

OLAW penalties should be denied, and the ruling called by OLAW will stand.

1. Potkay, S., Garnett, N.L., Miller, J.G., Pond, C.L. & Doyle, D.J. Frequently asked questions about the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*. *Lab Anim.* (NY) **24(9)**, 24–26 (1995).

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**RESPONSE**

**Don't ignore the proposal**

**Michael D. Mann, PhD**

According to Section IV.D.2 of the PHS *Policy*, “Applications or proposals (competing and non-competing) covered by this *Policy* from institutions which have an approved Assurance on file with OLAW shall include verification of approval (including the date of the most recent approval) by the IACUC of those components related to care and use of animals . . . . If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification shall state the modifications, if any, required by the IACUC.” Of this section, the only part modified in 2002 by the advent of “just-in-time” verification is the timing of the required submission. “The existing PHS *Policy* requirement that modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval remains in effect, and it remains the responsibility of institutions to communicate any IACUC-imposed changes to NIH staff”<sup>1</sup>. Thus the nature of the submission is unchanged by this procedural alteration.

PHS *Policy* does not state how the IACUC is to review and approve the animal care and use components of the grant proposal—whether to review the grant proposal itself or compare it with an approved IACUC protocol. In a national IACUC meeting, Nelson Garnett, at that time the Director of OLAW, indicated that OLAW does not care whether an institution uses protocols or not. What OLAW wants to know is that the IACUC reviewed and approved the animal

care and use aspects of the grant proposal. Clearly, Great Eastern had an obligation to either review the grant proposal or compare it with the IACUC protocol and to report to the NIH changes required in the protocol to obtain approval; in this scenario, the IACUC did neither.

The specific changes required by the IACUC in the protocol would probably not have caused a mismatch between the proposal and the protocol if a comparison had been made. NIH grant proposals often do not specify either the number of animals or the care before and after the proposed procedure. On the other hand, a thorough comparison should have detected procedures in the grant proposal not in the protocol. It is not unusual for a protocol to contain procedures that are not in the proposal, and this is normally not a cause for alarm. It is common in our institution for protocols to contain studies covered by more than one grant proposal. Such procedures could cause alarm if the investigator attempted to pay for them using money from this grant. However, if the investigator considered the change in species to be part of the grant proposal, then this may constitute a noncompliance. OLAW has made it clear that it considers a change in species to be a significant change<sup>2</sup>.

Many IACUCs neither review grant proposals nor compare them with IACUC protocols. Rather, they rely on the investigator’s statement that they correspond. Our experience is that nearly 25% of the time this would lead to a ‘false’ verification of the approval. Perhaps that is the error made by the IACUC. A recent survey indicates that Great Eastern is not alone in “playing with the rules.” In the survey 30% of respondents indicated that their institutions regularly act similarly (M.D.M. and E.D. Prentice, unpublished observations).

It is unclear what would have happened to the IACUC’s report had it made such a report. Although the PHS makes policy, it is the responsibility of the individual institutes to implement it. There does not seem to be a written policy what will happen if the IACUC demands changes in a project once it has been reviewed and just-in-time verification has been requested. Grants administrators at the NIH also seem uncertain about it.

1. NIH. NOT-0D-02-064. Laboratory animal welfare: change in PHS Policy on Humane Care and Use

- of Laboratory Animals. (8 August 2002)
2. Potkay, S., Garnett, N.L., Miller, J.G., Pond, C.L. & Doyle, D.J. Frequently asked questions about the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*. *Lab Anim.* (NY) **24(9)**, 24–26 (1995).

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**RESPONSE**

**Modular doesn't apply**

**Michele Cunneen, BA, LATg & Regina Correa-Murphy, RLATg, CIP**

Great Eastern’s assertions that these changes did not need to be communicated to OLAW because of the inherent flexibility in the Modular Grant System may show a lack of knowledge about the system, or they may be trying to deflect the responsibility for an error in their reporting to OLAW. The intent of the modular system is to minimize rebudgeting, forecasting, and adjustments by providing noncategorical, total direct cost awards in modules of \$25,000. These modules permit flexibility in how the money is spent, eliminating the need for line item rebudgeting. Therefore, under the modular grant system, Markowitz would not have had to rebudget the animal line item from mice to rats or to notify NIH of the change. This applies only to the finances. Nowhere in the modular grant process is there a modification or modularization of the reporting requirement with respect to “just-in-time” IACUC approval.

The other area in which Great Eastern appears not to understand reporting requirements is in the IACUC review process, in which the IACUC protocol must correspond to the grant submission. Although the OLAW does not require a direct review and matching, “PHS *Policy* (IV.D.) requires the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. This position is reiterated in NIH Grants Policy Statement under Part II, Terms and Conditions. Most institutions have developed an IACUC protocol form and require investigators to provide detailed information about the proposed use of the animals on this