



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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January 28, 2008

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

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 January 22, 2009 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Emory University, following up on an initial email report on December 22, 2008. According to the information provided, OLAW understands that twelve rabbits failed to receive post-operative analgesia which was contrary to what had been described in the Institutional Animal Care and Use Committee (IACUC) approved protocol.

The corrective actions consisted of the Principal Investigator (PI) suspending the study, requiring the PI to provide documented pain management as outlined in the approved protocol, placing the laboratory under enhanced IACUC oversight, and requiring the PI to obtain prior IACUC approval before implementing any significant changes to the protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Axel Wolff, M.S., D.V.M.  
Director  
Division of Compliance Oversight

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



EMORY  
UNIVERSITY

Office of Research Administration

January 22, 2009

Axel Wolff, DVM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes 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 an incident of protocol non-compliance associated with the following protocol:

Protocol #: 021-2007; *Rabbit model of retinoblastoma*  
Funding agency: NIH

IACUC Director David Knight initially reported this matter to OLAW by email communication with you on December 22, 2008.

On December 16, 2008 during the IACUC's semi-annual inspection of the PI's laboratory, the inspectors ascertained that rabbits had not been provided the approved post-surgical pain management as described in the IACUC protocol. The IACUC determined that 10 to 12 rabbits underwent the surgical procedure without the post-surgical pain management. The PI voluntarily halted the study until lab procedures were fully evaluated, and a corrective plan was developed and approved by the IACUC.

After reviewing the matter on January 7, 2009, the IACUC voted unanimously to cite the findings as protocol noncompliance and to require corrective action. The PI was sent a noncompliance letter on January 13, 2009, that required the following corrective actions:

1. The PI was required to ensure that all animals receive the appropriate pain management as described and approved in the protocol. Pain medication administration was required to be documented for each animal and records kept and available for veterinary and IACUC staff review.
2. Frequent post-approval monitoring visits were required to be conducted by the IACUC Compliance and Training Specialist. As part of this requirement, the Compliance and Training Specialist was required to be in attendance at the next procedure scheduled by the PI. Following the first procedure, the PI's laboratory also would be subject to other unannounced post-approval monitoring visits.

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