

A Word from OLAW

The Office of Laboratory Animal Welfare (OLAW) provides the following recommendations on ways the IACUC could streamline the protocol review process when additional approval(s) is required in a way that reduces burden on the investigator while maintaining compliance with PHS Policy requirements.

In research using animals, occupational health and safety considerations require coordination between the investigator, the IACUC, and the safety office¹. It is incumbent on all involved to obtain the necessary review and approvals before the work can begin. The IACUC at Great Eastern has chosen to employ a burdensome process that delays the investigator's work. Numerous approaches could mitigate this burden. One option is for the IACUC to delay notification of approval to the investigator until after the safety review is complete². The approval date of the protocol should be on or after the date of the safety approval as determined by the individual IACUC's operating procedures³. An equally effective option is to submit the work that requires safety approval as an amendment to the protocol after the safety office has cleared the activities and provided any instruction or training². Many IACUCs conduct protocol review in parallel with the safety review. This practice expedites the process as long as the outcome of both reviews are effectively communicated. If the safety office approves the work without modifications, the IACUC may document this approval administratively without further IACUC review by, for example, a check box, an approval number or a safety representative's signature². Any of these methods are acceptable for documentation of the safety approval.

Another consideration in avoiding misconceptions by investigators about the status of a submitted animal use protocol is to avoid the phrase "conditional approval". As stated in OLAW guidance, the PHS Policy does not allow IACUCs to grant conditional approval for animal use protocols². Committees may only approve, require modification (to secure approval) or withhold approval of a protocol⁴.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. p. 17 (National Academies Press, Washington, DC, 2011).
2. Brown, P. & Gipson, C. A word from OLAW and USDA. *Lab Anim. (NY)* **40**, 297 (2011).
3. Office of Laboratory Animal Welfare. *Guidance to Reduce Regulatory Burden for IACUC Administration Regarding Alternate Members and Approval Dates*. Notice NOT-OD-11-053. (National Institutes of Health, Washington, DC, 18 March 2011). <http://grants.nih.gov/grants/guide/notice-files/Not-od-11-053.html>
4. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*, IV.B.6. (US Department of Health and Human Services, Washington, DC, 1986, revised 2015).

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we can think of two potential ways to improve its processes: they could defer review of Animal Use Protocols until all the ancillary approvals are in place, which would help manage PIs' expectations; or they could consider letting the IACUC administrator confirm receipt of delayed ancillary approvals, which would trigger an expedited approval by Designated Member Review, as long as said approvals did not affect conclusions previously reached by the IACUC.

1. U.S. Department of Health and Human Services. Public Health Service Policy on Humane Care and Use of Laboratory Animals (2015).
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
3. Greer, William G., & Ron E. Banks. The IACUC Administrator's Guide to Animal Program Management: Setting Up and Directing an IACUC Office (CRC Press, Boca Rotan, FL, 2016).
4. National Research Council, Commission on Life Sciences *et al. Occupational Health and Safety in the Care and Use of Research Animals* (National Academies Press, Washington, DC, 1997).
5. United States Department of Agriculture. *Animal Welfare Inspection Guide* (2013)
6. National Institutes of Health, Office of Laboratory Animal Welfare. *Institutional Animal Care and Use Committee Guidebook* (2002).
7. *The IACUC Handbook* 3rd edn. (ed. Silverman, J., Suckow, M. & Murthy, S.) (CRC Press, Boca Raton, 2014).
8. Petrie, W.K., Podolsky, M.L, Wallace, S.L., & Lukas, V. The Care and Feeding of an IACUC: The Organization and Management of an Institutional Animal Care and Use Committee (CRC Press, Boca Raton, FL, 1999).

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RESPONSE

Did the IACUC jump the gun?

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Before directly addressing the question posed, someone considering this situation would have to make a number of assumptions. The first assumption is that Neiman and her lab have already obtained the required DEA registration and state licenses necessary for using controlled substances in research. A second assumption is that Neiman is not using opioids from

of the common tasks of IACUC administrators is to confirm approval(s) by other institutional committees⁸.

Given the responsibility of the IACUC to provide oversight of the OHSP in conjunction with animal use, and given the IACUC's mandate to either approve, require modification, disapprove Animal Use Protocols, or table or defer review, common and best practice is to wait for all relevant approvals from other institutional committees to approve an Animal Use Protocol³. This is why it is surprising that Great Eastern University had "approved" the Animal Use Protocol before receiving

word from the ancillary committees, which may have given Neiman unfounded hopes that her animal work could start.

The Great Eastern University IACUC office is correct that PHS policy¹ and AWIG⁵ do not allow polling as a means to secure votes from IACUC members. Votes must take place simultaneously at convened meetings. These meetings can be virtual in certain circumstances, but require synchronous voting in real-time.

Aside from the confusion caused by calling the Animal Use Protocol "approved" before it was truly so, Great Eastern University is playing by the rules. However,