wants to grossly examine the anastomosed intestines of one group endoscopically and to examine microscopically the anastomosed intestines of the other, at specific time points, through necropsy. I believe the IACUC wants to know why the two groups can't be combined. Rosen could still examine the intestines endoscopically whenever he chooses, and at specific time points he could euthanize the rabbits for histological sections. I happen to agree with the IACUC. Why waste more rabbits for something that can be done with a little refinement and reduction? However, I believe that had he addressed the IACUC and justified his need for the two groups, then the Committee would have assisted him in finding a solution that would satisfy both the investigator and themselves.

There are quite a few good articles published that help explain the need for different numbers of animals. That doesn't mean that investigators are going to read any of them, but if their protocols are put on hold they may change their minds. I do believe that some of these researchers have a great deal of literature to read anyway. Examples would be reviewing articles from a scientific journal or reviewing grants for a study section or reading papers that come out monthly about their own project area. So I think the issue calls for some patience from the IACUC.

Goldberg is Laboratory Animal Anesthesia Specialist, Departments of Physical Therapy and Anatomy and Neurobiology, and IACUC Member, Virginia Commonwealth University/Medical College of Virginia, Richmond, VA.

RESPONSE

The 3Rs of our ways

Sarah Bro Hinds, DVM, MPH

I support Gooding's assessment that the IACUC wants to "make sure that [Rosen] is going to use the smallest number of animals that can give you scientifically acceptable results." Let's see if we can get Rosen to see (at least a couple of) the 3Rs of our ways.

It appears from this example that Rosen would like to use two groups of rabbits for this experiment, and both groups would be subjected to the same major surgical procedure. If the only difference between the groups is that one will be used to visualize grossly the anastomoses (via endoscope) while the other will be serially euthanized for histopathological exam, then the IACUC is serving its function to identify the terrific opportunity for Rosen to both reduce his rabbit numbers and achieve the same scientific aims.

Although Rosen correctly interpreted the language in the AWA regarding the IACUC's role of not setting the standards for scientific design, his biostatistician and/or veterinarian should have raised this issue before it even went to the Committee. Using one group of animals, Rosen can do the surgery, examine the rabbits endoscopically, and then serially euthanize each animal for histology. In this repeated-measures design, he will adequately correlate the two different methods of observation for each subject. His current design will provide no correlation between those undergoing endoscopy and those viewed histologically. I think Rosen believes he can get that correlation with two groups. He just needs guidance.

The IACUC probably identified this flaw and, championing the use of fewer animals, would like a justification for using two groups. If Rosen can justify that the endoscopic procedure will somehow alter the colon histologically, he may be able to succeed in his proposal as designed, but if the colon is damaged or altered by this method, then why not seek a refinement for the rabbit? He can instead do CT or MRI scans on his rabbits. He could consider ultrasound. In this manner, he has only to anesthetize his rabbits for restraint, not for analgesia for the potential pain or discomfort that may be associated with insufflation of the colon.

Rosen has a friend in Gooding, who is really trying to get Rosen to see the light. It's a committee that decides, not one individual, and if the Committee saw an opportunity to implement any of the 3Rs (especially when the same scientific goals will be achieved), then they are justified in asking Rosen to reconsider his experimental design.

Hinds is Chief of Small Animal Protocol Support, US Army Medical Research Institute of Infectious Diseases, Ft. Detrick, MD. Disclaimer: Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

RESPONSE

Freedom without accountability

James R. Owiny, BVM, PhD, DACLAM

While examining the policies of the AWA, Rosen missed a few steps. For example, the congressional statement of policy specifies both that the intent of the Act is "to insure that animals intended for use in research facilities … are provided humane care and treatment[1]" and that "measures which eliminate or minimize the unnecessary duplication of animals can result in more productive use of Federal funds; and … measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress[1]". While Rosen quotes from §2143(6)(A) of the Act, he should read a little more of this section, which authorizes the Secretary to promulgate standards that address humane handling, care, treatment, and transport as well as focus specifically on pain and distress. The mandate of the IACUC is to oversee these issues at the institutional level. Similar language is in the AWA regulations. In recognition of the possibility of the scenario raised by Rosen, the United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training principle IX states that "… the decisions should not rest with the investigators directly concerned but should be made, with due regard to principle II, by an appropriate review group such as an institutional animal care and use committee[2]."

The spirit of the law is to ensure welfare of the animals and not to impede research. The law specifically recognizes the benefits to humans and animals that accrue from the use of animals for research. Most institutions do not expect its investigators and employees to be familiar with all the nuances of federal laws and regulations, and the additional layers of state and local laws and ordinances. The IACUC, in concert with the Institutional Official (IO), has the mandate to ensure that standards are satisfied. Increasingly, IACUCs are using the resources of specialized staff members or the legal affairs department to