



P.O. Box 1623 Fayetteville, GA 30214 (770) 719-5348 primatefreedom.com

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EDUCATION ADVOCACY SUPPORT

August 19, 2009

Paulette Gray, PhD.  
Mail Stop 8327  
Bldg. 6116  
6116 Executive Blvd. 8001  
Rockville, MD. 20852

Mr. John Burke  
Office of Policy for Extramural Research Administration  
Office of Extramural Research, OD  
National Institutes of Health, DHHS  
6705 Rockledge Drive, Room 3510/MSC 7974  
Bethesda, MD 20892-7974

Dear Dr. Gray and Mr. Burke,

We are writing to inform you about an incident of PHS Policy noncompliance that occurred at Emory University --Assurance #A3180-01. We are asking you to investigate and request repayment of the relevant funds per the dictates of the NIH Grants Policy Statement (NIHGPS) section on "Enforcement Action" (Part II, Subpart A) and the NIH's Policy on Allowable Costs for Grant Activities Involving Animals When Terms and Conditions are not Upheld (NOT-OD-07-044). We request that all principal investigators on the project be debarred from receiving any future funding from the NIH and any other government agencies.

Enclosed you will find letters from Emory University and OLAW discussing a willful disregard of Emory's IACUC policy and directives by a member of a PI's staff where improperly anesthetized animals involved in an experiment were being used and the staff were ordered to stop the experiment and return the animals to their housing room. According to Emory's letter of Feb. 25, 2009, "Approximately four hours later, it was discovered that animals had been removed from the animal housing facility to the PI's laboratory, and the same procedures were again being conducted. The procedures were again halted and the animal access cards were deactivated for all personnel on the PI's protocol after consultation with the AV and IACUC Chair".

Emory's letter describes an intentional, willful, and blatant disregard for animal welfare and apparently a disregard for those in positions of authority who oversee animal welfare.

The Dept. of Health and Human Services regulations published in 45 CFR Part 76.305 state that persons can be debarred from eligibility to receive federal grant funds if they exhibit "a willful failure to perform



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in accordance with the terms of one or more public agreements or transactions" or "a willful violation of a statutory or regulatory provision or requirement applicable to a public agreement or transaction.".

It should be further noted for the record that Emory's own investigation revealed there was little evidence to support these animals were given any pain medication during the experiment before, during or after the procedures.

There is no excuse for these actions and Primate Freedom Project is requesting that all funding be returned for the projects:

NIH-P01 CA098912  
NIH-P20 CA132388  
NIH-R01 CA122602  
DOD-W81XWH-07-1-0172

Primate Freedom Project and our fifty thousand supporters, along with the millions of Americans who care about the pain and suffering of all animals look forward to hearing from you on this issue.

Thank you,



Jean Barnes  
Director

CC:

Jeanette Gordon, OPERA  
Joe Ellis, OPERA  
Dr. John Niederhuber, NCI  
Sally Rockey, PhD. OLAW  
Sen. Edward Kennedy, Chmn.  
Sen Charles Grassley  
APHIS - Animal Welfare  
Chairman David Obey  
Congressman Jerry Lewis



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

March 3, 2009

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

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

Dear Dr. Wynes,

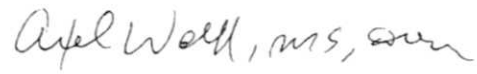
The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 25, 2009 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Emory University, following up on an initial telephone report on February 12, 2009. According to the information provided, OLAW understands that inadequately anesthetized mice were subjected to experimental procedures. In addition there was a failure to provide post-procedural analgesics, failure to appropriately maintain post-procedural and controlled drug records, use of expired and improperly labeled anesthetics/analgesics, failure to stop inappropriate animal work as ordered by the veterinarian, failure to maintain a sterile field, and failure to follow the procedures described in the approved protocol. The work was supported by NIH grants: **P01 CA098912, P20 CA132388, R01 CA122602.**

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) prohibiting the individual responsible from working with animals, requiring extensive retraining, and re-evaluating the person's qualifications in order to determine whether to reinstate animal use privileges. The laboratory was placed under direct veterinary oversight and all laboratory staff was required to certify understanding of the protocol. The Principal Investigator was required to ensure adequate training of staff, to conduct procedures as described in the approved protocol, to ensure appropriate pain relief and documentation, and to use only in-date supplies.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Note that the conduct of animal procedures not approved by the IACUC cannot be charged to the grant and must also be reported to the funding component.

Thank you for keeping OLAW apprised on this matter.

Sincerely,

A handwritten signature in cursive script that reads "Axel Wolff, M.S., D.V.M.".

Axel Wolff, M.S., D.V.M.

Director

Division of Compliance Oversight

cc: Samuel Speck, Ph.D., IACUC Chair  
Leo Buscher, Jr., Chief GMO, NCI



February 25, 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 #: 254-2008; *Translational prostate cancer research, from basic research to clinical applications*  
Funding agency: NIH-P01 CA098912  
NIH-P20 CA132388  
NIH-R01 CA122602  
DOD-W81XWH-07-1-0172

IACUC Director David Knight initially reported this matter to OLAW by telephone on February 12, 2009.

On February 5, 2009 the Division of Animal Resources (DAR) veterinary staff discovered a member of the PI's laboratory conducting procedures on improperly anesthetized animals. The Attending Veterinarian (AV) ordered the animal work to cease until the issue could be discussed with the PI and the laboratory personnel. Consequently, the IACUC Director instructed the laboratory personnel to stop the procedures, recover the animals, and to return the animals to the housing room. Approximately four hours later, it was discovered that animals had been removed from the animal housing facility to the PI's laboratory, and the same procedures were again being conducted. The procedures were again halted and the animal access cards were deactivated for all personnel on the PI's protocol after consultation with the AV and IACUC Chair.

An investigation was conducted and the following determinations were made:

- 1) Inadequate anesthesia was used for the procedure being conducted. This included improper monitoring of the anesthetic depth of the animal.
- 2) Post-procedural analgesics were not given as described in the approved IACUC protocol. No records existed showing prior use of analgesics.
- 3) Expired ketamine was being used for anesthesia.
- 4) The buprenorphine that was in stock was expired.
- 5) The vial of anesthetic solution was not labeled properly.

Emory University  
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1599 Clifton Road NE, 4th Floor  
Atlanta, Georgia 30322

Tel 404.727.3889  
Fax 404.727.1094

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- 6) The animals were removed to the laboratory where work continued despite the order by the AV to cease the animal work until further discussions could be undertaken with the PI.
- 7) Procedures were performed on nude mice on an open bench in a non-sterile environment.
- 8) Procedures were conducted differently than described in the approved IACUC protocol.
- 9) The controlled substance log had not been updated since 1/12/09.

After reviewing the matter on February 18, 2009 the IACUC voted unanimously to cite the findings as protocol noncompliance and to require appropriate corrective actions. The PI was sent a noncompliance letter on February 18, 2009 that included the corrective actions listed below:

**Required Corrective Actions for Laboratory personnel X:**

1. The individual who performed the procedures is not allowed to work with animals until completion of intensive re-training on the proper methods of anesthesia, determining anesthetic depth, monitoring anesthesia, and pain management conducted with the DAR veterinarian staff.
2. The individual is also required to repeat the CITI training modules on "Working with the IACUC", "Working with mice in a research setting", and "Post-procedural care of rodents". The IACUC Compliance and Training Specialist will follow up to ensure proper familiarity with these modules.
3. Once the IACUC receives a written report from the DAR veterinary staff that the individual has completed the training, and the IACUC office has confirmed completion of the CITI modules, then the individual will be required to submit a new credential form to the IACUC office. The credentials and training will be discussed at the next appropriate IACUC meeting. The full IACUC will then decide on whether to reinstate permission for the individual to work with animals at Emory University.

**Additional Required Corrective Actions:**

1. All laboratory personnel in the PI's laboratory will be supervised by DAR veterinary staff when conducting any invasive procedure requiring anesthesia until further notice.
2. All personnel in the PI's laboratory working with animals are required to document that they have read the protocol. The PI is required to conduct discussions with the laboratory regarding the proper way to do all procedures listed in the protocol, the proper anesthesia to use, how to monitor anesthetic depth, the need for proper analgesia, and keeping proper records. Documentation of these discussions is also required. The IACUC Compliance and Training Specialist will attend the first meeting of the PI's laboratory personnel when these issues are discussed and any additional meetings as needed.
3. The PI must ensure that all experiments are conducted as approved and described in the protocol. Should the PI decide to seek modification of the above-referenced

protocol, then an appropriate modification form must be prepared and submitted to the IACUC for its review and approval prior to implementing the modified procedures.

4. The PI must ensure that all animals receive the appropriate pain management as described and approved in the protocol. Pain medications must be documented for each animal and these records must be available for IACUC inspection.
5. The PI must ensure that records for all controlled substances are maintained appropriately.
6. The PI must ensure that all food and drugs being used in animals are being used within the manufacture's recommended expiration date.

On February 23, 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)  
Departmental Chair  
AAALAC (accredit@aaalac.org)  
DoD Animal Care and Use Review Office (acuro@amedd.army.mil)

**Wolff, Axel (NIH/OD) [E]**

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**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Wednesday, February 25, 2009 12:03 PM  
**To:** 'Knight, David L'  
**Subject:** RE: OLAW Letter Reporting Emory Non-compliance

Thanks for this report, Mr. Knight. We'll respond shortly.

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

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**From:** Knight, David L [mailto:DKNIGHT@emory.edu]  
**Sent:** Wednesday, February 25, 2009 9:52 AM  
**To:** Morse, Brent (NIH/OD) [E]; Wolff, Axel (NIH/OD) [E]  
**Cc:** Brinsfield, Casey; accredi@aaalac.org; acuro@amedd.army.mil; Speck, Sam  
**Subject:** OLAW Letter Reporting Emory Non-compliance

Dear Dr. Morse,  
Attached is a letter from the Emory Institutional Official describing an incident of non-compliance at Emory University. This was initially reported to OLAW on February 12, 2009. 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  
Email: david.knight@emory.edu  
Web Site: <http://www.emory.edu/IACUC>

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2/25/2009





# Initial Report of Noncompliance

Date: 2/12/09

Time: 10:00

Name of Person reporting: David Knight  
 Telephone #: 704 727 6212  
 Fax #:  
 Email:

Name of Institution: EMORY U.  
 Assurance number: A3180

Did incident involve PHS funded activity? Yes  
 Funding component: \_\_\_\_\_  
 Was funding component contacted (if necessary): \_\_\_\_\_

What happened?  
*not using appropriate anesthesia, not using analgesia,  
 language issue*

Species involved: *Mice, 20*  
 Personnel involved:  
 Dates and times:  
 Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY  
 Case # \_\_\_\_\_



## 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: 2/2/2009 By: tc

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  
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Atlanta, GA 30322  
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Phone: (404) 727-3889 Ext:  
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POC: David Knight  
Title: IACUC Office

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