



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
Facsimile: (301) 402-2803

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



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:

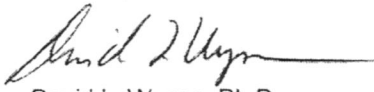
1. The PI was required to ensure that all animals receive the appropriate pain management as described and approved in the protocol. Pain medication administration was required to be documented for each animal and records kept and available for veterinary and IACUC staff review.
2. Frequent post-approval 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.

3. The PI was required to file a modification for any changes in the procedures described in the approved protocol. IACUC approval would be required prior to implementing any modified procedures.

On January 13, 2009, the IACUC received a written response from the PI indicating that all corrective actions would be followed. The IACUC believes the mandated corrective actions are appropriate and will prevent the reoccurrence of the non-compliance.

Please feel free to contact me or the IACUC Director, David Knight, if you would like further information regarding this matter.

Sincerely,



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

cc: Sam Speck, Ph.D. (IACUC Chair)
David Knight (IACUC office)
AAALAC

Morse, Brent (NIH/OD) [E]

From: Knight, David L [DKNIGHT@emory.edu]
Sent: Thursday, January 22, 2009 1:09 PM
To: Morse, Brent (NIH/OD) [E]
Cc: Wolff, Axel (NIH/OD) [E]; Brinsfield, Casey; Lawley, John
Subject: OLAW Letter Report Emory Non-compliance
Attachments: OLAW Letter Final 1-22-09.pdf

SORRY, I forgot the attachment.

Dear Dr. Morse,
Attached is a letter from the Emory IO describing the non-compliance found during a semi-annual inspection at Emory University. This was initially reported to you on December 22. Please let me know if further information is required on this incident.

Sincerely,
David

David L. Knight

Director IACUC
Emory University
1599 Clifton Road, 1599-001-1AU
Room 5.309
Atlanta, Georgia 30322-4250
Phone: 404-712-0734
Fax: (404) 727-8877
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Web Site: <http://www.emory.edu/IACUC>

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Wolff, Axel (NIH/OD) [E]

A3180-15

From: Wolff, Axel (NIH/OD) [E]
Sent: Tuesday, December 23, 2008 7:21 AM
To: 'Knight, David L'
Cc: Morse, Brent (NIH/OD) [E]
Subject: RE: Initial Emory University Report on Non-Compliance

Thank you for this preliminary report Mr. Knight. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

From: Knight, David L [mailto:DKNIGHT@emory.edu]
Sent: Monday, December 22, 2008 4:52 PM
To: Morse, Brent (NIH/OD) [E]; Wolff, Axel (NIH/OD) [E]
Subject: Initial Emory University Report on Non-Compliance

I got a message that Dr. Morse was out of the office so I am forwarding this to you also.

Dr. Morse,

This is initial notification to OLAW of a non-compliance incident with a NIH funded animal protocol here at Emory University. During a semi-annual inspection of a laboratory using rabbits, it was found that the laboratory personnel were not giving analgesics as described in the protocol. In our estimate, this has occurred with 10-15 rabbits on this protocol. All work on this protocol has been voluntarily halted until the IACUC can meet and decide on the corrective actions that will be required.

I will follow up with a final report on this incident as soon as possible. Please let me know if you need any further information at this time.

David

David L. Knight

Director IACUC
 Emory University
 1599 Clifton Road, 1599-001-1AU
 Room 5.309
 Atlanta, Georgia 30322-4250
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Full Assurance Agreement Printout

Assurance Number: A3180-01
Institution Name: Emory University School of Medicine
Institution Address: Atlanta, GA

Prior Assurance Number: A1544
Site: 00

Dates:

Conditional Data Due:
Effective: 03/19/2008
Expiration: 03/31/2012
AR Reporting Cycle: 01/2009

AAALAC Status: 1
PHS Grant / Contract #:
Last Modified: 5/19/2008 **By:** bw

Chairman: Samuel H. Speck
Title: Professor
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1462 Clifton Road, 429 Dental Building
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Degree: Ph.D.
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Official: David L. Wynes, Ph.D.
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1599 Clifton Road, NE, 4th Floor
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POC: David Knight
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