



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
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6705 Rockledge Drive
Bethesda, Maryland 20817
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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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