

November 22, 2004

Dr. Richard Tallman, Chair ILACUC
Office of Responsible Research Practices
300 Research Foundation
1960 Kenny Road
Columbus, Ohio 43210

Re: Approval of Instructional Protocol 2003A0096

Dear Dr. Tallman:

As you know, the ILACUC review board of which you are chair derives its authority from the Health Research Extension Act (HREA) and the Animal Welfare Act (AWA). I would like to address some concerns with the above referenced protocol in relation to the Ohio State University ILACUC's responsibility to assure compliance with the HREA.

As a research facility that conducts biomedical and behavioral research with funds provided under the HREA, Ohio State University (OSU) is required to abide by Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) established under the HREA. As part of this required compliance, awardee institutions must provide a written Animal Welfare Assurance of Compliance (Assurance) to the Office of Laboratory Animal Welfare (OLAW) detailing the institution's procedures for compliance with PHS Policy. Once this Assurance is approved by OLAW, the institution (in this case, Ohio State University) and all its personnel must comply with the PHS Policy, including the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (US Principles) and the Guide for the Care and Use of Laboratory Animals (Guide).

As further part of this required compliance, any use of live animals for testing, research, and training must be approved by the ILACUC. The approval process requires that the ILACUC "review concerns involving the care and use of animals at the institution" and "determine that the proposed research projects are in accordance with this [PHS] Policy." Finally, the ILACUC is "authorized to suspend an activity involving animals..." including activities that have been previously approved.

A fundamental goal of the PHS Policy and the Guide is the minimization of animal pain and distress via the consideration of non-animal alternatives. To this end, Principle III of the US Principles states that a minimum number of animals should be used and alternatives be considered. Chapter One of the Guide states that considerations must be made with regard to "Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation."

As part of this consideration and as part of the United States Department of Agriculture's Animal and Plant Health Inspection Services animal policy guideline #12, the Principal Investigator (PI) of an activity involving the use of animals must provide a written narrative to the ILACUC for the body's consideration. This written narrative should include adequate information for the ILACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative

methods. If a database search or other source identifies a *bona fide* alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

The referenced instructional protocol submitted to the ILACUC on June 9, 2003, and titled "Spinal Cord Injury Techniques Course," seems to contain such a narrative. The PI describes a search on the MEDLINE online database for "spinal cord injury, central nervous system injury, [and] experimental spinal cord injury." The PI explains that no suitable alternatives to the use of 1245 mice and rats over five years could be found. Further explanation is provided by discounting the use of tissue culture models in experimental spinal cord injury research, and an explanation of the need for "confirmation of the results [of research projects] across a number of laboratories" (page 6).

However, this cursory search does not fulfill the intent of the guidelines it is meant to address. If one is searching for alternatives to the use of animals *in this course* then one should be searching for alternative teaching methods, not research methods. Alternatives to the course as proposed include anything from mentoring with established researchers to the use of simulators or models to videotaped techniques demonstrations.

Consequently, there is no justification for the use of animals in this course, and the instructors who have requested approval for their use, the ILACUC that has approved their use, and OSU itself is in violation of the Animal Welfare Act and its implementing regulations and policies, the HREA, PHS Policy, and US Principles. As professionals knowledgeable in topics relating to medical research and scientific education, my colleagues and I have offered to meet with the OSU President, Ms. Holbrook, and other University representatives, and as yet have not received a response.

Accordingly, the Physicians Committee for Responsible Medicine requests that you use your authority as chair of OSU's ILACUC to suspend this course immediately. We are troubled that appropriate action has not yet been taken. We believe that, if no action is forthcoming, this matter must be brought to the attention of OLAW for investigation.

Thank you for your prompt attention to this important issue.

Sincerely,



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