



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163 ext 7
Facsimile: (301) 402-7065

December 4, 2003

Re: Animal Welfare Assurance
#A3368-01

R. Timothy Mulcahy, PhD
Associate Dean, The Graduate School
University of Wisconsin-Madison
500 Lincoln Drive - Bascom Hall
Madison, WI 53706-1380

Dear Dr. Mulcahy:

Thank you for your letter of December 2, 2003 providing additional information regarding the suspension of an animal study protocol (ASP) at the University of Wisconsin-Madison (UW-M) reported in correspondence dated September 22, 2003.

Based on the information provided in your correspondence and in the initial May 13, 2003 telephone notification, the Office of Laboratory Animal Welfare (OLAW) understands that the Animal Care and Use Committee (ACUC) suspended the ASP when it determined that the principal investigator failed to provide continuous monitoring of rhesus monkeys that were restrained in chairs for extended periods. As a consequence of the broader investigation undertaken into this incident, in which one monkey died, we also recognize the ACUC determination that, over the course of three years, the investigator conducted numerous activities involving animals that had not been approved by the Committee. These unauthorized significant changes to the approved ASP, each of which represents serious noncompliance with the PHS Policy, included: the use of unapproved drugs and unapproved dosages of approved drugs; the conduct of unapproved numbers of drug challenges; unauthorized blood collections; using animals in more than the authorized number of experiments; and conducting unauthorized multiple survival surgery. *Please note that any of these violations, had they been known to the ACUC prior to the described review, were reportable to OLAW.* Further guidance in this topic is provided in the enclosure.

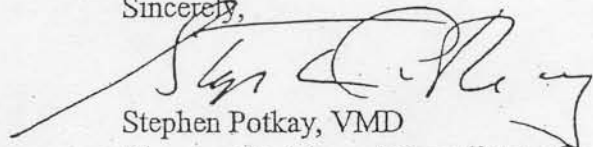
We acknowledge that the ACUC reinstated the ASP when the investigator agreed 1) to meet, along with her staff, with an ACUC member to receive instruction on the requirement to adhere to approved protocols and 2) to certain stipulations regarding monitoring for a period of at least six months. This Office notes that the proposal to monitor the investigator's research program utilizing the services of an independent, ACUC-appointed individual to review and approve all experimental procedures may not be consistent with provisions of the PHS Policy at IV.B.7. & 8. which require the ACUC itself to review and approve, require modifications (to secure approval) or withhold approval of activities related to the care and use of animals and of proposed

significant changes regarding the use of animals in ongoing activities—using one of the mechanisms described in the PHS Policy at IV.C.2. **Please notify OLAW as to whether use of the independent reviewer/approver is in addition to or in place of the standard ACUC review process. If it is in place of procedures required by the PHS Policy, please modify this aspect of the corrective action plan to comport with these Policy requirements.** We understand that other aspects of the monitoring include: veterinary assessment of the clinical status of all animals assigned to the study and to document unusual outcomes associated with the study; and post-experimental review of laboratory and clinical records. OLAW also recommends, but does not require, that the ACUC also consider monitoring that includes scheduled or unannounced oversight during the conduct of procedures.

In view of the apparently extended period of time that the research was conducted in noncompliance with provisions of the PHS Policy, we suggest that the UW–M evaluate the uses that might be made of the data collected data during that time. Consideration should include editorial policies and other professional society statements regarding animal welfare requirements, inasmuch as most societies are explicit in not allowing publication or presentation of papers not conducted in compliance with applicable regulations and policies, as well as the issue using of such data in PHS grant applications.

OLAW requests a response to the item indicated above in **bold by January 16, 2004.** Thank you for your assistance with this matter.

Sincerely,



Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

Enclosure

cc: Elizabeth Goldentyer, DVM - USDA
Kenneth Gosnell - GMB - NICHD
Christine Parks, DVM