Check for updates

protocol review

What's in store for a whistleblower?

J oshua Richmond knew that the procedure he performed on a rat was not approved by Great Eastern University's IACUC. He had reminded Dr. Paul Levine, his graduate studies mentor, that they needed IACUC approval before initiating the procedure, but Levine became irate, as he often did, and told him to do what he was told to do or find another lab to work in. That was not a desired option for Richmond, so he performed the procedure.

Still bothered by the incident after a few months had passed, Richmond wrote an anonymous letter to the IACUC, relating the noncompliance. When the IACUC began its investigation, the rat was long gone. When confronted with the accusation. Levine denied the claim and demanded to know who his accuser was because the university's bylaws specified that a faculty member accused of wrongdoing had a right to know his or her accuser. Richmond denied writing the letter but eventually admitted that he performed the procedure. Levine did not think Richmond was the whistleblower, assuming that would be too obvious; however, because Richmond was the only person working for him, he told Richmond to find another mentor, as he was no longer welcome in his laboratory.

Distressed by the impending loss of his job and possibly revealing himself as the letter writer, Richmond began reading. The school's IACUC policy manual stated that the identity of a whistleblower would remain confidential if that was the preference of the whistleblower, but the policy said nothing about protection from reprisals. Nevertheless, he was somewhat heartened to find that the Guide for the Care and Use of Laboratory Animals stated that "The process [of reporting concerns] should include a mechanism for anonymity, compliance with applicable whistleblower policies, nondiscrimination against the concerned/reporting party, and protection from reprisals."1 Richmond told the IACUC that Levine obviously imposed a reprisal against him, but the IACUC chair opined that the Guide was only referring to reprisals against a known whistleblower. The IACUC chair was also concerned with the comment in the Guide about protection from reprisals because a document from the federal Office of Laboratory Animal Welfare (OLAW), stated that "OLAW may withhold identifying information to protect whistleblowers, but protection from reprisal for whistleblowers must be addressed at the institutional and/or state level."2

Is Richmond both a whistleblower and the target of a reprisal even though he denied writing the letter? Is there a conflict between the OLAW statement which assigns responsibility against reprisals to the institution or state, and the *Guide*, which is incorporated into the PHS Policy^{3,4} and appears to expect an institution to provide protection from reprisals? Should Richmond tell the whole truth and look for another lab? How should the IACUC deal with these issues?

Jerald Silverman [⊠]

University of Massachusetts Medical School, Worcester, MA, USA. [™]e-mail: Jerald.Silverman@umassmed.edu

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Protect the gatekeeper

his scenario investigates whistleblower protection for reporting noncompliance issues in an animal research setting. Here, Richmond is an institutional laboratory employee that performed an animal research procedure without Great Eastern University's (GEU) Institutional Animal Care and Use Committee's (IACUC) approval, as instructed by his mentor Dr. Levine. As "conducting research animal activity without the IACUCs approval is a serious noncompliance with the Animal Welfare Act and Regulations,"1 Richmond never should have performed the procedure without IACUC approval in the first place, but he risked losing his job with Levine's lab if he refused to conduct the experiment.

After some time passed, and in good faith, Richmond anonymously sent a letter

to GEU's IACUC reporting the allegation; he then later denied doing so when confronted. Richmond likely denied writing the letter in order to keep his job, but, as no one else was involved with the procedure, he had to leave the lab once Levine knew that no one else could have reported the noncompliance. Therefore, Richmond appeared to be a whistleblower and a target of reprisal.

As Richmond was let go from Levine's lab, there seems to be a conflict with the Office of Laboratory Animal Welfare (OLAW) and the *Guide*'s statements that whistleblowers should be protected from retaliation by the state or institution. OLAW assigns responsibility against reprisals to the institution or state, and the *Guide* expects an institution to provide protection from reprisals^{2,3}. If individuals report allegations of wrongdoing anonymously, every effort should be made to keep it that way. The regulatory agencies seem to want whistleblower protection, and the research institution should have a policy or Standard Operating Procedure in place to protect whistleblowers; otherwise, whistleblowers may not come forward due to fear of retaliation.

Ultimately, Richmond shouldn't have conducted the animal procedure in the first place. He should tell the whole truth and look for another lab to work in. There will be other labs in which to seek employment, and hopefully they'll be fully compliant. The IACUC meanwhile has the responsibility to investigate any animal concerns raised by whistleblowers. Institutional and IACUC contact information should be posted throughout all research facilities so anyone that has questions or concerns can report them. Contact information should include the IACUC Chair Person, Attending Veterinarian, other institutional veterinarians, and animal care managers and supervisors. Any allegations of animal-related wrongdoing made anonymously should be kept that way as best as possible. The research institution and IACUC should have a plan in place to shield whistleblowers that in good faith come forward with concerns. Research employee protections matter and should be established. Any individual working in these environments and witness wrongdoing should be willing to come forward without fear of retaliation. The whistleblower is the gatekeeper in the workplace and should be protected.

Jeffrey Etue ⊠

University of Kentucky, Lexington, KY, USA. [™]e-mail: jjetue2@email.uky.edu

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The problem with a murky whistleblower policy

hile OLAW cannot guarantee protection from reprisals, OLAW does refer to the *Guide*¹(p. 24), which states that "mechanisms for reporting concerns should be posted in prominent locations in the facility and on applicable institutional website(s) with instructions on how to report the concern and to whom. Multiple points of contact, including senior management, the IO, IACUC Chair, and AV, are recommended."

Richmond did the right thing by reporting the noncompliance to the IACUC. Levine is using 'guilt by association' to punish Richmond, as only Levine and Richmond knew about the noncompliance. Richmond told the whole truth when he admitted to performing the procedure. There is nothing inherently wrong with anonymity, so admitting that he reported the noncompliance is not necessary. Richmond has seen his employer's true colors. We would encourage him to find a lab that is more ethical, as well as aware of current legal and appropriate HR practices.

As OLAW is not the employer, they would not be able to guarantee there were no reprisals at the institutional level. However, the *Guide* does further refine OLAW's expectations, stating "The process should include a mechanism for anonymity, compliance with applicable whistleblower policies, nondiscrimination against the concerned/reporting party, and protection from reprisals." We assume that Great Eastern University has an Assurance on file with OLAW. Because of this, they are bound by the principles in the *Guide*, and therefore, should have "protection from reprisals" documented in their whistleblower policy.

The IACUC needs to revisit their policy on whistleblowers to include protection from reprisals and ensure it is consistent with the rest of OLAW and the Guide's recommendations. To protect anonymous reporters, outlining examples of reprisal, such as termination of employment of lab members without adequate justification, will help avoid similar situations in the future. The investigation into non-compliance in Levine's studies should continue, but it may proceed as post approval monitoring. Considering this investigator's temperament and willingness to overlook one area of non-compliance, it is not unreasonable to think there may be other protocol non-compliances.

If the IACUC does not already have one, a written policy on how non-compliances are dealt with would be advantageous. The IACUC should also consult with their legal department to revise the university's bylaws, as they are in direct conflict with a federal mandate. On a slightly separate note, the PI needs to be trained from Human Resources on appropriate employee termination practices.

Christine Boehm¹[⊠] and Kristina Pugh²

¹Texas Tech University Health Science Center at El Paso, El Paso, TX, USA. ²William Beaumont Army Medical Center, El Paso, TX, USA. [∞]e-mail: chris.boehm@ttuhsc.edu

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Coming clean

o maintain public trust in the welfare and ethical treatment of animals used in biomedical research, it is imperative that institutions have policies that explicitly forbid reprisal against whistleblowers for reporting noncompliance and humane concerns. In the case of Joshua Richmond, it is unfortunate that the IACUC's policy did not address reprisal, especially since the broader institution also does not seem to have any such policy. The Office of Laboratory Animal Welfare (OLAW) assigns responsibility against reprisals to the institution, and the IACUC is the delegated authority to make recommendations and develop policies specific to its areas of animal care program oversight, consistent with the *Guide*. If Great Eastern University has a valid OLAW assurance on file, it would clearly state that they are in compliance with the *Guide* such that nondiscrimination against the concerned/reporting party and protection from reprisals is enforced^{1,2}.

Because Richmond did not identify himself as the whistleblower, such a policy may still not have helped him, as Levine

A WORD FROM OLAW

In response to the issues posed in this scenario, the National Institutes of Health - Office of Laboratory Animal Welfare (NIH-OLAW) provides the following clarification:

In this scenario, a graduate student under duress from his mentor performs an unapproved procedure on a rat. Subsequently, the student reports the noncompliance anonymously to the IACUC. Then, the mentor, assuming the student was the whistleblower, retaliates. During its investigation of the unapproved activity, the IACUC uncovers the mentor's reprisal and must decide a course of action.

The PHS Policy requires the IACUC as an agent of the institution to review concerns involving the care and use of animals at the institution¹. Although the PHS Policy does not have explicit whistleblower protections, OLAW expects institutions to vigorously enforce both institutional and state protections for individuals who come forward with valid concerns regarding research animal welfare and research integrity as mandated by the Guide for the Care and Use of Laboratory Animals². OLAW disagrees with the IACUC chair's interpretation of the *Guide's* requirements for reporting animal welfare concerns. Protection from reprisals should be afforded to any person reporting a concern whether identified or anonymous. When anonymous complaints are made to the IACUC, it is important to have a feedback mechanism to inform the complainant of the outcome. This may prevent those reporting anonymously who may feel the concerns have not been acknowledged from reporting to oversight agencies or other outside parties.

While OLAW is not tasked specifically in the PHS Policy with determining if retaliation has occurred, it takes allegations of retaliation seriously and in such cases carefully monitors institutional animal care and use programs for compliance with PHS Policy and the *Guide*, particularly regarding reporting policies related to animal welfare concerns¹⁻⁴. OLAW considers whistleblower protections imperative to ensure effective institutional oversight. A whistleblower may be the only individual willing or able to provide information about an animal welfare issue even at institutions with effective reporting structures for animal welfare concerns.

Whistleblowers should use the institution's internal reporting structure to report animal welfare concerns but may also call OLAW to either make a report or receive anonymous consultation. Once an incident has been reported to the IACUC and the institution has verified that a noncompliance has occurred, an authorized individual at the institution must contact OLAW promptly with a preliminary report³. If reprisals are reported to OLAW's Division of Compliance Oversight, the institution will be asked to reaffirm their reporting policy for animal welfare concerns and clearly state that the policy complies with the institution's Animal Welfare Assurance with OLAW and the Guide.5 It is important to note that the source of a whistleblower complaint to OLAW is not releasable under the federal Freedom of Information Act^{3,6}.

Patricia Brown 🖂

Director, OLAW, OER, OD, NIH, HHS, Bethesda, MD, USA. [™]e-mail: brownp@od.nih.gov

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could claim any number of acceptable reasons to terminate him. The lack of evidence and witness accounts regarding the exchange between Richmond and Levine make this a 'he said/he said' situation. With proper training and awareness, Richmond should have reported the conflict to the IACUC as soon as it happened, before performing the procedure, so that resolutions could have been made to prevent noncompliance. At present, Richmond should identify himself as the whistleblower to the IACUC so he can at least provide a witness account of the interaction that Levine is denying and be afforded protection from reprisal.

Richmond's relationship with Levine is already beyond repair, and the ethical murkiness of the mentor's philosophy is not a nurturing and welcoming place to learn. Richmond should reconsider the hostile working environment in the laboratory and anticipated mentorship value from a researcher who is clearly not adhering to IACUC authority, who is performing unethical research, and who belittles and intimidates others who may question his practices. A noncompliance of this magnitude requires reporting to OLAW, and the report should also go to the department chair. The chair, working with the IACUC, could lend support to identifying a more welcoming research environment for Richmond. While coming clean will not change the need for Richmond to find a new lab, it could salvage his reputation, self-esteem, and possibly his research career while assisting the IACUC in holding Levine accountable for promoting noncompliance and punishing thoughtful dialogue.

Jon Reuter [⊠]and Sara Hashway

University of Colorado Boulder, Boulder, CO, USA.

[™]e-mail: Jon.Reuter@Colorado.edu

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