

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