

Reportability of protocol suspensions

The Great Eastern University IACUC always informed the federal Office of Laboratory Animal Welfare (OLAW) about significant animal welfare concerns that the IACUC was investigating. After an investigation was complete, it would inform OLAW of its findings and any subsequent actions taken by the committee. On occasion, the IACUC deemed it appropriate to suspend all or part of a protocol. When this happened, the IACUC would also inform the USDA and appropriate federal funding agencies if the involved species was covered by the Animal Welfare Act (AWA) and its regulations.

Dr. Hillary Banks used hamsters as part of her photoperiodicity studies. She had a well-deserved reputation as an outstanding researcher and an equally well-deserved reputation as a difficult customer of the IACUC. The IACUC previously had issued a warning to Banks about her blatant disregard for following her protocol. The warning

contained an ultimatum that all or part of her study would be suspended if any additional study-related problems were verified by the IACUC. True to form, another significant protocol violation occurred, and Banks was called in front of the full IACUC. She readily admitted to the infraction, blaming one of her technicians for the incident, and said that she had suspended the technician without pay for one week and had also voluntarily suspended any further animal work on the protocol. The IACUC thanked her for her cooperation and said that it would get back to her with the committee's decision.

After Banks left the room, Larry Covelli, the IACUC chairman, turned to the committee and announced that because another protocol violation had occurred, he would inform OLAW of the problem and of Banks' remedial actions, if the committee was in agreement with what she had done. However, he added that there was no need to inform

the USDA or any federal funding agency, since neither the IACUC, the Institutional Official nor any other university official had suspended the protocol. This bothered some of the members who had had their fill of problems with Banks. They wanted some form of punitive sanctions against her, in addition to the voluntary suspension. Covelli calmly said that punitive sanctions could occur with IACUC approval, and he would inform OLAW of the same, but any such sanctions would be wholly based upon the authority given to the IACUC by the university. Nonetheless, he was adamant that under the AWA regulations, there was still no need to report anything to the USDA.

Do you agree with Covelli that a voluntary suspension of an animal activity by an investigator need not be reported to the USDA and the appropriate federal funding agency; or is any suspension of an animal activity, no matter how it occurred, a reportable action?

RESPONSE

Reporting may vary

Judy Daviau, DVM, DACLAM and Troy Wilkins, BS

Unfortunately, those of us in academic communities are sometimes faced with situations similar to that described above. It is important that the IACUC be well versed in reporting procedures in order to prevent regulatory citations at a later date.

In this circumstance, Great Eastern University is dealing with an individual who has been a challenge to the IACUC. Although there is a great deal of history presented, it is important to consider the facts in the immediate scenario to make a decision on whether the incident is reportable. It is stated that a protocol violation occurred, for which Banks voluntarily suspended any further animal work on the protocol. Covelli, the

IACUC chairman, agreed to inform OLAW. This action is appropriate, as the Public Health Service Policy on Humane Care and Use of Laboratory Animals¹ requires prompt reporting of any serious or continuing noncompliance with this Policy, any serious deviation from the provisions of the *Guide* or any suspension of an activity by the IACUC (IV.C.6 & 7 and IV.F.3 & 4). Therefore, even though the activity was not suspended by the IACUC, reporting is required owing to the deviation from the approved protocol.

The question of whether this matter needs to be reported to the USDA is somewhat different. Even though hamsters are a regulated species, this does not in itself mandate reporting. The USDA requires notification when an activity has been suspended by the IACUC². Because the IACUC did not suspend the activity, this threshold has not been breached. Voluntary suspension of work by the investigator is not addressed in the AWA, and discussions

with our Veterinary Medical Officer have indicated that it is not reportable.

Reporting suspensions of animal activity to other funding sources can vary. It is imperative that the sponsorship agreement between the institution and the funding agency is reviewed for specific terminology on this issue. Again, Great Eastern needs to differentiate between a voluntary cessation of activity and an IACUC-mandated suspension. A recent review of agreements with the Centers for Disease Control and Department of Defense at our university showed that the default terminology referred to the AWA requirements. Thus, in this case, voluntary cessation of activity would not be reportable.

One caveat supersedes this entire discussion: Great Eastern University is bound by its PHS Assurance Statement. Reportable actions are clarified in that document. If Great Eastern has indicated that it will report all protocol violations to the funding agencies, it must abide by that statement and report

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:

The primary question posed in the scenario is whether a voluntary suspension of an animal activity by an investigator needs to be reported to the USDA and to the appropriate federal funding agency.

There are two Animal Welfare regulations (AWRs) that require notification be made to USDA and to any federal agency funding the research activity. These provisions were enacted to provide an effective mechanism to ensure that suffering animals are given prompt relief, and they include the following: (i) an IACUC suspension of a research activity (at a convened meeting, with a majority vote of the quorum present)¹ and (ii) an uncorrected significant deficiency². USDA does not require research facilities to report all serious noncompliances or deviations from the AWRs, as these will be documented by the USDA inspector.

In this particular scenario, the IACUC is investigating a report of a significant protocol violation. The IACUC must still prepare a report to the Institutional Official (IO) identifying the noncompliant items, including a reasonable and specific plan and schedule with dates for correcting each deficiency. This report becomes part of the IACUC records and must be made available to the USDA inspector for review. If the research facility fails to adhere to the plan and schedule and the significant deficiency remains uncorrected, or if the IACUC must take drastic action and suspend the protocol, the IACUC (through the IO) would then be expected to report this in writing to USDA and to any federal funding agency.

In addition to the AWRs, institutions receiving funds from the Public Health Service (PHS) should be aware that the situation described in this scenario falls into the category of conduct of animal activities in the absence of valid IACUC approval, and institutions are required to report such situations to the Institute/Center supporting the award³. The Office of Management and Budget Cost Principles and the National Institutes of Health Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld, which includes lack of IACUC approval³. NIH expects grantees to continue to maintain and care for animals during the period described.

The IACUC chair's actions were appropriate. Sanctions imposed by the IACUC or by an institutional official due to serious or continuing noncompliance with the PHS Policy⁴ or serious deviations from the *Guide for the Care and Use of Laboratory Animals*⁵ must be reported to OLAW. More detailed guidance on reporting noncompliance can be found in the NIH Guide for Grants and Contracts NOT-OD-05-034 (ref. 6). Institutions should use rational judgment in determining which situations meet the provisions of the PHS Policy, IV.F.3, and should consult with OLAW if in doubt about reporting requirements.

Both USDA and OLAW welcome reporting inquiries and discussion and will provide guidance with regard to specific situations.

1. 9 CFR Chap. 1, Subchapter A, Part 2, Subpart C, Section 2.31(d)(7).
2. 9 CFR Chap. 1, Subchapter A, Part 2, Subpart C, Section 2.31(c)(3).
3. Notice NOT-OD-07-044, Guidance Addressing the NIH Policy on Allowable Costs for Grant Activities Involving Animals when terms and Conditions are not Upheld [online] <<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html>>.
4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
5. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* (National Academies Press, Washington, DC, 1996).
6. Notice NOT-OD-05-034, Guidance on Prompt Reporting to OLAW [online] <<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>>.

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this incidence. In addition, the Great Eastern IACUC should consider what was stated in its previous correspondence with Banks. If the IACUC previously threatened Banks with suspension, the committee may indeed want to suspend this activity for consistency, given the disagreement between committee members regarding the appropriate action to take in this incidence. If it does so, then this becomes a reportable incident.

At our institution, we strive to provide the highest quality of compliance without overburdening the regulatory agencies with

unnecessary reporting. Some instances are not clearly defined in the guidelines and may lead to differences of opinion. In these circumstances, we contact the appropriate agencies and request guidance. This has proven to clarify the expectations of the governing bodies and provide a liaison between our IACUC team and pertinent officials. Great Eastern University may choose to do this in the case of Banks in an effort to not only educate but also possibly unite the IACUC in its decision. Banks may be a difficult individual who will require

IACUC-sanctioned actions to avoid further issues. The voluntary cessation of activity gives hope that Banks has an understanding of regulatory oversight and will strive to remain compliant in the future.

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. 9 CFR Part 2, Subpart C 2.31(d)(7).

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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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