

Human Services, Washington, DC, 2006; revised 2009). <http://grants1.nih.gov/grants/olaw/faqs.htm>.

- Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 2nd edn. (CRC Press, Boca Raton, FL, 2007).

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## RESPONSE

### Addition is significant

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It is not uncommon for a Principal Investigator to request an amendment to add additional animals to an approved animal use protocol because it can sometimes be difficult to know exactly how many animals might be needed to complete a study. In fact, both the PHS Policy<sup>1</sup> and USDA Animal Welfare Regulations<sup>2</sup> use the word “approximate” when referring to the number of animals to be used in a proposal to conduct an activity or to make a significant change in an ongoing activity.

Although there is no official federal regulation or policy that defines what constitutes a “significant” change to an animal activity, NIH/OLAW<sup>3</sup> and USDA Animal and Plant Health Inspection Service, Animal Care (APHIS/AC)<sup>4</sup> have published some guidance on this issue, and a change in the approximate number of animals has been listed as a significant change. As stated in *The IACUC Handbook* (10:3)<sup>5</sup>, owing to the variety and complexity of institutional animal care and use programs, NIH/OLAW has recommended that each IACUC develop a policy to address significant protocol modifications and make this policy available to its investigators. Therefore, with due consideration given to guidance provided by NIH/OLAW and APHIS/AC, it is up to each individual IACUC to determine what constitutes a minor versus significant change.

In the case of the Great Eastern IACUC, its policy of allowing up to 10% additional animals as a minor amendment to a protocol was adjusted to include only rats and mice, following a request for clarification in its PHS Assurance at the time of renewal. Because

Great Eastern’s policy applied to all species prior to this request for clarification, we can only assume that the IACUC deliberated over this matter, adjusted its policy because it made sense to do so and included its modified decision in the renewal of their PHS Assurance. This change should also have been communicated to the research community.

Did Great Eastern’s IACUC make the appropriate decision? In our opinion, any addition of animals should be considered a significant change, regardless of the species involved, and should therefore be handled like any other significant change to a protocol, following the institution’s standard IACUC review process for major amendments. The IACUC should be looking at the reason for the increase, not just the fact that a certain percentage increase is requested. For example, have more studies been added without a change in the approved study design, or has there been a study design change that impacts the goals and objectives of the research? Additionally, the IACUC may want to consider other factors, such as pain category or type of procedure, rather than just a percentage increase in animal numbers when making its decision as to what constitutes a minor versus significant change. As we are asking research animals to serve as surrogates for humans in the conduct of research, we should give due consideration to each and every one of them, rat, mouse or dog.

- Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV.D.a. (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
- Animal Welfare Regulations, 9 CFR, Chapter 1, Subchapter A, Part 2, Subpart C, Section 2.31(e) (1).
- Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions*. Protocol Review, Question No. 9. (US Department of Health and Human Services, Washington, DC, 2006; revised 2009). <http://grants.nih.gov/grants/olaw/faqs.htm>.
- Animal and Plant Health Inspection Service. *Animal Care Resource Guide: Research Facility Inspection Guide*. Part 18. (US Department of Agriculture, Washington, DC, 2001). [http://www.aphis.usda.gov/animal\\_welfare/rig.shtml](http://www.aphis.usda.gov/animal_welfare/rig.shtml).
- Silverman, J., Suckow, M.A. & Murthy, S. *The IACUC Handbook* 2nd edn. (CRC Press, Boca Raton, FL, 2007).

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## RESPONSE

### No relevant difference

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Legal issues aside, one reason that an institution may have different policies for dogs (and other large animals) than for rodents may be the notion that their use in research is ethically more problematic. This idea in turn may be explained using the socio-zoological scale<sup>1</sup>. The basis of the socio-zoological scale is that people rate animals as morally more or less important, and therefore more or less worthy of protection, according to a number of factors having to do with the role of the animals in our lives. These factors may include the animal’s usefulness, association with humans, physical attractiveness and potential to be harmful. By these measures, companion animal species, notably dogs and cats, are at the top of the scale in many North American and European societies today, whereas rodents are at the bottom.

The socio-zoological scale may be a reasonable description of commonly found attitudes, but its use as a basis for animal protection can be criticized on both scientific and ethical grounds. Scientifically, there is nothing in the biology of these animals that justifies their different positions on the scale. Both dogs and rodents are mammals, and in terms of capacity to feel pain or otherwise suffer—which arguably is the main issue in the legal framework for present laboratory animal science—there is no reason to expect these species to differ. Ethically, many people who have thought about the issue might argue that the general likeability of the species is not a fair basis for deciding how to treat animals but rather is unfair discrimination.

It is not clear whether Marchetti’s study involves potentially painful procedures. Although it may seem provocative, one could argue that it is more problematic to apply potentially painful procedures to a rodent than to a dog. We are more accustomed to interacting with dogs than with rodents, and our daily routines caring for dogs may focus more on optimizing individual welfare than do those for rats and mice. People may also