

Difficult situation=difficult solution

Animal research is a privilege entrusted to scientists by the public. This situation is unfortunate, but the bottom line is that without an approved animal protocol, the publication, regardless of the findings, cannot stand as submitted.

First, it is the responsibility of the PI to submit an animal protocol for the work that was already done and self-report the misstep in an official manner to the IACUC. It is a difficult situation, but not correcting this situation would make it

worse. If the IACUC approves the protocol as the work was previously completed, then the PI should contact the journal to request an addendum to the article be placed explaining the mistake. Additionally, the IACUC could require that the investigator be present at a full committee meeting and explain in person to at least a quorum of the committee why there was a failure to ensure that the animal work was on an approved animal protocol before beginning the study.

If the IACUC cannot approve the experiment as performed, the PI must request the article be retracted. When the IACUC does approve the experiment with necessary modifications, the work should be repeated using the approved methodologies and then submitted to the same journal. If the science is good, reproducing the study should occur without incidence. The public would be more understanding of a mistake like this if the time and effort was taken to correct it.

The solutions proposed, while difficult for the new scientist, adhere to the spirit of the 3Rs while also maintaining the highest standards for ethical publication. It is important that the situation is not minimized, regardless of how prestigious the journal is or how compliant a researcher may have been in the past. "Laboratory animals play a crucial role in biomedical research—indeed many advances now incorporated into human health care, would not have been possible without them. Informed and well-trained scientists have the privilege, but not the automatic right, to use animals as experimental subjects. This privilege must not be abused."¹

Scientific research is based on the truthful and accurate data that the scientist discovers and ethically the PI must follow the rules of the institution when it pertains to using live animals in their experiments. The public and the institution depend on IACUC to make sure this right is not abused. □

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A WORD FROM OLAW

In response to this scenario, the Office of Laboratory Animal Welfare offers the following guidance:

In the scenario, a doctoral student and his advisor completed and published a study without IACUC approval of the animal activities. The problem was identified by the IACUC Chair after the student graduated and embarked upon a research career in his home country. The author poses the question, "How should the PI and IACUC handle this situation?"

All of the respondents correctly identified the serious noncompliance of conducting animal activities without IACUC approval. As identified by two of the respondents, the IACUC must investigate the incident, the investigation must be documented, and, if PHS funded, the noncompliance must be reported promptly to OLAW. A plan, schedule, and timeframe for correction, and prevention of recurrence of the noncompliance must be developed, reported to OLAW, and implemented, as described on the OLAW website, Reporting Noncompliance¹. The PI should cooperate with the IACUC to develop and implement procedures to prevent recurrence.

In addition to the complete and well described procedures suggested by two of the respondents for investigation and correction of the noncompliance, the institution is required to 1) contact the NIH funding component to negotiate the potential refund of grant money used on an animal study without IACUC approval, and 2) notify the Program Officer about the publication of unapproved activities, as described in Guide Notices NOT-OD-07-044² and NOT-OD-10-081³.

Additionally, The PHS Policy section V.B.⁴ and the NIH Grants Policy Statement chapter 4.1.1.2⁵ require the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications related to the care and

use of animals. Institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with that provided in the grant application. Accordingly, the institution must assume responsibility for this serious noncompliance and negotiate a return of funds with NIH.

The journal in which the experiment was published must be notified that the animal activities were incorrectly identified as having been conducted with IACUC approval. The journal, not the IACUC or the authors, is responsible for determining their response.

The IACUC may not retroactively review and approve the animal activities. Such an action would not mitigate the noncompliance that has been committed and would extend the impact of the noncompliance. □

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5. National Institutes of Health. NIH Grant Policy Statement, chapter 4.1.1.2, <https://grants.nih.gov/policy/nihgps/index.htm>