

changes in contact, changes in unit size and OLAW/USDA investigations ([http://www.aaalac.org/accreditation/faq\\_landing.cfm#H2](http://www.aaalac.org/accreditation/faq_landing.cfm#H2)). Even if the institution is accredited by AAALAC, protocol deviations such as this would be reportable to AAALAC only if it is considered to constitute a lack of veterinary care.

The performance standards referred to in the *Guide* and the AAALAC position statement (<http://www.aaalac.org/accreditation/positionstatements.cfm#ag>) refer to housing and care, interpreted to mean husbandry. When the protocol is being reviewed, these and other standards that apply to practices such as piglet castrations could be discussed to determine whether the proposed procedures are appropriate, but the use of performance standards does not allow deviation from the protocol once it is approved.

Regarding the use of agricultural animals in biomedical research, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (the *Ag Guide*)<sup>3</sup> is frequently used as reference material for both USDA<sup>4</sup> and AAALAC. The *Ag Guide* states, “regardless of the teaching or research objective, the *Ag Guide* should serve as a primary reference document for the needs and requirements of agriculture animals”<sup>3</sup>. While the *Guide* and the *Ag Guide* suggest that castration is not a major surgery, castration would constitute major survival surgery according to the AWARs definition as it permanently impairs a physiological function<sup>1</sup>. While there is evidence that castration causes signs of pain and discomfort in pigs, which can be reduced with anesthetics, results are inconsistent across experiments. The *Ag Guide* recommends that castration be done as early as possible to minimize the stress and recommends anesthesia for piglets more than 14 days old<sup>3</sup>.

Whether or not castration without anesthesia is inhumane is a discussion for each IACUC. Conquer’s IACUC did a good job in the protocol review and approval process to require administration of a local anesthetic prior to castration. The protocol could perhaps have been further improved by including mild sedation to reduce the stress to the piglets prior to anesthetic administration and post-operative pain relief with an appropriate analgesic.

1. Animal Welfare Act Regulations. 9 CFR, Chapter 1, Subchapter A, Parts 1–3.
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
3. *Guide for the Care and Use of Agricultural Animals in Research and Teaching* 3rd edn. (Federation of Animal Science Societies, Champaign, IL, 2010).
4. United States Department of Agriculture, Animal and Plant Health Inspection Service. *Animal Care Policy Manual*. Policy #17: Regulation of Agricultural Animals. (USDA, Beltsville, MD, 2011). <[http://www.aphis.usda.gov/animal\\_welfare/downloads/policy/Policy%2017%20Final.pdf](http://www.aphis.usda.gov/animal_welfare/downloads/policy/Policy%2017%20Final.pdf)>

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## RESPONSE

### Amend or follow

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This scenario raises two main questions: was Ballantine’s method of castration humane, and why was Ballantine, as a swine consultant, not more involved in the development of the protocol?

There are several points to consider in answering the first question. First, the position statement of the Association for Assessment and Accreditation of Laboratory Animal Care International (<http://www.aaalac.org/accreditation/positionstatements.cfm#ag>) that the IACUC member quoted refers to husbandry and housing standards, not to veterinary procedures and is not relevant in determining how castration should be done by the veterinarian. Second, Ballantine alluded to the *Guide for the Care and Use of Laboratory Animals*<sup>1</sup> (the *Guide*) as stating that castration “usually doesn’t cause much pain” because it is a minor procedure. However, the *Guide* does not specifically say that castration does not cause pain but rather states that animals do not show significant signs of post-operative pain with minor procedures like castrations<sup>1</sup>. Furthermore, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* indicates that castration is considered to cause clear signs of pain and discomfort in pigs that can result in behavior changes<sup>2</sup>. Finally, Ballantine would have been willing to provide additional anesthesia,

as he himself stated, “If you wanted me to use an anesthetic you should have said so.” His statements tell us more about what he is used to doing rather than what is humane. So, was his method humane? Administration of local anesthetics can reduce both behavioral and physiological responses of piglets to castration<sup>3</sup>. If a refinement to an existing method is able to reduce pain and distress, then the old method would not be considered humane. Proper justification would be needed in order for the IACUC to approve a study in which piglets are castrated without administration of a local anesthetic. Such justification should ideally be determined in collaboration with Ballantine.

That brings up the second question of why Ballantine was not involved in this veterinary decision in the first place. Because Conquer Pharmaceuticals is not an NIH Assured institution, its IACUC needs only three members, as defined by the Animal Welfare Act regulations, one of them being a veterinarian trained in laboratory animal medicine<sup>4</sup>. Perhaps a different veterinarian was in charge of developing this protocol, explaining why Ballantine was not legally required to be a part of the process.

The *Guide* makes it very clear that all personnel, including consulting veterinarians, must have adequate training in laboratory animal science<sup>1</sup>, which should include information regarding IACUC protocol review. It is the IACUC’s responsibility to ensure that Ballantine understands what is expected to take place in an approved procedure. His failure to follow the protocol constitutes an oversight on the part of the IACUC as well as on his part. Ballantine should have followed the protocol or requested an amendment.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
2. *Guide for the Care and Use of Agricultural Animals in Research and Teaching* 3rd edn. (Federation of Animal Science Societies, Champaign, IL, 2010).
3. Zimmerman, J.J., Karkiker, L.A., Ramirez, A., Schwartz, K.J. & Stevenson, G.W. *Diseases of Swine* 10th edn. (John Wiley & Sons, Ames, IA, 2012).
4. Animal Welfare Act Regulations. 9 CFR, Chapter 1, Subchapter A, Part 2. Section 2.31. Institutional Animal Care and Use Committee (IACUC).

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