to read the approved protocol. At that point, he would have realized that the protocol required provision of a local anesthetic.

Ballantine carried out a procedure that was not in compliance with the approved protocol. It is appropriate to report this non-compliance to the USDA if that is Conquer's standard operating procedure or if the piglets were used in a biomedical study that was suspended by the IACUC as a result of the non-compliance.

A breakdown or lack of communications can be blamed for this incident, but the real problem seems to be the training program for new IACUC members. Simply providing copies of the Animal Welfare Act regulations[3] and the *Guide for the Care and Use of Laboratory Animals*[2] is not the best practice nor does it adhere to federal regulations. The training program for IACUC members should be reviewed and updated to include institutional policies and standard operating procedures as well as federal requirements and other applicable guidelines.

1. *Guide for the Care and Use of Agricultural Animals in Research and Teaching* 3rd edn. (Federation of Animal Science Societies, Champaign, IL, 2010).
2. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
3. Animal Welfare Act Regulations. 9 CFR, Chapter 1, Subchapter A, Parts 1–3.

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A word from USDA

In response to the questions posed in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offers the following guidance:

This scenario addresses several regulatory issues which are of concern to USDA, APHIS: regulatory requirements for the use of farm animals in biomedical research, personnel training and required reporting. The facility in the scenario does not fall under the jurisdiction of the US National Institutes of Health Office of Laboratory Animal Welfare because it does not possess an Assurance.

Activities that use farm animals in biomedical research are required to adhere to the same regulatory requirements under the Animal Welfare Act Regulations (AWARs) as activities that use traditional laboratory animals. This includes minimizing pain and distress[1]. Policy #17 in the *Animal Care Policy Manual* provides additional guidance regarding the regulation of farm animals used in biomedical research[2]. The AWARs also require IACUC approval for the proposed activity and proposed significant changes to that activity, along with the use of aseptic procedures during survival surgery[2].

It is the research facility's responsibility to ensure that all those involved in animal care and treatment are qualified to carry out their duties. Such persons are to receive appropriate training and instruction[2]. This requirement includes consulting veterinarians.

The AWARs do not require research facilities to report violations of the animal research activity to APHIS; however, facilities may choose to self-report incidents before they are discovered by the inspector. Self-reporting establishes a sign of good faith, which may be taken into consideration in the event that a facility becomes involved in an enforcement action[3]. Voluntary reports may be subject to requests made in accordance with the Freedom of Information Act.

1. Animal Welfare Act Regulations. 9 CFR, Chapter 1, Subchapter A, Part 2. Sections 2.31 and 2.32.
2. 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/policy.php>
3. United States Department of Agriculture, Animal and Plant Health Inspection Service. *Questions and Answers: Inspection Procedures in Response to an Incident or Adverse Event* (USDA, Riverdale, MD, 2012). <http://www.aphis.usda.gov/publications/animal_welfare/2012/inspection_incident_response_faq.pdf>

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RESPONSE

Making the IACUC squeal

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It's clear in this scenario that Ballantine did not fully understand the Animal Welfare Act regulations[1] (AWARs) or the *Guide for the Care and Use of Laboratory Animals* (the *Guide*)[2] when it came to the role of the IACUC and its review and approval of animal care and use. The AWARs require IACUC approval for the care and use of animals in ongoing activities[1]. This includes review to ensure that procedures minimize discomfort, distress and pain and that procedures that cause more than momentary pain and distress be performed with appropriate analgesics or anesthetics[1]. In this case, appropriate IACUC review had occurred, but Ballantine failed to recognize the importance of following the procedures as outlined in the protocol, leading to a protocol deviation. Failure to follow the procedure approved by the IACUC is a protocol deviation regardless of whether the non-approved method can be supported by other documentation.

What is reportable to USDA? According to the AWARs, there are very few instances in which the USDA must be notified. To our knowledge this includes change in the name, address, management or control of business ownership; IACUC suspension of a protocol; failure to correct a significant deficiency as planned during program review; the annual report; and incidents resulting in injury to cetaceans or humans in interactive programs[1]. Protocol deviations described in this scenario, which are not pervasive in the program, do not represent a significant deficiency in the program that would require reporting to the USDA.

What is reportable to the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)? AAALAC expects prompt reporting of unexpected animal deaths, natural disasters, animal rights activities, inappropriate euthanasia methods, allegation of animal welfare concerns, lack of veterinary care,