



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 15, 2009

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

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 November 25, 2008 letter informing us of an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Emory University. According to the information provided, OLAW understands that on October 23, 2008 an adult female monkey was anesthetized for IACUC-approved protocol procedures, including blood collection. Unfortunately a large hematoma eventually developed and despite thorough treatment, the monkey died from blood loss related to blood collection. This activity was funded by the NIH.

The corrective actions consisted of the institution of a refresher course for training in blood collection procedures. This course will also be used for newly hired employees. Technicians responsible for blood collection will be regularly monitored to ensure all procedures are being followed.

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 unfortunate 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

November 25, 2008

Axel V. Wolff, M.S., D.V.M.
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institute 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 Institutional Animal Care and Use Committee (IACUC), and in accordance with applicable regulatory requirements, I am writing to report the accidental death of a monkey during a research procedure. This incident and the corrective actions taken are described below. This was initially reported to OLAW by e-mail to Dr. Brent Morse November 3, 2008.

Protocol Title: *Studies of the natural SIV infection of sooty mangabeys*
IACUC Protocol #: 254-2007
Sponsor: NIH (R01 AI066998) and Departmental Funds
Principal Investigator: Cynthia A. Derdeyn, PhD (Subcontract from University of Pennsylvania, Guido Silvestri, PI)

On October 23, 2008, an SIV-negative adult female monkey was anesthetized for IACUC-approved protocol procedures, including blood collection. Blood was collected from the inguinal area. The monkey recovered normally but was later found in poor condition and treated by veterinary staff. During treatment, a large hematoma was noted in the inguinal area. Despite thorough treatment, the monkey died from blood loss related to blood collection.

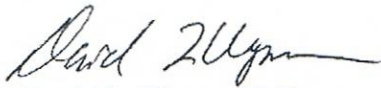
Although instances of accidental death associated with a blood collection are rare, a refresher course for training in blood collection procedures instructed by a clinical veterinarian is being instituted. The training will be well documented for use in refresher courses as well as with newly hired employees. Technicians responsible for blood collections will be regularly monitored to ensure all procedures are being followed.

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1599 Clifton Road NE, 4th Floor
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An equal opportunity, affirmative action university

Tel 404•727•3889
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The Emory IACUC discussed these findings and actions at its November 5, 2008, meeting. The committee found that although unfortunate, this was an accidental death. The IACUC believes that the corrective action taken is appropriate and will reduce the likelihood of this type of accident reoccurring. Please feel free to contact me or IACUC Chair Dr. Sam Speck if you would like further information regarding this matter.

Sincerely,

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

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

cc: Sam Speck, Ph.D.
James Else, DVM
Guido Silvestri, Ph.D.
AAALAC

Morse, Brent (NIH/OD) [E]

From: Knight, David L [DKNIGHT@emory.edu]
Sent: Wednesday, November 26, 2008 9:43 AM
To: Morse, Brent (NIH/OD) [E]
Cc: Else, Jim; gsilvest@mail.med.upenn.edu; Speck, Sam
Subject: RE: Emory University Report on Non-Compliance
Attachments: Emory OLAW Report 11-26-08.pdf

Sorry, here is the attachment!

Dear Dr. Morse,
Attached is the final report from the IO of Emory University on the accidental monkey death at Emory. Please let me know if you need further information on this incident.

Thanks,
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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Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, November 10, 2008 7:47 AM
To: 'Knight, David L'
Subject: RE: Emory University Incident Report

Mr. Knight,

Thank you for this additional information. Although U. Penn. Is ultimately responsible for the grant, the report can come from either institution. Since we need information from the IACUC at the performance site (Emory) it makes sense that you would report it to us and copy U. Penn.

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: Friday, November 07, 2008 12:16 PM
To: Morse, Brent (NIH/OD) [E]
Subject: Emory University Incident Report

Dr. Morse,

I am working on the final report that will come from the IO to OLAW. Here is some additional information for you:

This occurred on October 23, 2008.

The NIH grant is R01 AI066998.

Our IACUC has determined that this was an accidental death resulting from a routine blood draw.

Now, I have a question for you - which institution should this report come from (or both)? This grant was awarded to the University of Pennsylvania and Emory is working on a subcontract from them. Should my IO just notify their IO and let him notify you - or should reports come from both? Or is a report from Emory directly to OLAW sufficient?

Your advice will be greatly appreciated.

Thanks,
 David

David L. Knight

Director IACUC
 Emory University School of Medicine
 1599 Clifton Road, 1599-001-1AU
 Room 5.309
 Atlanta, Georgia 30322-4250
 Phone: 404-712-0734

11/10/2008

Fax: (404) 727-8877
Email: david.knight@emory.edu
Web Site: <http://www.emory.edu/IACUC>

From: Morse, Brent (NIH/OD) [E] [mailto:morseb@mail.nih.gov]
Sent: Monday, November 03, 2008 3:12 PM
To: Knight, David L
Subject: RE: Emory University Report on Non-Compliance

Thank you Mr. Knight. I will open a new case file. Please provide other basic information (dates, PHS funding, etc.) via e-mail if they become available before the 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: Monday, November 03, 2008 1:37 PM
To: Morse, Brent (NIH/OD) [E]
Subject: Emory University Report on Non-Compliance

Dr. Morse,
I need to make an initial report of an accidental monkey death on an Emory IACUC protocol that was NIH funded. Initial evidence points to problems with a blood drawing procedure. The Emory IACUC is investigating and a full report should be available soon.

David

David L. Knight
Director, IACUC
Emory University

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11/10/2008

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

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

Official: David L. Wynes, Ph.D.
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Email: david.wynes@emory.edu

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

Address:
Email: dknight@emory.edu

Phone: (404) 727-6212 Ext:
Fax: (404) 727-8877

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, January 09, 2009 2:15 PM
To: 'SSPECK@EMORY.EDU'
Subject: status of preliminary report to OLAW

Hello Dr. Speck,

OLAW received a preliminary report of noncompliance on 8/1/03 regarding the death of a rhesus monkey on a malaria study. Please let me know when to expect the final report or provide an interim report.

Thank you.

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

1/9/2009