

THE
GRADUATE
SCHOOL
UNIVERSITY OF WISCONSIN-MADISON

December 2, 2003

Dr. Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 1050, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Potkay:

This letter is in response to your correspondence of October 28, 2003 regarding the suspension of an animal study protocol at University of Wisconsin-Madison. You asked for a full explanation of the circumstances that led to the suspension and the species of animal involved.

On May 13, 2003 the Graduate School Animal Care and Use Committee (ACUC) at the University of Wisconsin-Madison suspended a protocol covering neuroscience research involving rhesus macaques. OLAW was notified of the suspension by telephone on May 13, 2003 and in a follow-up letter from the University dated September 22, 2003. This incident was also noted in a USDA report filed May 15, 2003.

The suspension sparked a thorough investigation of clinical and research records associated with the principal investigator's neuroscience research for the past three years. In dialog with the principal investigator, it became clear that the ACUC and the investigator had differing interpretations of the long-term experiments described in the protocol. During the detailed investigation, several violations of the corresponding study protocol were identified, many by the investigator as a result of her own examination of the records.

In addition to the lack of continuous monitoring that originally prompted the suspension, other violations documented during the three-year interval reviewed by the ACUC included:

- drug-challenges exceeding the number approved in the protocol;
- administration of drugs not listed in the protocol;
- administration of drug doses exceeding those stated in the protocol;
- exceeding the maximum number of experiments per animal
- one animal was subjected to one additional major survival surgery more than was approved by the ACUC;
- blood was collected on occasions where blood draws were not described in the protocol; and
- prophylactic antibiotics were administered before and after surgical procedures even though such treatment was not included in the protocol.

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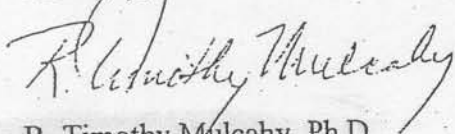
Following its review, the ACUC the PI that re-instatement of the protocol was contingent on acceptance of the following conditions:

- the PI and research staff must meet with a designee of the ACUC to ensure that all members of the research team recognize the importance of protocol compliance
- the university will provide close oversight of the investigator's research program for a minimum of 6 months. The oversight will include the following actions:
- an independent reviewer approved by the ACUC must review and approve all experimental procedures and each animal's history prior to all experiments
- protocol compliance must be confirmed by a post-experiment review of corresponding laboratory and clinical records
- [REDACTED] veterinarians will closely monitor the clinical status of all animals assigned to the protocol to document typical as well as unusual outcomes associated with the study.

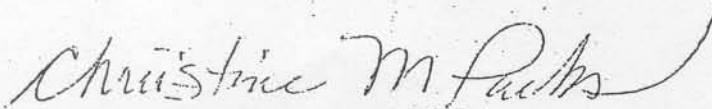
The PI has agreed to these terms and the protocol has been re-instated.

If you have further questions or concerns, please contact Dr. Parks at 608/265-2697.

Sincerely,



R. Timothy Mulcahy, Ph.D.
Associate Vice Chancellor for Research Policy
Chair, All Campus ACUC



Christine M. Parks, D.V.M., Ph.D.
Director, RARC