A standoff in post-approval monitoring

Dan Gold began his new job in post-approval monitoring with a wealth of past technical experience in animal care and use. Therefore, he was confident that he was being both helpful and correct when he told Dave White, a new postdoctoral scholar, that White’s aseptic surgical technique was good but could be improved by draping the surgical site on the mouse. White was pleased and said that he had described everything he would do, including the preparation of the animal, on his IACUC-approved protocol and that the reviewers had never said a word about having to drape the animal. “I don’t want to seem ungrateful,” White added, “but I’m making a two centimeter abdominal incision. If I drape the surgical site alone, there won’t be any convenient place to put my instruments and sutures, and if I drape a larger area, I won’t be able to see the animal’s breathing. Nobody else in my lab has ever been told to drape a mouse for a splenectomy, so why am I special?”

“Well,” Gold replied, “the Guide says that aseptic technique should be used for all surgical procedures and aseptic technique includes a sterile drape over the incision site. You can use a clear plastic surgical drape and cut a small hole in it where the surgery will be. Would that be possible for you to do?”

“Not really,” White responded. “It seems to me that if there are few or no postoperative infections—as with my surgeries—if the IACUC is happy with what I’m doing, and if the Guide doesn’t specifically say that animals have to be draped, then I don’t want to do anything I don’t have to do.”

White is arguing, in part, that his outcomes justify the means and that he is following his protocol. Gold is monitoring compliance with White’s protocol and agrees that he is in compliance, but at the same time, he was trained that surgical draping is an integral part of aseptic technique. How can this standoff be resolved?

First do no harm

Gail T. Colbern, DVM, MS, DACT

Post-approval monitoring (PAM) is a critical and difficult position. Gold is approaching his PAM duties in a helpful and positive manner and with a lot of enthusiasm. Because “PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures...which may also serve as an educational tool”1, this should be ideal for the animal care and use program at Gold’s institution. But in this scenario, Gold may be overreaching his authority.

Aseptic technique is required for surgery in all species1. The procedure described by the researcher White is a major, survival surgery in rodents; therefore, aseptic technique must be used to avoid post-operative infections and animal pain and distress. Both Gold and White seem to agree on this point. The difference in opinion arises in the exact definition of aseptic technique.

The Guide for the Care and Use of Laboratory Animals (the Guide) states that “regardless of species, aseptic technique includes preparation of the patient, preparation of the surgeon, sterilization of instruments, supplies and implanted materials and use of intraoperative techniques to reduce the likelihood of infection”2. White has described a list of procedures in his approved protocol that he follows to achieve aseptic technique. This list of procedures was approved by the IACUC and appears to be successful, as White is not encountering any post-operative infection among his animals.

Gold has suggested using drapes as an additional technique to improve aseptic technique. This technique is promoted in various reviews of prevention of surgical site infections3,4. Drapes can be helpful in maintaining an aseptic surgical field in rodent survival surgery4. But other elements of successful, aseptic survival surgery in rodents should also be considered. The Guide states that “the contribution and importance of each practice (of aseptic technique) varies with the procedure”4. White has considered using a drape but is afraid he will not be able to monitor the animal as well with a drape in place, risking anesthesia problems. In addition, a drape would alter his current, successful aseptic surgical field and could result in additional contamination. The small size of mice makes these very real concerns, and the Guide states that “the species of animal may influence the manner in which principles of aseptic technique are achieved”4.

The concept of ‘primum non nocere,’ or ‘first do no harm,’ is a hallmark of medical ethics and must be considered in this case. There is a real possibility that Gold’s insistence on using drapes could make the situation worse, resulting in increased post-operative infection and a negative perception of Gold and the PAM program. According to the Guide, “PAM programs are more likely to succeed when the institution encourages an educational partnership with investigators”4. Because no one else in White’s lab is draping rodent surgical sites, Gold should approach this as a potential educational opportunity for everyone in White’s lab. He should obtain a number of different drape samples (clear, sticky, flexible, stiff) and invite everyone from the lab to come and see how they work. He should collect documentation on how to successfully use the drapes in rodent aseptic surgery. He should demonstrate how


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the aseptic surgical field can be set up and improved with the drapes. Great for the training records!

Through cooperation and education, a successful PAM program will continue to improve the condition of all research animals.


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RESPONSE

Develop a collegial relationship

Susan R. Blumenthal, PhD & Joshua A. Robbins, BA

Despite the relative youth of formal post-approval monitoring (PAM), the foundational concepts of IACUC oversight of all animal activities at an institution have a long history and developed culture. The lack of history and developed culture with formal PAM can create issues within animal research programs. There is a distinct culture in regulatory compliance that is necessary to have an effective program, and in this particular area of compliance, that is to balance concerns for animal welfare with facilitation of scientific research. The inherent conflict in that balance presents a great challenge to PAM staff.

In this case, Gold has recently been hired into a PAM program, bringing with him substantial technical experience in animal care and use. Although his background provides excellent qualifications for the position, effective PAM requires more than technical expertise. Crucial to this effectiveness is to have ‘permission to advise’ from researchers. This ‘permission’ is developed through the establishment of relationships and can be based on prior history with personnel in an office or program that conveys that permission to all members of the department or through the development of personal relationships between PAM staff and researchers.

Based on his experience and training, Gold is confident in his recommendations to postdoctoral scholar White and has every intent of being helpful and not obstructive. But Gold is new in his position and lacks an established relationship with researchers. In addition, the PAM program for which he works may or may not have a history of a client-friendly culture, which affects the reception of his recommendations. Although a researcher’s reaction to a recommendation from a PAM monitor does not determine its validity, there are problems with Gold’s recommendation beyond his lack of ‘permission to advise’.

Gold’s recommendation is based on his training in surgical research. Although he is correct that draping can facilitate aseptic technique, there is no indication that Gold’s recommendation would provide benefit to the animals. In fact, based on some of White’s responses, draping might have a negative effect on animal welfare.

White appears to be following the letter and intent of both the regulations and his reviewed, approved IACUC protocol (which should have been developed in conjunction with the veterinarian). In that regard, there is no basis for requiring him to change his procedures. White’s other responses, though common, are not adequate reasons for a refusal to improve his procedures. Furthermore, his responses reflect flawed logic and a lack of understanding of animal research and the role of PAM.

Finally, Gold’s position does not enable him to autonomously change what the IACUC has approved but rather to assist in balancing animal welfare concerns with facilitation of scientific research. In this case, Gold has created an adversarial rather than collegial situation without demonstrated or suggested concern for animal welfare and has lost an opportunity to develop that ‘permission to advise’ with White. Given that White is in compliance with his IACUC protocol and animal research regulations and that there appear to be no animal welfare concerns, Gold should learn from this standoff and move on.

Blumenthal is President and Managing Director and Robbins is Consultant at Gracewood Associates, Charlotte, NC.

RESPONSE

Make a collaborative effort

Ann Marie Dinkel, RLATG & Deyanira Santiago, RLATG

While Gold is experienced with both animal care and surgery, his assessment of White’s surgical technique, though correct, may be overzealous. White’s protocol was properly reviewed and approved by the IACUC, and he is following it as written. Although draping may be a best practice for aseptic surgery, it is not a requirement, and common sense should guide its use.

White has many good reasons not to drape the animals, and these are mainly research-related. The ability to observe the animal’s breathing is critical but might be hampered by a standard paper drape. Although paper drapes are common, they cause difficulty monitoring the animal during a surgical procedure. According to one report, “plastic drapes, usually with an adhesive, offer the advantage of more visibility and better patient monitoring”1. While Gold’s suggestion of a clear drape indicates an understanding of the problem, it is only a partial solution, especially on a small animal with a very small incision.

Gold’s criticism is that draping, though not specifically required by the Guide for the Care and Use of Laboratory Animals (the Guide)2, is still a refinement to White’s surgical aseptic technique. Researchers and IACUCs should continually evaluate their methods and guidelines in order to refine them as acceptable practices evolve2,3. White also indicates that his technique has been successful. If there is any doubt about the effectiveness of his technique, a review of animal complications will identify any problems. The Guide indicates that a
regular review for adverse or unexpected experimental outcomes should be included as part of post-approval monitoring.

There should be no standoff between Gold and White: no apparent clinical issues have been noted, protocol and institutional policies are being followed, and Gold’s responsibility is to recommend better practices. The IACUC may choose to adopt a requirement for draping at a future time, as a refinement to the standard of aseptic technique. At that point, all approved protocols would need to comply, either immediately or when the protocol comes up for review or renewal, as the committee decides. Gold may discuss and advocate for this at a meeting and may guide the IACUC in its decision to include this additional technique in its surgical guideline.

Overall, this can be a learning experience for all involved. White may learn some additional techniques that might improve animal outcomes, and Gold may learn that in the role of compliance, he is first a collaborative partner in research, providing information, technique improvement, and then overseeing compliance of all federal and local regulations and institutional policies. This does not have to result in butting heads; collaborative efforts provide the best outcomes.


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Launch of LASA CPD Scheme

Why CPD?

Continuing Professional Development (CPD) is a prerequisite for many professional medical and scientific disciplines but less common for those involved in laboratory animal work.

Revision of Directive 86/609EEC requires that persons “are adequately educated, competent and continuously trained” (Article 23A). This comes into effect from 1st January 2013.

The scheme will be available FREE to LASA members.

If you would like further details of the LASA CPD scheme or becoming a member of LASA please email the Secretariat - info@lasa.co.uk

New Appointment Strengthens Agenda Board

Agenda Resource Management, one of the UK’s leading specialists in the recruitment and contract placement sectors of the biomedical research industry, has announced the appointment of Tim McGuire to the company’s Board of Directors.

Commenting on his appointment, Tim says: “I am thrilled to accept the offer to join the Agenda Board. We are a customer focused, ‘can do’ operation, a people company with a work and life ethic that is closely aligned to my own.”

Paul Sanders, Managing Director says he is delighted to welcome Tim to the Board. “Tim has been with us for almost two years now and this promotion is a hugely deserved recognition of his efforts, ambition and standing within the research community. Tim’s credentials as an outstanding business development professional were well proven before he joined Agenda but we have been delighted with the enthusiasm and strategic thinking he brings to the team, and he has integrated seamlessly with our values and culture.”

Fellow Director, Norman Mortell, adds “Tim has been instrumental in the continued growth of Agenda and has played an important part in the company achieving its status as one of top five employers of animal technicians in the UK. He has had a positive impact on all parts of the business, not least in enhancing and refining our facility management services and opportunities.”

The appointment of Tim McGuire further underlines the ambition of the company and its determination to build on its impressive success, as Paul Sanders explains: “Over the last couple of years we have made significant investments in our infrastructure and technology including, most recently, the introduction of the Tech Talk resource and electronic timesheets for our staff. We’re not ones to stand still and we have fantastic plans for the continued growth of Agenda in the coming years. Tim will be an integral part of that strategy.”