

pliance. *Contemp. Top. Lab. Anim. Sci.* 40(6), 8 (2001).

2. 9 CFR, Subchapter A.

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## The More Emails, the Better

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PHS *Policy* outlines the procedure for Designated Member review of IACUC protocols, stating that the IACUC Chair may select one or more members qualified to review the protocol. The Designated Members act on behalf of the entire IACUC to approve the protocol, request additional information from the PI, or to refer it for a Full-Committee review. There are, however, no specific guidelines for the emailing of Designated Member approval. Each IACUC must devise a comprehensive system to satisfy all possible contingencies and comply with federal regulations. I agree not with the IACUC's decision to have a PR email approval to the IACUC office, but rather with the IACUC Administrator's request that each DR email his or her approval to the IACUC office. I feel that the IACUC office must have some documentation from each reviewer that they do indeed approve the protocol. The IACUC Administrator has a valid fear that a case could arise in which an approval is recorded while one of the DRs did not truly believe they had approved it. We are all familiar with downed servers and the failure of some emails ever to arrive. What if the PR sends the approval email to the IACUC office with copies to each Designated Member, but the one member who did not truly feel he or she approved the protocol is not in the office that day, or does not receive the email right away? It is much easier to catch the dissent before approval is recorded, than to have to rescind a protocol approval. Is it that difficult and time consuming for each DR to email the IACUC office rather than the PR?

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## KISS and Redesign

**Susan R. Blumenthal, PhD**

The problems facing Great Eastern's IACUC are not unique to their institution or the use of electronic communications. Although the use of electronic communications in IACUC processes and procedures is relatively new, they do not fundamentally change regulatory requirements for these processes and procedures. Under PHS *Policy* and AWA/USDA Regulations, there are two acceptable methods of protocol review—Full-Committee review and DR review—both of which are specifically described. It is not clear whether the protocols are being handled properly by allowing for any member of the Committee to call for Full-Committee review before assignment of the protocol to the DR process. However, for the purposes of this discussion, we will assume that the Committee has properly assigned the protocols.

Although the primary concern of the Committee was about the details of expression of agreement among the DRs and the PR for protocol approval when communications were conducted electronically, this

is a minor issue that is amplified by the awkward system currently in use. The authenticity of the electronic communications is not in question in this situation, as they are in most problems using electronic communication as part of the review process; instead, it is the lack of documentation being provided to the Committee, a concern about the absence of the usual full and open communication among all of the DRs, the PR, and the Administrator, and the use of an overly complex, quasi-legitimate process that is creating the problem.

Regulations do not require full and open communication among the DRs, nor do they require a PR. Regulations do require that one or more DRs be appointed by the Committee to review a protocol. The DRs can then either approve the protocol or refer the protocol for Full-Committee review; they cannot reject a protocol or withhold approval. In addition, not only must all DRs approve or require the same modifications, but all DRs must also review each revision of the protocol. The Great Eastern system is not fully satisfying these requirements.

DRs do not function as true DRs, but act as a subcommittee performing a prereview of the protocol, which is forwarded to a PR, who then functions as a facilitator of the prereview and/or as a true DR. The DRs do not seem to have final authority on approval or referral to Full-Committee review of a protocol (that seems to be indirectly under the

### 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 clarification and guidance:*

IACUC communications can be complex. USDA regulations and PHS *Policy* allow the IACUC Chair to designate (if Full-Committee review has not been requested by any IACUC member) at least one qualified IACUC member to review research projects involving the care and use of animals. The phrase "primary reviewer" does not exist in regulation or policy. Each Designated Reviewer has the authority to approve, require modifications in (to secure approval), or request Full-Committee review. If any Designated Reviewer calls for Full-Committee review, then the protocol must go to Full-Committee review. If modification of the protocol occurs at any stage of the review, all Designated Reviewers must see and approve the changes. If each Designated Reviewer approves the protocol they must all reference the same version of the protocol. All Designated Reviewers' approvals, requests for modifications, or calls for Full-Committee review must be documented.

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