignoring IACUC critiques in the pre-review process was a committee deliberation. An argument can be made that this information must be included in the minutes since the reprimand arose from a committee decision. We do not find it acceptable—and doubt that regulatory

agencies would find it acceptable—for the IACUC chairperson to singlehandedly and permanently remove information concerning a committee deliberation from the minutes. If committee members have no opportunity to revise the minutes after the IAUC chairperson alters them, then Cornish’s policy would seem to contradict the spirit, if not the letter, of the law.

Compromise might be possible between Cornish and the IACUC administrator and members who believe that the full committee should be allowed to approve the minutes. The chairperson wants to exclude information from the minutes to spare possible harm to the faculty member. Minutes are considered records that might be subject to disclosure under the Freedom of Information Act³. Federal law does not specify that names of individuals involved in discussions must be included in IACUC meeting minutes. It might be possible to protect the faculty member’s anonymity by referring to him by a generic title or code or by simply mentioning that the committee discussed the issue of investigators choosing to ignore IACUC pre-review comments.

(As an aside, there is no law that investigators must respond to pre-review comments. However, if, on review, the IACUC agrees with the comments, approval of the protocol can be withheld until the revisions are made.) As part of the compromise, all IACUC members should have access to the minutes on a secure website and should be able to request alterations if they believe that relevant information has been omitted. Members should also be able to request deletion of material that does not fall within the guidelines (e.g., records of attendance, activities of the committee and committee deliberations), particularly if the information is of a sensitive nature. By working together, the chairperson, IACUC administrator and IACUC members can come to an agreement to protect sensitive information while providing the required information in the IACUC minutes.

1. Animal Welfare Act and Animal Welfare Regulations. 9 CFR.
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).

A word from OLAW and USDA

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

The scenario asks two questions: whether the IACUC must approve the minutes of its meetings and whether it is acceptable for a committee member to alter the minutes without IACUC input. The Animal Welfare Act regulations and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* provide identical requirements on IACUC meeting minutes. Specifically, research facilities are required to maintain “minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations”^{1,2}. The minutes should document major issues discussed by the IACUC and the outcomes in sufficient detail for an outsider to ascertain the nature of the discussion and the conclusions reached without compromising security, privacy or proprietary information³.

Previous guidance on IACUC meeting minutes⁴ is applicable to this scenario. OLAW and USDA expect IACUC members “to be involved in assuring the accuracy of the minutes, to correct identified errors and to certify that the records factually reference the discussions and outcomes regarding the proposals reviewed and the business conducted”⁴. The guidance provides latitude on possible options to approve the final version of the minutes, which 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 document⁴. An environment of censorship created by the IACUC’s new policy is not in keeping with OLAW and USDA’s expectations for a cooperative and engaged committee.

1. Animal Welfare Act and Regulations. Code of Federal Regulations. Title 9. Section 2.35 (a).
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 No. B.7. (US Department of Health and Human Services, Washington, DC, 2006, revised 2013).
4. Brown, P. & Gipson, C. A word from OLAW and USDA. *Lab Anim. (NY)* 39, 299 (2010).

Patricia Brown, VMD, MS, DACLAM
 Director
 OLAW, OER, OD, NIH, HHS

Chester Gipson, DVM
 Deputy Administrator
 USDA, APHIS, AC

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- Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 3rd edn. (CRC Press, Boca Raton, FL, 2014).

Martin is Chief, Veterinary and Educational Services, Center for Animal Resources and Education, and Bellezza is Senior IACUC Administrator, Office of Research Integrity and Assurance, at Cornell University, Ithaca, NY.

RESPONSE

Recipe for disaster

Mandy J. Kozlowski, BA, CPIA & Stephen I. Levin, DVM, PhD, DACLAM

Cornish's new policy is a recipe for disaster. Both the Animal Welfare Act and Regulations¹ and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*² require that IACUCs maintain meeting records that include committee deliberations. This requirement is further reiterated in the *Guide for Care and Use of Laboratory Animals*³. The US Department of Agriculture, the Association for Assessment and Accreditation of Laboratory Animal Care International and potentially the Office of Laboratory Animal Welfare use the IACUC's meeting minutes to gauge the level of engagement by the committee and to determine how the IACUC responds to issues brought before it. Therefore, the minutes should clearly

reflect the deliberations of the committee. Regulatory bodies could misconstrue the new policy as an attempt to hide important information, which could lead to increased scrutiny by regulators.

Cornish is overstepping the bounds of his duties as chairperson with the proposal of his new policy. Not only does this policy give him authority that is not specified in any of the regulations, but it also has the potential to take a voice away from committee members who have opinions that differ from those of the chairperson or the majority.

Because the regulations do not specifically require approval of the minutes, institutions use best practices to guide procedures in this regard. A common best practice includes review and approval of the previous meeting's minutes by the full committee. This includes any changes to the minutes, as well as a report of redacted or corrected information reported to the committee. Many institutions redact identifying information from IACUC minutes, but in an effort to remain transparent, the minutes should still be reviewed and approved by a majority of the members that attended the meeting.

In this instance, Great Eastern University approved Cornish's new policy. But the policy should be revised to put specific limitations on what the chairperson is allowed to change or redact (e.g., researchers' names or protocol numbers). Additionally, this policy should be revised to require review and approval of the minutes by

the full IACUC to ensure that Cornish is complying with the revised policy and that Great Eastern University is meeting the regulatory requirements for record-keeping.

As a last resort, the Institutional Official (IO) should be made aware of Cornish's actions and the potential consequences of those actions. Each IACUC and administrative staff member should have a direct line of communication to the IO. The committee member who was opposed to Cornish's policy should submit a minority view with the semi-annual report to the IO as well. Each member is entitled to his or her opinion, and use of the minority view allows each member an opportunity to have that opinion heard. This can be a very effective tool for preventing Cornish from controlling the committee, as minority views must be included in the report to the IO and are accessible to the regulatory bodies^{2,3}.

- Animal Welfare Act Regulations. 9 CFR. Part 2, Subpart C.
- Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV, E, 1, b (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
- Institution for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

Kozlowski is Post-Approval Monitoring Program Administrator, Institutional Animal Care and Use Committee, and Levin is Director of Clinical Operations, Center for Comparative Medicine, at Northwestern University, Evanston, IL.