

RESPONSE

More or less administrative burden

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The laboratory animal and research communities all understand and struggle with the increasing administrative burden that has been thrust upon us with new regulations and revised interpretations of existing regulations. Nonetheless, in the scenario presented here, the IACUC office gave Waite the correct information. As described in the *Guide for the Care and Use of Laboratory Animals*, a clear and concise sequential description of the procedures involving the use of animals that can be easily understood by all members of the committee should be described in the IACUC protocol¹. The PHS *Policy on Humane Care and Use of Laboratory Animals* requires an IACUC to review and approve activities on a project-specific basis, taking into account such factors as the aims of the study, consideration of alternatives and minimization of pain and

distress². Applications and proposals for awards submitted to the PHS require a complete description of the proposed use of animals and procedures to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research. Prior to protocol review, each IACUC member should be provided with written descriptions of each research project that involves the care and use of animals. It is essential that IACUC members be able to review a protocol in its entirety without needing to pull information from other protocols in order to ascertain the full effect that proposed procedures will have on an individual animal.

Since each IACUC protocol requires a complete, *de novo* review at least once every three years, failing to describe procedures fully in each protocol could result in additional challenges for Waite and the institution. If IACUC approval of Waite's protocol M22-16 should expire, that protocol would then lack valid approval. If Waite references protocol M22-16 methodologies and equipment in protocol M33-16, then, in theory, those referenced procedures in M33-16 would also be invalid when M22-16 expires.

In order to minimize administrative burden for Waite and other PIs, the IACUC could consider having on hand policies that

have already been reviewed and approved—guidance documents and standard operating procedures (SOPs)—available for citation by PIs in their IACUC protocols³. These policies should be reviewed by the IACUC at least once every three years to ensure they are up-to-date and accurate. In the case presented here, Waite's IACUC could review and approve an SOP for insulin tolerance tests, at which time Waite could reference the SOP in her protocols. We presume that the IACUC protocol for the transgenic core has associated SOPs and that is why Waite can reference the core's protocol but not her own IACUC protocol M22-16.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*. (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. National Institutes of Health. NOT-OD-14-126: Guidance on significant changes to animal activities. *National Institutes of Health Office of Extramural Research*. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html> (2014).

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