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Expediting assignment of protocol reviewers

The IACUC at Great Eastern University put into effect many new policies to help implement recent guidance from the National Institutes of Health supporting the use of performance standards and professional judgment to reduce the regulatory burden when changes to IACUC-approved protocols were requested¹. One such policy was only tangentially related to the guidance as it was designed to facilitate the assignment of protocol reviewers. The policy stated that protocols destined for full committee review (FCR) would have a primary reviewer assigned by the IACUC chairperson to present the study to the full committee. Those protocols intended for designated member review (DMR) would have one or more reviewers assigned by the chairperson. If a requested modification to the protocol required

IACUC review, the original DMR reviewers would carry out a new DMR (if DMR would be used to review the modification), and the original presenter of an FCR protocol would carry out the same task if FCR would be used to review the modification. The committee unanimously voted to approve the policy as it would expedite the protocol review process.

One person who was not in agreement with this policy was the IACUC manager, a non-voting participant at the meeting. In her opinion the school's policy contradicted the Animal Welfare Act regulations (AWARs)² and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals (PHS Policy)*³, both of which stated that the IACUC chairperson had to assign designated member reviewers. She believed that meant a new DMR

reviewer assignment had to be made. The chairperson and the attending veterinarian disagreed with her, stating that the school's new policy was fully compliant with the AWARs and the PHS *Policy*.

What is your opinion? Is the university's new policy compliant with the AWARs and PHS *Policy* or did the committee, in its eagerness to save time, approve a policy that should not have been approved?

1. National Institutes of Health. Guidance on significant changes to animal activities. Notice NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).
2. Animal Welfare Act regulations. 7 U.S.C. 2131-2159. §2.31, d, 2.
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals IV, C, 2* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

RESPONSE

Compliant but not complete

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As members of a large institution with an IACUC that reviews over 1,000 protocols and protocol amendments a year, we understand the motivation behind Great Eastern University's decision. In theory, we think it could be an appropriate and efficient solution. The original reviewers or presenter of a protocol were likely chosen by the IACUC chairperson because they were qualified to carry out the review¹, so it stands to reason that the same individuals would be among the best qualified to review the protocols again in the future if they were subject to significant change. But we think that Great

Eastern's policy should include statements indicating that the chairperson can deviate from this policy as he or she deems appropriate, that a full committee review (FCR) can be called by any designated reviewer and that all IACUC members will still have the opportunity to call for a full review should they see fit¹. It is not clear from the scenario whether these concepts are implied in the new policy.

The additional language would allow flexibility in instances where the policy would be inappropriate, inefficient or cumbersome. For example, the Public Health Service *Policy on Humane Care and Use of Laboratory Animals (PHS Policy)* states, "No member may participate in IACUC review or approval of a project in which the member has a conflicting interest...except to provide information..."². We can envision a situation in which conflict of interest did not exist during the approval process but developed later owing to a new collaboration. It is also conceivable that extenuating circumstances like extended medical leave could prevent

the original member from reviewing a protocol modification in a timely manner. Flexibility in this policy would also allow equitable distribution of protocol review responsibilities and prevent any member from becoming overburdened. Finally, significant change requiring protocol review can encompass many modifications such as a change in species, experimental manipulations or procedures that could affect personnel safety³. It is therefore possible that the original reviewer or presenter is no longer the best person on the committee to carry out the designated member review (DMR) or present the change for FCR.

Additionally, as this policy is put into practice, the quality of the reviews should be monitored, as continuous review by the same person could lead to complacency over time. Assignment to a new reviewer could add a fresh perspective and provide for a more thorough review. Furthermore, this new institutional policy should be described in the institution's Assurance

with the Office of Laboratory Animal Welfare (OLAW).

We feel the policy should be acceptable, with the changes suggested here, as it was unanimously agreed upon in writing by all committee members. This approval process is endorsed by OLAW for establishment of DMR subsequent to FCR for approval of protocols requiring modifications and supported by a guidance statement relating to reducing regulatory burden⁴. Most importantly, it is our view that nothing in this institutional policy goes against the Animal Welfare Act regulations or the PHS Policy, both of which allow any IACUC committee member to call a protocol to FCR^{1,2,5}.

1. Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 2nd edn. 121–124 (CRC Press, Boca Raton, FL, 2007).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals IV, C, 2* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. National Institutes of Health. Guidance on significant changes to animal activities. Notice NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).
4. National Institutes of Health. Guidance to IACUCs regarding use of designated member review (DMR) for animal study proposal review subsequent to full committee review (FCR). Notice NOT-OD-09-035. (National Institutes of Health, Washington, DC, 8 January 2009).
5. Animal Welfare Act regulations. 7 U.S.C. 2131-2159. §2.31, d, 2.

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RESPONSE

Overly cautious IACUC manager

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IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after full committee review (FCR) or designated member review (DMR)¹. It appears that Great Eastern University is looking to streamline this process by maintaining the same DMR reviewers or FCR presenter for the life of the protocol.

The DMR process was implemented to facilitate research. It is the responsibility of

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 describes an IACUC policy to reuse the same reviewer for protocol modifications that had been previously assigned as either primary reviewer for full committee review (FCR) or designated reviewer for designated member review (DMR). The scenario considers whether the policy is compliant with the Animal Welfare Act and regulations (AWARs) and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy). The AWARs and the PHS Policy have similar requirements regarding the review of protocols or amendments. Any member can request a FCR, but if FCR is not requested, at least one member can conduct a DMR. This member is appointed by the IACUC chairperson and qualified to conduct the review. The only decisions arising from a DMR are to approve, to require modifications (to secure approval) or to request FCR^{1,2}.

Although it may be a common practice, assigning a primary reviewer to present a protocol during FCR is not described in the AWARs or the PHS Policy. The IACUC has flexibility to use such a practice and may consider the continued service of this reviewer for continuity both when significant changes to the approved protocol are requested and if DMR subsequent to FCR is needed to address IACUC-required modifications. There are a variety of ways to have the reviewer for DMR designated by the chairperson, including creating a policy such as the one described. Use of a rotational list of reviewers approved by the chairperson and based on identified expertise is another practice to improve efficiency of the appointment. The policy should allow for necessary changes to a future assignment created by a conflict of interest or unavailability while ensuring that the member assigned is qualified to conduct the review. Appointment of a vice chairperson to assign reviewers in the chairperson's absence is another mechanism to increase efficiency.

1. Animal Welfare Act Regulations. 9 CFR §2.31(d)(2)
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals IV, C, 2* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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the IACUC to determine how the process will be executed at an institution, ensuring that the process follows the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) and is documented in their Animal Welfare Assurance. If the entire IACUC has agreed to the procedure of retaining the same reviewers or presenters of a protocol to review or present any changes to that protocol and if the procedure has been updated in Great Eastern's Assurance and the IACUC's standard operating procedures, then the policy should be upheld. I emphasize that the entire IACUC should approve this procedure. It should be voted on at a convened meeting, and absent members should have the opportunity to provide their input. At my facility, all IACUC members approved the DMR process when

it was instituted to ensure that everyone agreed with the process.

In the case of FCR, maintaining the same presenter adds continuity to the process, and he or she should be familiar not only with the protocol but also with the principal investigator and therefore be able to ask more detailed questions. The protocol and any changes will be reviewed by a quorum of the IACUC.

In the case of DMR, all voting committee members should have access to "written descriptions of research projects that involve the care and use of animals" and have the opportunity to "request full committee review of those research projects" in accordance with PHS Policy².

In my opinion, the IACUC manager is being overly cautious. As long as the new

policy is in keeping with existing IACUC policies and the PHS *Policy* and was not made solely by the IACUC chairperson and attending veterinarian, but by a fully convened IACUC, it upholds the intention of the law. It will be the IACUC manager's responsibility to ensure that the assigned presenter or reviewers are able to complete the review. Committee membership changes, investigators are busy and people take time off, sometimes for extended periods. The biggest problem with this policy would be a delay in approval resulting from the lack of a reviewer.

1. National Institutes of Health. Guidance on significant changes to animal activities. Notice NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals IV, C, 2* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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RESPONSE

Laws should reflect reality

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Great Eastern's IACUC should be commended for trying to establish a policy that saves time and meets the spirit of the laws governing the use of research animals. The policy might seem like a reasonable

solution, but in our experience, it would not be acceptable because the reviewers for each modification to be reviewed by designated members (notwithstanding that they would be the same individuals who reviewed the original protocol) were not assigned by the IACUC chairperson.

Both the Animal Welfare Act regulations¹ and the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*² (PHS *Policy*) require that the IACUC chairperson assign the reviewers for designated member review (DMR) of protocol modifications. In considering Great Eastern's dilemma, however, we wondered whether it might be time to revisit this requirement.

Many research institutions do not have a dedicated IACUC chairperson. Instead, most IACUC chairpersons are individuals with multiple demands on their time. Many are investigators themselves responsible for their own laboratories. Depending on the type of institution in which they work, they may also have responsibilities with regard to teaching, multiple committee responsibilities, required participation in National Institutes of Health study sections and clinical responsibilities. Waiting for a response from an IACUC chairperson could waste precious time.

The research community needs to consider whether the research environment is the same now as it was when the laws were first passed. We suggest that things have changed and that flexibility is needed to meet the spirit of the law without compromising the health and wellbeing of the animals. It has been almost 50 years since the

passage of the Laboratory Animal Welfare Act, known to us now as the Animal Welfare Act, and more than 40 years since the passage of PHS *Policy*, and both have had many revisions. Have any revisions ever modified the requirement for the IACUC chairperson to assign DMR reviewers?

We feel it is time for the laws to recognize a role in addition to the institutional official, the attending veterinarian and the IACUC chairperson—that of the IACUC administrator. A half century ago, when the current laws and policies were being written, there was no such role; now, the Certified Professional IACUC Administrator is a recognized profession with certification through the national organization Public Responsibility in Medicine and Research. The IACUC administrator of an organization would be the individual best placed to provide assurance that the requirements of the laws are being met. An IACUC administrator is qualified to determine appropriate assignments using his or her knowledge of the regulations, institutional IACUC policies and the expertise of individual IACUC members. Recognizing and utilizing an IACUC administrator to his or her full potential would be a great benefit to our field. This scenario is just one example.

1. Animal Welfare Act Regulations. 7 U.S.C. 2131-2159. §2.31, d, 1, xi, 2.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals IV, C, 2* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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