

A word from OLAW and USDA

In response to the issues raised 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. This commentary assumes that the research project in question was PHS-supported.

The primary questions posed in the scenario are whether an IACUC can suspend selected parts of an investigator’s protocol and whether provisions of the PHS Policy are applied differently depending on the animal species involved. The column also asks whether the institution has other options not addressed in the scenario.

OLAW has defined ‘suspension’ as any IACUC intervention that results in the temporary or permanent interruption of an animal activity¹. USDA, APHIS, AC and OLAW have also stated that the “PHS Policy, USDA Regulation, and the Guide language presume that all ongoing animal activities have received prospective review and approval. Accordingly, the IACUC’s authority to suspend unauthorized activities is always implied, if not explicit².”

Regarding options available to the institution other than those described in the scenario, OLAW has previously indicated that “while the PHS Policy does not contain specific sanctions other than suspension, most institutions have developed procedures for disciplining individuals.... Institutionally imposed sanctions vary from counseling, temporary suspensions of privileges, and imposition of monitored probation to permanent withdrawal of animal-use privileges and the termination of employment³.”

Provisions of the PHS Policy apply to all live vertebrate animals used or intended for use in research, research training, experimentation, biological testing, or related purposes. These provisions do not distinguish between species.

IACUCs and IOs are expected to follow their promises to adhere to provisions of the PHS Policy contained in their Assurances of Animal Welfare. They are required to assess the research facility’s animal program and procedures, and legally commit the research facility to compliance with the Animal Welfare Act and Regulations. While collegiality is important in attaining this goal, IACUCs and IOs should not enable or condone unacceptable behavior. OLAW and USDA have addressed this issue in comments on scenarios posed in past Protocol Review columns and reiterate them here:

- “Regardless of the issues of investigator intent, history, or subsequent harm to animals, circumvention of institutional animal welfare oversight mechanisms for prospective IACUC review constitutes serious noncompliance with the PHS Policy⁴.”
- “No amount of rationalization about lack of harm done can erase the fact that the PI knowingly violated the protocol⁵.”

- “The IACUC’s willingness to accept such behavior is [unacceptable], given the potential consequences for the institution that include violations of PHS Policy, NIH Grants Policy (including possible disallowance of charges against the grant), and the federal False Claims Act (31 U.S.C. §§ 3729–3730)⁵.”

OLAW has elaborated further on the potential effects of violations, stating that “[a]lthough certain changes in funded scientific research programs are allowable, some require prior notification of NIH grants management or program staff. Also, compliance with the PHS Policy, including prior IACUC approval of significant changes, is a term and condition of award. Failure to satisfy these commitments exposes the institution to potential disallowance of charges against the grant and other more serious sanctions⁴.”

Arguments that previously unauthorized work should be allowed to continue so as not to waste animals must be critically evaluated. These arguments may be moot when it is understood that data from activities not conducted in compliance with applicable federal regulations may not be publishable. From that perspective, the animals as well as all of the other institutional resources used to support the unauthorized work may already have been wasted. Along these lines OLAW has cautioned that “Publication of articles in many refereed journals requires conformity with certain editorial or professional society animal welfare policies. Most are clear about accepting only those studies conducted under fully compliant conditions. Therefore, the integrity of the investigator and the institution could be damaged by misrepresentation of the conditions under which...animal work was conducted⁴.”

1. Office for Protection from Research Risks. Requirements for prompt reporting of problems to OPRR. OPRR Reports (12 January 1994). <http://grants.nih.gov/grants/olaw/references/dc94-2.htm>.
2. Garnett, N.L. & DeHaven, R.W. The view from USDA and OPRR. *Lab Anim. (NY)* **27(9)**, 17 (1998).
3. Potkay, S. & DeHaven, W.R. OLAW and APHIS: common areas of noncompliance. *Lab Anim. (NY)* **29(5)**, 32–37 (2000).
4. Garnett, N.L. A word from OLAW. *Lab Anim. (NY)* **31(5)**, 21 (2002).
5. Garnett, N.L. & Gipson, C.A. A word from OLAW and USDA. *Lab Anim. (NY)* **32(9)**, 19 (2003).

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