

RESPONSE

Amendment necessitates re-review

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During the course of a research project, a need may arise for the investigator to submit to the IACUC an amendment to the animal research protocol for that project. This may occur when there is a significant change in the original protocol, to include but not be limited to the number of animals used, personnel changes and additional procedures or tests. According to the *IACUC Guidebook*¹, “significant changes to an IACUC-approved protocol must be reviewed and approved before they occur (PHS Policy IV.C.1; and AWR §2.31[d][1])” or are implemented. The review can be done by the full committee or by a designated member.

White was questioning whether the submission of an amendment warrants a complete re-review of an already approved protocol. In response to this, the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*² (PHS Policy) requires that a complete IACUC review of PHS-supported protocols be conducted at least once every three years beginning on the date of IACUC approval. The triennial review can be done by the full committee or by a designated member. On the other hand, the Animal Welfare Regulations (AWRs) require an annual review³. In either case, we know that all research activities must conform to the statutes of the Animal Welfare Act³ and the guidelines of the PHS as described in the *Guide for the Care and Use of Laboratory Animals*⁴ (the *Guide*). Depending on when White’s original protocol was approved by the Great Eastern University IACUC, and whether the approval was to comply with both the PHS Policy and the AWRs, it might be necessary to completely re-review her protocol.

The designated reviewer chosen by the IACUC thought it was necessary to review White’s entire protocol. Covelli understood the prerogative of a designated reviewer and

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:

The question raised in this scenario is: “When an amendment to a protocol is submitted by an investigator, does the reviewer have the authority under federal regulations to re-review sections of the protocol, in addition to the amendment?”

Section IV.C.5. of the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) authorizes the IACUC to conduct continuing review of previously approved ongoing activities¹. This includes reviews conducted during designated member review of an amendment to a previously approved protocol. Section IV.C.1. of the PHS Policy also requires that the IACUC determine that the research project conforms to requirements for procedures to avoid or minimize discomfort, distress or pain unless justified for scientific reasons¹. The reviewer is within his or her authority to re-review any sections of the protocol in addition to the amendment.

For those species under the jurisdiction of the USDA, section §2.31(d)(1) of the Animal Welfare Regulations (AWRs) give the IACUC authority to “conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter”². This authority includes designated member reviews and is not limited to just the activities described in a proposed amendment; it applies to all “components of the activities related to the care and use of animals.” In addition, all reviews are required to address the criteria listed in section §2.31(d)(1) of the AWRs, including the requirement to avoid or minimize discomfort, distress and pain to the animals². The AWRs under section §2.31(d)(5) also allow the IACUC to “conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually”². Complete reviews conducted during a designated member review of an amendment to a previously approved protocol are well within the IACUC’s authority. It is also within the IACUC’s authority to determine the intervals at which such reviews are conducted.

1. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington DC, 1986; amended 2002).
2. Code of Federal Regulations. Title 9, Ch. 1, Part 2, Subpart C.

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the authority granted to him or her by the IACUC to make sound judgment for the benefit of animal welfare and good research. Therefore, in our opinion, it is fitting to re-review the entire protocol in addition to the submitted amendment if the entire IACUC or the designated reviewer determines that it will conform to the statutes of the Animal Welfare Act and the guidelines of the PHS as issued in the *Guide*.

2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington DC, 1986; amended 2002).
3. Animal Welfare Act and Animal Welfare Regulations. 9 CFR Ch.1 §2.31[d][1].
4. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

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1. ARENA/OLAW. *Institutional Animal Care and Use Committee Guidebook* 2nd edn. (National Institutes of Health, Bethesda, MD, 2002).

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