

should be arranged (this should be standard practice). Members of the IACUC could also participate in the post-operative evaluations. The rats that unequivocally appear not to experience any unalleviated pain or distress could retroactively be classified as category D. Furthermore, during the annual review process, based on the outcomes of the evaluations and an established history at Great Eastern, the IACUC could consider whether, henceforth (either by amending the current protocol or in future protocols), a percentage of the total number of rats could initially be placed in category D, and those expected to experience unalleviated pain or distress in category E.

Parlett is an independent consultant in Randolph, NH. The opinions expressed above are entirely his own and in no way should be construed to represent those of any organization that employs his services.

RESPONSE

Oversensitive IACUC

Craig L. Wardrip, DVM, DACLAM & George P. Langan, DVM, DACLAM

Great Eastern University's IACUC is overly sensitive to the need to classify these rats into pain and distress category E. The use of such categories is required on Annual Reports for the USDA but is not required by OLAW. Assuming Subaraman's rats are of the genus *Rattus* and are bred for use in research¹, they are not covered by the USDA. There is no requirement to include information about these rats on the Annual Report to the USDA, and Great Eastern University would be foolish to do so. The report indicating unalleviated pain or distress would be posted on the USDA's website and would be subject to disclosure under the Freedom of Information Act (http://www.aphis.usda.gov/animal_welfare/efoia/7023.shtml). This could attract unwanted attention from animal rights activists and protesters.

Great Eastern University should retroactively classify USDA-covered animals into pain category E depending

upon their response to experimental treatment. They must carry out this classification effectively each year for the period October 1 through September 30 and accurately report it on their Annual Report to USDA. There is no requirement by either USDA or OLAW to classify animals prospectively into pain category E if only a small number of animals will reach that state and they cannot be identified in advance.

Subaraman has already described the manipulations on the rats in detail, and the treatment he is testing will minimize pain and distress if successful. He has proposed withholding of any other treatment for pain or distress based on scientific justification and has fulfilled the requirement of the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*². Subaraman has a plan to identify and count any rats that develop clinically apparent neuropathy and to report them to the IACUC for categorization into pain category E. This plan leaves the rats without clinically apparent neuropathy in pain category D, as appropriate.

Because these are not USDA-covered animals, annual reporting of animals in pain categories to any agencies is not required. The IACUC may require an annual accounting as the study progresses, and it should require re-evaluation of endpoint criteria when the protocol is resubmitted after three years.

The ability of the stimulation by heat or cold to elicit hypersensitivity early in the project is irrelevant and should not be considered by the IACUC. Application of heat or cold to the area of concern is not part of the normal husbandry of the rats. This IACUC is hypersensitive!

1. Code of Federal Regulations. 9 CFR, Subchapter A, Part 1.1 Definitions.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* Section IV, C, 1, b. (US Department of Health and Human Services, Washington, DC, 1986, amended 2002).

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RESPONSE

Actual pain vs. potential for pain

Tracey Dabbs, BS, RLATG & James Finlay, DVM

To determine which pain and distress category Subaraman's experimental rats should be placed in, the IACUC should consider the actual pain and distress that the rats will experience rather than a "reasonable potential for pain"¹. Our ability to recognize pain in animals varies among species; we rely on behavioral signals as well as appearance to identify when an animal is in pain². According to Subaraman, his research team has done this procedure hundreds of times. He testifies that when the procedure is successful, the rats will be able to walk and groom, will gain weight and will not show any abnormalities except increased sensitivity to hot and cold during specific neurological tests. The Great Eastern IACUC is basing its decision on the potential for pain or distress that may be experienced by the rats, not actual pain or distress. We believe it is more appropriate to place clinically normal rats in category D and to place those that develop clinical neuropathy in category E. Even though some rats will be placed in category D, the protocol should still include strong scientific justification for not providing pain relief to the rats placed in category E.

Because there is potential for the rats to develop clinical neuropathy, post-procedure monitoring should be detailed in the IACUC protocol. We would suggest daily monitoring of the rats for signs of pain including but not limited to signs of clinical neuropathy and more than momentary pain or distress associated with the neurological testing. Observations that could be noted include activity level, weight loss or gain, self-mutilation, guarding behaviors, aggressiveness, locomotion, writhing, piloerection, porphyrin staining, and food and water intake. The IACUC should also require Subaraman to include other ways of managing pain in the rats that develop clinical neuropathy such as using a softer bedding material.