

RESPONSE

Report a suspension

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Protocol violations that involve significant deficiencies need to be reported to OLAW, regardless of whether or not the Principal Investigator (PI) acknowledges the problem and corrects it herself. The PHS Policy on Humane Care and Use of Laboratory Animals¹ defines a significant deficiency as “one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.”

In this scenario, a USDA-regulated species (hamsters) was involved in the

protocol violation. The APHIS/AC report must include this event because it is a significant deficiency and the Animal Welfare Act (AWA)² clearly requires that “significant deficiencies must be distinguished from minor deficiencies.” Furthermore, the AWA requires research facilities to provide an explanation for any deviations from an approved protocol during an inspection and similarly on the APHIS/AC annual report. Instinctively, it seems that a significant deficiency resulting in a protocol suspension would be a reportable event, and the very act of reporting the problem may help prevent it from being repeated. An important feature of self-reporting is to include a corrective plan, which, in part, was offered by the PI. This must be a reasonable and detailed

plan with dates of action. However, with a long-standing pattern of infringement, additional corrective actions may need to be administered, such as post-approval monitoring. Even if technician error caused the deficiency, the PI is nonetheless ultimately responsible, and the blatant disregard for complying with activities on her protocol must be handled in a more rigorous manner.

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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. Animal Welfare Act and Animal Welfare Regulations. 9 CFR.

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