



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
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July 3, 2008

Re: Animal Welfare Assurance
#A3180-01 (OLAW Case 1J)

Dr. David L. Wynes
Vice President for Research Administration
Emory University
1510 Clifton Road-Suite G65
Atlanta, GA 30322

Dear Dr. Wynes,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 1, 2008 letter informing us of an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Emory University. Your letter was subsequent to an initial report to our Office by Mr. David Knight on April 1, 2008. According to the information provided, OLAW understands that a lab was found to have been withholding protocol-required post-operative analgesia on approximately 125 mice since the beginning of 2008. The initial report indicated that these activities were PHS supported.

The corrective actions consisted of the stopping of surgical procedures until the noncompliance was corrected. A protocol modification was submitted utilizing a lower analgesic dose and to provide the analgesics after recovery. The PI also met with the research staff to enforce the need to adhere to protocols.

The Emory University School of Medicine's handling of the matter was consistent with the philosophy of self regulation. Similarly, the timely and appropriate action taken to resolve the issue and prevent recurrence was appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Samuel Speck, Ph.D., IACUC Chair



MAY 14 08 AM 9:33

May 1, 2008

Dr. Axel Wolff
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institute of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

**Re: Emory University Institutional Animal Care and Use Committee (IACUC)
Reporting AWA # A3180-01**

Dear Dr. Wolff:

As Institutional Official for Emory University's Institutional Animal Care and Use Committee (IACUC), and in accordance with applicable regulatory requirements, I am writing to report protocol violations involving the following protocols:

- Protocol #221-2005: *Vascular specific ACE expression and atherosclerosis;*
- Protocol #081-2006: *Molecular mechanisms of AAA formation; Nanotechnology; Detection and Analysis of Plaque Formation;*
- Protocol #095-2007: *Determining the role of the Renin receptor in atherosclerosis; and*
- Protocol #154-2007: *AGEs and vascular Inflammation*

This matter was initially reported to OLAW by telephone to Dr. Brent Morse on April 1, 2008.

On March 4, 2008, during the AAALAC site visit of Emory University, which also constituted the IACUC semi-annual inspection, concern was expressed over a laboratory's failure to use analgesics as described in the protocols listed above. In response, members of the IACUC Office conducted a review of the protocols and met with the Principal Investigator (PI) on March 24, 2008 to discuss the concern. All surgeries were halted until the non-compliance could be corrected. The review indicated that the surgical procedures described in these protocols were similar and that the use of analgesics after surgery was prescribed in all of the protocols. The evaluation of animal records indicated a failure to provide analgesics as described in the approved protocols. The PI reported that the recommended dose of analgesic resulted in a higher mortality from respiratory failure immediately after surgery on mice. This seemed to be the result of a synergistic effect with the anesthetic being used. Since the beginning of 2008, it is

estimated that 125 mice underwent surgical procedures without having received the proper analgesics.

The PI was issued a noncompliance letter on April 1, 2008 which outlined the corrective actions to be taken in order to proceed with the study. The noncompliance letter requested that the PI respond by April 8, 2008 indicating that the corrective action plan had been implemented, and including a description of preventative measures to ensure continued compliance.


The PI complied with the requirements of the noncompliance letter. The PI requested to use a lower dose of analgesic thereby avoiding the respiratory failure of the higher dose when used in conjunction with the anesthetics. The IACUC required the submission of a modification for this change in procedures. The modification was approved by the IACUC on April 8, 2008 with the additional recommendations to provide the analgesics after recovery and to consult with veterinary staff if further complications occur. In addition, the PI met with the laboratory staff to review all protocols and to reinforce with the laboratory the expectations to adhere to protocols.

The IACUC Compliance and Training Specialist met with the laboratory staff to further discuss the proper record keeping requirements for documenting post-op analgesics on April 22, 2008. Proper recording was confirmed on April 25, 2008 during an unannounced visit to the laboratory.

The IACUC believes that the corrective action taken is appropriate and will prevent the re-occurrence of such activities by the research staff.

Please feel free to contact me or IACUC Chair Dr. Sam Speck if you would like further information regarding this matter.

Sincerely,



David L. Wynes, Ph.D., Institutional Official
Vice President for Research Administration

cc: Sam Speck, Ph.D., IACUC Chair
David Knight, Director, IACUC
Michael Huerkamp, DVM, Director, Division of Animal Resources
AAALAC



Initial Report of Noncompliance

By: *[Signature]*

Date: 4/1/08

Time: 9:50

Name of Person reporting: David Knight
Telephone #: 404-727-6212
Fax #:
Email:

Name of Institution: Emory Univ.
Assurance number: A3180-01

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? [W. Robert Taylor (PI)] During AAALAC site visit, the tech, stated that they had stopped giving analgesic (Buprenorphine) after the Ket/Xy anesthesia.

Species involved: Rats or mice

Personnel involved: PI + Tech

Dates and times:

Animal deaths: No

Projected plan and schedule for correction/prevention (if known):
Investigation started.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____