



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  
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November 3, 2008

Re: Animal Welfare Assurance  
A3196-01 [OLAW Case 4G]

Dr. Roberto Peccei  
Vice Chancellor for Research  
University of California, Los Angeles  
405 Hilgard Avenue  
Los Angeles, CA 90024-1405

Dear Dr. Peccei,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 17, 2008 letter reporting the suspension of an animal activity at the University of California- Los Angeles (UCLA), following up on an initial email report on August 28, 2008. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action in response to the use of dry ice to generate CO2 for euthanasia and to the conduct of research procedures with mice by an individual not listed on the protocol.

In addition to the protocol suspension, the corrective actions taken consisted of the investigator agreeing not to use dry ice for euthanasia and not allowing the new laboratory member to conduct animal procedures until after being added to the protocol. The investigator submitted a protocol amendment to include the new person, initiated regular meetings for laboratory staff, developed checklists for staff to use to ensure compliance with the protocol, and developed a checklist outlining steps that need to be taken when new staff is hired. The IACUC accepted the investigator's actions and subsequently lifted the suspension.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at UCLA are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

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

cc: William McBride, Ph.D., IACUC Chair  
Kathy Wadsworth, Associate Director-Animal Subjects Research  
MaryAnn Gray, Assistant Provost

October 17, 2008

Box 951405, 2147 Murphy Hall  
Los Angeles, CA 90095-1405  
phone: 310-825-7943  
fax: 310-206-6030  
rpeccei@conet.ucla.edu

Axel V. Wolff, M.S., D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

**RE: Final Report of an Incident of Noncompliance**  
Animal Welfare Assurance A3196-01

Dear Dr. Wolff:

I am writing to provide you with a final report regarding a suspension of activities, which was initially reported to you by Assistant Director Andrew Perkins on August 28, 2008, in accordance with PHS Policy IV.C.8<sup>1</sup>. The protocol was not supported by federal funds, and did not involve USDA-covered species. As Mr. Perkins informed you, during a routine, semiannual inspection of the investigator's laboratory on July 31, 2008, the inspection team learned of the following noncompliances:

1. Although the approved protocol specified that mice would be euthanized via carbon dioxide, the ARC learned that research personnel were using dry ice for euthanasia, in violation of the AVMA Guidelines on Euthanasia and ARC requirements.
2. A new lab member who had been involved in research procedures involving mice was not listed on the ARC-approved protocol. However, this individual had completed all ARC-mandated training and occupational health requirements.

In accordance with the ARC Policy, Investigating Allegations of Mistreatment or Other Noncompliance Issues<sup>2</sup>, the investigator was notified of these concerns the same day as the inspection and was asked to respond to the allegations.

<sup>1</sup> PHS Policy IV.C.8, "If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW"

<sup>2</sup> ARC Policy, Investigating Allegations of Mistreatment or Other Noncompliance Issues: "In every investigation, the person(s) against whom the complaint has been raised shall be given notice of the concern and provided an opportunity to address the allegations in writing."

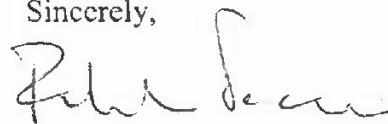
During the convened meeting of August 25, 2008, the ARC reviewed the investigator's response to the above concerns. In her response, the investigator assured that dry ice had been discontinued as a method of carbon dioxide euthanasia, and that the new staff member had been instructed not to conduct any procedures involving live animals until this individual had been added to the approved protocol. The investigator had also submitted a protocol amendment request to add this individual to the protocol. However, the ARC remained concerned that a detailed plan was not provided that would ensure that all personnel who are or will be involved in her research understand all ARC and federal requirements as they pertain to her research studies and to prevent future noncompliance. As such, the Committee voted to suspend the investigator's protocol until the ARC was satisfied that a detailed corrective action plan is in place to prevent future incidents of noncompliance.

On September 18, 2008, the investigator met with senior representatives of the ARC and veterinary staff to discuss federal requirements and University policies regarding the use of animals in research. As part of this meeting, the ARC and veterinary representatives reviewed the proposed plan to ensure that all personnel are aware of their expectations regarding animal use. As requested by the ARC, the investigator assured that she will conduct regular lab meetings. She also developed checklists specific to her experiments to ensure that her staff carry out all procedures in accordance with the approved protocol. The investigator will also implement a new staff checklist to ensure that new staff and students complete all required trainings and certifications, and are listed on the approved research protocol, prior to working with animals.

The Committee reviewed the above referenced corrective plan during the convened meeting of September 22, 2008 and found the plan to be appropriate. As such, the ARC voted to lift the suspension of activities.

If you have any questions or concerns, please do not hesitate to contact me at (310) 825-7943.

Sincerely,



Roberto Peccei  
Vice Chancellor for Research

cc: Maryann Gray, Assistant Provost  
William McBride, Chair, ARC  
Judith L. Brookshire, Director, OPRS  
Kathy Wadsworth, Associate Director, Animal Subjects Research

Wolff, Axel (NIH/OD) [E]

A3196-01

**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Thursday, August 28, 2008 10:51 AM  
**To:** 'Perkins, Andrew'  
**Subject:** RE: IACUC Suspension of Research Activities - Assurance #A3196-01

Thank you for this preliminary report, Mr. Perkins. I will start 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

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**From:** Perkins, Andrew [mailto:APerkins@OPRS.UCLA.EDU]  
**Sent:** Thursday, August 28, 2008 10:39 AM  
**To:** Wolff, Axel (NIH/OD) [E]  
**Subject:** IACUC Suspension of Research Activities - Assurance #A3196-01

Dear Dr. Wolff:

On behalf of the Chancellor's Animal Research Committee (ARC) at the University of California, Los Angeles (UCLA, Assurance #A3196-01), I am writing to inform you of an IACUC suspension of an investigator's approved research protocol resulting from serious noncompliance with PHS Policy. The activities conducted under the research protocol involve mice and are not federally funded. During a routine, semiannual inspection of the investigator's laboratory on July 31, 2008, the ARC learned of the following noncompliances:

1. Although the approved protocol specified that mice would be euthanized via carbon dioxide, the ARC learned that research personnel were using dry ice for euthanasia, in violation of the AVMA Guidelines on Euthanasia and ARC requirements.
2. A new lab member who had been involved in research procedures involving mice was not listed on the ARC-approved protocol. However, this individual had completed all ARC-mandated training and occupational health requirements.

The investigator was notified of these concerns on the same day and was asked to respond to the allegations. During a meeting held on August 25, 2008, the ARC reviewed the investigator's response to the above concerns. In her response, the investigator assured that dry ice had been discontinued as a method of carbon dioxide euthanasia, and that the new staff member had been instructed not to conduct any procedures involving live animals until this individual had been added to the approved protocol. The investigator had also submitted a protocol amendment request to add this individual to the protocol.

However, the ARC remained concerned that a detailed plan was not provided that would ensure that all personnel who are or will be involved in her research understand all ARC and federal requirements as they pertain to her research studies and to prevent future noncompliance. As such, the Committee voted to suspend the investigator's approved protocol until the ARC was satisfied that a detailed corrective action plan is in place to prevent future incidents of noncompliance.

The investigator is currently in the process of scheduling a meeting with senior representatives of the ARC and veterinary staff to discuss federal requirements and University policies regarding the use of animals in research. As part of this meeting, the ARC and veterinary representatives will review the proposed plan to ensure that all personnel are aware of their expectations regarding animal use. The ARC will further encourage the investigator to include in her corrective plan regular meetings, checklists, and/or other training tools to ensure that all personnel under her direction clearly understand the research methods described in her above-referenced protocol as well as the research team's collective responsibility for adhering to all relevant guidelines and regulations. Following this meeting, the investigator will be asked to submit a comprehensive plan detailing the procedures she will take to ensure full compliance with the approved protocol. The ARC will review the corrective plan at a convened meeting prior to lifting the suspension.

A final report will be submitted by our Institutional Official, Vice Chancellor for Research Roberto Peccei, following successful

8/28/2008

resolution of these concerns.

Please feel free to contact me at (310) 206-7364 if you have any questions.

Sincerely,  
Andy

Andrew D. Perkins  
Assistant Director, Chancellor's Animal Research Committee  
UCLA Office for Protection of Research Subjects  
11000 Kinross Ave., Suite 102  
Los Angeles, CA 90095-1694  
tel (310) 206-7364, fax (310) 794-9565



## Full Assurance Agreement Printout

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Assurance Number: A3196-01  
Institution Name: University of California - Los Angeles  
Institution Address: Los Angeles, CA

Prior Assurance Number: A1440  
Site: 00

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**Dates:**

Conditional Data Due:  
Effective: 07/11/2006  
Expiration: 07/31/2010  
AR Reporting Cycle: 01/2009

AAALAC Status: 1  
PHS Grant / Contract #:  
Last Modified: 7/15/2008 By: th

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Chairman: William H. McBride, Ph.D.  
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11000 Kinross Avenue, Suite 102  
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Official: Dr. Roberto Peccei  
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Email:

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POC: Ms. Kathy Wadsworth  
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