



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

February 11, 2009

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

Dr. David L. Wynes
Vice President for Research Administration
Emory University
1599 Clifton Road, NE, 4th Floor
Atlanta, Georgia 30322-1599

Dear Dr. Wynes,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 26, 2009 letter informing us of an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Emory University. This was initially reported to our Office via e-mail by Mr. David Knight on January 21, 2009. According to the information provided, OLAW understands that on January 5, 2009, during the IACUC's semi-annual inspection, it was ascertained that eight pigs on Protocol # 045-2008 had not been given post-surgical pain management as described in the IACUC protocol. The activity was voluntarily halted and the matter reviewed by the IACUC on January 7, 2009. This activity was funded by the NIH.

The corrective actions consisted of the IACUC requiring the PI to ensure that all animals receive pain management as described in the protocol and for this to be documented for each animal. Concurrence with the IACUC requirements was acknowledged in writing from the PI.

The Emory University's handling of the matter was consistent with the philosophy of self regulation. Similarly, the timely and appropriate action taken to prevent recurrence was appropriate. We appreciate being informed of this incident 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



EMORY

Office of Research Administration

January 26, 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 #: 045-2008; *Airborne Nanoparticles for Therapeutic Applications*
Funding agency: NIH

IACUC Director David Knight initially reported this matter to OLAW by email communication with you on January 21, 2009.

On January 5, 2009 during the IACUC's semi-annual inspection of the PI's laboratory, the inspectors ascertained that pigs had not been provided the approved post-surgical pain management as described in the IACUC protocol. The IACUC determined that 8 pigs underwent the surgical procedure without the post-surgical pain management. No additional surgeries have occurred since the discovery of this issue on January 5th.

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.
2. 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.

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Atlanta, Georgia 30322
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On January 21, 2009, the IACUC received a written response from the PI indicating that all corrective actions would be followed. The PI will give the analgesic as documented in approved protocol. 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,

A handwritten signature in cursive script, appearing to read "David L. Wynes".

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: Morse, Brent (NIH/OD) [E]
Sent: Thursday, February 05, 2009 8:56 AM
To: 'Knight, David L'
Cc: Wolff, Axel (NIH/OD) [E]; Brinsfield, Casey
Subject: RE: OLAW Letter Report Emory Non-compliance

Thank you Mr. Knight. You will receive a response from OLAW directly.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Knight, David L [mailto:DKNIGHT@emory.edu]
Sent: Thursday, February 05, 2009 8:48 AM
To: Morse, Brent (NIH/OD) [E]
Cc: Wolff, Axel (NIH/OD) [E]; Brinsfield, Casey
Subject: OLAW Letter Report Emory Non-compliance

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 January 21st. 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
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2/5/2009

Morse, Brent (NIH/OD) [E]

A3186-17

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, January 22, 2009 10:57 AM
To: 'Knight, David L'; Wolff, Axel (NIH/OD) [E]
Cc: Brinsfield, Casey; Lawley, John
Subject: RE: Initial Emory University Report on Non-Compliance

Thank you Mr. Knight. We'll start a case file and await your final report.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Knight, David L [mailto:DKNIGHT@emory.edu]
Sent: Wednesday, January 21, 2009 4:40 PM
To: Morse, Brent (NIH/OD) [E]; Wolff, Axel (NIH/OD) [E]
Cc: Brinsfield, Casey; Lawley, John
Subject: Initial Emory University Report on Non-Compliance

Dear 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 pigs, it was found that the laboratory personnel were not giving analgesics as described in the 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
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1/22/2009



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
Address: Division of Microbiology/Immunology
1462 Clifton Road, 429 Dental Building
Atlanta, GA 30322
Email: SSPECK@EMORY.EDU

Degree: Ph.D.
Phone: (404) 727-7665 **Ext:**
Fax: (404) 712-9736

Official: David L. Wynes, Ph.D.
Title: Vice President for Research Administration
Address: Office of Research Administration
1599 Clifton Road, NE, 4th Floor
Atlanta, GA 30322
Email: david.wynes@emory.edu

Phone: (404) 727-3889 **Ext:**
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POC: David Knight
Title: IACUC Office
Address:
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Phone: (404) 727-6212 **Ext:**
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