

## A word from USDA and OLAW

In response to the questions posed in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) and the Office of Laboratory Animal Welfare (OLAW) offer the following clarification and guidance:

Abuse of a privately owned animal by the owner is outside the jurisdiction of USDA and of OLAW, even if the animal is on a PHS-supported study. The institution is obligated to report the abuse to the proper local or state authorities, and there are ethical and scientific reasons for removing the dog from the study.

Since the institution's Assurance covered all species used for research, OLAW would expect the IACUC to review the trial. USDA would expect likewise, if the clinical trial was conducted under funding from a Federal agency.

**Chester Gipson, DVM**  
Deputy Administrator

**Carol Wigglesworth**  
Acting Director  
OLAW, OER, OD, NIH, HHS

Compliance and Contract's Management before protocol review by the IACUC. This may help to clarify follow-up care more specifically and outline owner, institutional, commercial partner, and/or contractor responsibilities as applicable.

IACUC approval was necessary, because conduct of this study involves the institution's facilities, faculty, and staff members<sup>3,4</sup>.

1. ARENA/OLAW. *Institutional Animal Care and Use Committee Guidebook* 2nd Edn. A.5; C.3 (2002). <http://grants1.nih.gov/grants/olaw/GuideBook.pdf>.
2. OLAW. NOT-OD-050034. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Animals. (24 February 2005). <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>.
3. 9 CFR, Chapter 1, Subchapter A—Animal Welfare.
4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV.B. 1–8 (US Department of Health and Human Services, Washington, DC, 1986; reprinted 2002).

*McTighe is a Clinical Veterinarian for the Division of Animal Care, Vanderbilt University, Nashville, TN.*

specifically address animal clinical trials, the following excerpt relating to farm animal studies, where animals are not necessarily housed at an institution, is relevant: "OLAW advises institutions that uniform and consistent standards are an essential ingredient in a quality animal care and use program. Public perception of a potential double standard should also be considered<sup>1</sup>." This reasoning seems to reinforce the reporting of this situation to OLAW.

Additionally, the study Director should confer with the University Counsel. An

independent consultant may need to review the case.

Reporting the case to USDA is not necessary. A private individual owns this animal, and the University is not housing Mr. Clyde. Qualified medical personnel have determined that the injury to the animal is animal abuse, caused outside of the realm of the study and the institution. Reporting to the state's anti-cruelty authorities should be sufficient.

In retrospect, it would have been wise to have a thorough review of the clinical trials agreement by University Counsel/