schedule 1, because if she were, according to the Controlled Substances Act of 1970 (ref. 1; §1301.18), she would have to submit some form of institutional approval in her application. Since her study is with animals, the third assumption is that the IACUC's final approval would have been the document to submit along with her DEA 225a form to attain her registration. If this were true, then the issues revealed in the situation would not have occurred.

According to the PHS Policy[2] and the AWAR[3], the IACUC can only approve, require modifications, or withhold approvals. In this situation the IACUC's approval occurred one week before the OHS' approval. So what was the "final approval" that was delayed? There currently is no regulation concerning provisional or conditional approvals. Furthermore according to the NIH website, if a protocol lacks substantive information necessary for the IACUC to make a judgment, then it should be considered incomplete and review deferred until the requisite information is provided by the investigator. Would the OHS approval be considered substantive enough? I propose that the IACUC should have waited until all documents were submitted before reviewing.

Was the OHS approval substantive or necessary for the IACUC to give their final approval? It may have been for this particular university, but is there regulatory support for this practice? According to the IACUC Handbook[4], the IACUC's role is to ensure that the controlled drugs to be used are available and used in accordance with the research protocols and that they are within established expiration dates. The OHS has a responsibility to assist researchers in negotiating the legal requirements necessary for using controlled substances. There is no regulatory requirement for either the IACUC or the OHS to serve as the regulatory body for DEA-regulated drugs in animals. Although it may be mandatory at this university, there is no regulatory support specified for this practice. All the relevant requirements for the use of controlled substances could be reviewed more intensely via post-approval monitoring process.

If the IACUC staff were uncomfortable with this approach, could they have used the polling method to ask of the IACUC members their agreement or disagreement? To help ease the frustration for Neiman, could they have contacted the IACUC members to simply indicate if the OHS approval now warranted a review of the entire protocol, or if the protocol could attain its final approval by the administrative route?

In conclusion, I believe that the best approach would have been for the IACUC to receive and review the entire package before letting the researcher know of their decision, thereby reducing the confusion experienced.

1. U.S Department of Justice. *Code of Federal Regulations* (2010). (§1301.18)
2. U.S. Department of Health and Human Services. Public Health Service Policy on Humane Care and Use of Laboratory Animals (2015).
3. United States Department of Agriculture. *Animal Welfare Act and Animal Welfare Regulations* (2013).
4. *The IACUC Handbook* 3rd edn. (ed. Silverman, J., Suckow, M. & Murthy, S.) (CRC Press, Boca Raton, 2014).

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RESPONSE

Let's talk about self-imposed regulatory burden

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Neiman is justifiably frustrated. This is an instance where someone in the IACUC office needs a deep understanding of, and experience with, the regulations to guide the institution with regard to federal requirements involving research animals. This is also an opportunity for Great Eastern University to look at their policies and procedures pertaining to the use of research animals to decrease self-imposed regulatory burden. Hopefully, this can result in increased PI satisfaction and compliance.

In its June 8, 2017 report "Reducing Regulatory and Institutional Burden Associated with Animal Research," the Council on Governmental Relations questioned the increasing incidents of self-imposed regulatory burden and challenged institutions to decrease what is perceived to be significant roadblocks to research that do not improve laboratory animal welfare. This is an important activity for all institutions, including Great Eastern University, to do.

Great Eastern University may have legitimate reasons to have the Department of Occupational Health and Safety (OHS) involved with controlled substance use in laboratory animals; however, it is unclear how and why this would entangle IACUC approval. The OHS approval only concerned information on drug safety, security, record keeping, and disposal of the controlled substances—nothing that had to do with the actual use in research animals; this information is in the IACUC protocol.

Let's assume that Great Eastern University's management team had performed a risk assessment for this process and felt that, in order to mitigate risks, the IACUC had to have oversight of the OHS approval. The process could have been simplified by having the required IACUC re-approval be administrative; the IACUC office could have confirmed that there was OHS approval and then given the final approval of the protocol. This action conforms to OLAW FAQ D.4 (https://grants.nih.gov/grants/olaw/faqs.htm).

In this case, the re-review requirements of the Great Eastern University IACUC also requires refinements. If, for some mysterious reason, it was necessary to have the IACUC re-approve the protocol, it could have been performed by the Designated Member Review system (DMR). The IACUC should tailor the time it takes for DMR reviews with what is being reviewed. A simple review to verify OHS approval should not take two weeks to perform; this is unnecessarily delaying research. The IACUC should develop guidelines for timeframes when using the DMR review process.

Given all the regulatory and financial burdens faced by PIs today, it is imperative that the IACUC do what it can to facilitate research. The IACUC should always be looking to streamline its review processes and this can involve critical self-examination. We propose that self-imposed regulatory burden is driven by the institution's need for the lowest possible risk when working with research animals. Institutions need to balance this need with the need for PIs to perform their animal work without undue hindrance. It is a difficult challenge for all of us working with research animals, but one that must be met.

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