

The change to IACUCs is in the formalizing of the proxy process, by having ‘written standard procedures’ that members have agreed to ‘in advance and in writing’ about deferring authority to their committee colleagues to make appropriate decisions on investigator responses to FCR requests.

We believe that the circumstance, described in NOT-OD-09-035 (section #2.a)², will serve to expedite the timeline for protocol approval in the periods between convened full committee meetings. The duties that IACUCs have—specifically, to facilitate institutional animal research programs while ensuring that thorough reviews of proposed animal care and use have been conducted—will be carried out in a more timely manner through the process of DMR subsequent to FCR. At no point does this guidance disallow any IACUC member from requesting to see correspondence for a particular animal protocol. The PHS Policy¹ maintains that ‘any member of the IACUC may obtain, upon request, full committee review of research projects’.

Additionally, Covelli’s assertion regarding approval of ‘required modifications’ is correct. If it is determined that a protocol requires very specific modifications before approval can be granted, the IACUC may handle the approval of these modifications or clarifications as administrative details that an individual, such as the Chair, could verify³. As with the formalization of DMR subsequent to FCR, this should be a ‘written standard procedure’.

In conclusion, while many animal care and use committees, including that at Great Eastern University, may already have institutional and administrative mechanisms in place to handle DMR and FCR, the NIH guidance asks that a formal standard operating procedure, signed by all members, be maintained for those institutions who hold meetings with only a quorum (and not all members) present.

Notice NOT-OD-09-035. (National Institutes of Health, Washington, DC; 8 January 2009). <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-035.html>

- Office of Laboratory Animal Welfare. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. (US Department of Health and Human Services, Washington, DC, 2002).

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RESPONSE

A time-saver

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Covelli and White are struggling over the meaning of “requires modification (to secure approval)¹.” This is demonstrated by White’s statement: “It seems to me that having a question for a PI and requiring modifications to secure approval are not one and the same.” They appear to be creating an artificial distinction between “required modifications” and “having questions,” which does not exist within the regulation. PHS Policy¹ allows for only three possible responses by the IACUC during a protocol review: “... approve, require modifications in (to secure approval) or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals as specified in IV.C of this Policy.”

More troubling is Covelli’s statement: “If the PI agrees to accept the required modification and revises the protocol to include it, the protocol can be administratively accepted.” As indicated in background section of NOT-OD-035, “PHS Policy does not allow for ‘approved pending modification’¹ and does not recognize this approval designation.” This is, in essence, what Covelli has described. Additional guidance on acceptable items for administrative review or acceptance can be found on the OLAW website FAQ page².

In the end, Covelli hits on the true benefit of NOT-OD-35: “Maybe it’s just a time-saver.” This notice outlines a process

whereby the IACUC can establish a method to send a protocol directly from FCR to DMR without the delay caused by polling members to see if they wish to call for FCR.

- Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
- Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions*. Protocol Review, Question No. 9. (US Department of Health and Human Services, Washington, DC, 2006; revised 2009). http://grants.nih.gov/grants/olaw/faqs.htm#proto_9.

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RESPONSE

Not a shortcut

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We believe that Covelli’s explanation of what constitutes a required modification is too narrow. Anytime the IACUC requires a PI to change what is written on the protocol form, it is essentially requiring a modification. Covelli is also incorrect in believing that the examples of modifications he describes can be accepted administratively. OLAW’s FAQ #4 under ‘Protocol review’¹ states that “requests for substantive modifications should result in the protocol coming back to the committee.” The same FAQ also uses a contact telephone number as an example of a modification that may be verified administratively. Because Covelli’s examples are substantive, they are not modifications that should be verified administratively. The IACUC encounters many scenarios during a protocol approval process; therefore, training members of the IACUC as well as administrators in what constitutes a substantive change is essential.

We also feel that the notice does not confuse questions with required modifications. The notice is intended to address both of these issues. The notice

- Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
- Office of Laboratory Animal Welfare. *Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR)*.