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RESEARCH INTEGRITY

What is Protocol for Reporting an Animal-Research Project Exceeding Its Expiration Date?

Reader Question: I reported to our Institutional Animal Care and Use Committee (IACUC) that another PI is conducting his animal research after his expiration date. IACUC has done nothing about it, but I know it's against Office of Laboratory Animal Welfare (OLAW) regulations. Should I report it directly to OLAW?

Expert Comments:

The PI is correct. Conducting research with an expired protocol is against OLAW regulations and is a reportable offense.

The requesting PI (RPI) does not state whether the infraction was reported anonymously or whether the RPI provided contact information. Specific methods for handling complaints vary from institution to institution, but according to the *Institutional Animal Care and Use Committee Guidebook* (OLAW, 2002), all methods should contain the following:

- "There should be a procedure for verifying stated concerns.
- Verified concerns should be related to Animal Welfare Regulations, Public Health Service (PHS) policy, or institutional policies.
- There should be appropriate corrective measures, when necessary."

It is general practice to acknowledge receipt of the reported incident, but the confidentiality of the complaint and person against whom the infraction has been alleged is usually maintained while the incident is under investigation. Once the investigation has been completed, information may be released under "sunshine laws" or the Freedom of Information Act, if the incident has been filed with federal regulatory agencies.

Situations regarding the health or well-being of animals should be dealt with immediately. While all incidents should be handled promptly, some may require additional investigation requiring up to several months. Not all result in notification to federal agencies.

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The alleged violation might have been resolved outside the questioner's knowledge. It could already have been reported to the appropriate federal agency but not yet acted upon by that agency, or a punishment may already have been levied.

I would suggest the RPI contact the IACUC chair once again. Then, if necessary, the next step would be to approach the Institutional Officer (IO) of the institution. Contacting OLAW before contacting the IO is suggestive of institutional misconduct, which is a serious charge and may not be the RPI's intent.

*Comments by **Debbi Cherney, PhD, MA**, associate professor in the Department of Animal Science and seven-year IACUC member, Cornell University.*

Here are additional comments from the Office of Laboratory Animal Welfare (OLAW):

Should this concerned investigator report a noncompliance directly to OLAW? It depends. Let's examine the question step by step. The answer to the first part of the question is Yes, this must be reported to OLAW.

Institutions that receive funds from the Public Health Service must conduct animal activities in accordance with the PHS *Policy on Humane Care and Use of Laboratory Animals*. Such institutions negotiate an Animal Welfare Assurance (Assurance) with OLAW as a condition of receiving PHS funds. It is a contract between the institution and the PHS, in which the institution describes its animal care and use program and OLAW verifies that the program meets all required standards.

The PHS *Policy* mandates that animal activities be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). Animal activities conducted without IACUC approval, including situations in which approval has not yet been granted, approval has expired or the animal activity has been changed from the originally approved protocol, must be reported to OLAW. In Guide Notice NOD-OD-05-034, "conduct of animal activities without appropriate IACUC review and approval" is listed as a situation that must be reported to OLAW. Conducting animal research after expiration of a protocol is also a violation of the terms and conditions of grant award and must be reported to the National Institutes of Health (NIH) Institute or Center supporting the award.

Welfare of animals used in PHS-funded research is the responsibility of those comprising the animal care and use program at the institution. Concerns raised by anyone must be investigated by the IACUC and reported to OLAW, and if deemed reportable, communicated to OLAW, which then will work with the institution to ensure that appropriate corrective actions are taken — a solution that will resolve the current problem and any action required to prevent future similar violations.

If the IACUC is not performing its function appropriately, what should the concerned PI do? The first step would be to inquire as to the resolution of the complaint. The PI should speak with the IACUC chair, another member of the IACUC or the IACUC administrator. If a satisfactory response is not provided, the Institutional Official (IO) should be informed. The IO has committed, on behalf of the institution, that the PHS *Policy* requirements will be met, including any reporting of noncompliance.

Ultimately, Yes, the investigator could notify OLAW. Such complaints can be filed with OLAW's Division of Compliance Oversight (olawdco@od.nih.gov). But reporting the concern to appropriate leaders within the institution may be a better choice because it gives the institution an opportunity to address, correct,

and report problems resulting in an improved program. The consequences to the institution can be quite serious if a reportable incident is not reported to OLAW. NIH expects an institutional climate that promotes compliance, relevant internal policies, effective checks and balances, and open communication channels within the institution and with NIH.

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