



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 4, 2008

Re: Animal Welfare Assurance
A3196-01 [OLAW Case 3W]

Roberto Peccei, Ph.D.
Vice Chancellor for Research
Office of the Chancellor
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 December 11, 2007 letter concerning an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California, Los Angeles (UCLA). According to the information provided, OLAW understands that the Chancellor's Animal Research Committee (ARC) was notified on May 8, 2007 that research procedures were performed on mice and rabbits on April 12, 19, 26 and May 3, 2007 though the IACUC approval for the study had expired on April 11, 2007. This study is funded in part by the PHS, grant #1 RO1 AR48179-01.

Corrective actions consisted of the investigator stating that she would review all protocol amendment and renewal applications with her staff. She had also scheduled training for herself and her staff. Her protocol renewal was reviewed and approved by the ARC on June 5th, 2007 and the Committee also requested that all approval notices and protocols be kept in a location that is accessible to her staff.

OLAW understands that the protocol involved was PHS supported, and concurs that the incident warranted reporting. The actions taken by the UCLA ARC appear appropriate for the incident. We also understand that this incident has been reported to UCLA's Office for Contracts and Grants Administration. Please be advised that **NIH expects UCLA to report this incident to the Institute/Center supporting the award** as required in the attached Notice. From the perspective of animal welfare, we 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: Dr. William McBride, IACUC Chair
Ms. Kathy L. Wadsworth, Associate Director - Animal Subjects Research
Ms. Diane Dean, Director, Division of Grants Compliance and Oversight, OER/OPERA
Mr. John Burke, Division of Grants Compliance and Oversight, OER/OPERA

UCLA
UNIVERSITY OF CALIFORNIA,
LOS ANGELES

A3196 3W
ROBERTO PECCEI
Vice Chancellor for Research

DEC 18 '07 PM 3:16

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December 11, 2007

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

Dear Dr. Wolff,

I am writing to provide you with a report of an incident of noncompliance involving a USDA and non-USDA covered species (mice and rabbits) used in a study conducted by a UCLA investigator. This study is supported by various sources, including an NIH grant #1 RO1 AR48179-01.

The Chancellor's Animal Research Committee (ARC) was informed May 8, 2007 of an incident of noncompliance involving the conduct of research activities following the date of expiration of ARC approval for the protocol. Specifically, it was learned that veterinary staff from the Division of Laboratory Animal Medicine (DLAM) were asked to perform blood draws from mice and adjuvant boosts for rabbits on April 12, 19, 26 and May 3, 2007, though ARC approval for the study had expired April 11, 2007.

In accordance with the ARC Policy, Investigating Allegations of Mistreatment or Other Noncompliance Issues¹, the investigator was provided an opportunity to comment on the incident.

¹ "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."

The investigator replied promptly, stating that at the time she made the arrangements with the DLAM staff to perform the blood draws and adjuvant boosts, she were unaware that her ARC approval had expired². She stated, "*Our protocol expired due to my misunderstanding of the difference between approvals for an 'amendment' and a 'continuation'. ... When I received the approvals [for her amendment] I thought that it was the approval for my yearly continuation, and not just a simple amendment. I misunderstood the difference between these two types of approval procedures.*"

To avoid future noncompliance, the investigator stated that she will review all amendment and renewal applications with her staff. The investigator also scheduled an ARC/DLAM Educational meeting for May 31, 2007 between herself, her lab staff, a clinical veterinarian, and Associate Director Kathy Wadsworth, to discuss ARC policies and DLAM procedures concerning the research.

The ARC reviewed the investigator's response during the convened meeting of June 25, 2007, and found her corrective action plan to be acceptable. The Committee also requested that she ensure that all approval notices and protocols are kept in a location accessible to her research staff.

As this incident constitutes a serious violation of PHS Policy IV.C and UCLA's Animal Welfare Assurance on file with the NIH Office of Laboratory Animal Welfare (OLAW), the ARC, through the Institutional Official, is required to report this violation to NIH/OLAW and to the USDA.

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: Dr. William H. McBride, Chair, ARC
Judith L. Brookshire, Director, OPRS
Kathy Wadsworth, Associate Director, Animal Subjects Research

² UCLA's Research Application Tracking System (RATS) automatically sends reminder notices to PIs 90, 60 and 30 days prior to expiration of ARC approval. The RATS program also automatically forwards an email notification to the PI and to UCLA's Office for Contracts and Grants Administration upon expiration of ARC approval. This notification system has been in place since 2003 and is in compliance with NIH Guidance document #NOT-OD-07-044.



Full Assurance Agreement Printout

Assurance Number: A3196-01 Prior Assurance Number: A1440
Institution Name: University of California - Los Angeles
Institution Address: Los Angeles, CA Site: 00

Dates: Conditional Data Due: AAALAC Status: 1
Effective: 07/11/2006 PHS Grant / Contract #:
Expiration: 07/31/2010 Last Modified: 5/9/2007 By: sm
AR Reporting Cycle: 01/2008

Chairman: William H. McBride, Ph.D. Degree: Ph.D.
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POC: Ms. Kathy L. Wadsworth
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NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld

Notice Number: NOT-OD-07-044

Key Dates

Release Date: January 26, 2007

Issued by

National Institutes of Health (NIH). (<http://www.nih.gov>)

The purpose of this Notice is to clarify that no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and Institutional Animal Care and Use Committee (IACUC) approval. This notice is applicable to grants and cooperative agreements involving activities with live vertebrate animals.

Background

Terms and conditions applicable to all grant awards that involve live, vertebrate animals - including research, research training, experimentation, biological testing, custom antibody preparation, or related purposes - require a valid Animal Welfare Assurance (Domestic, Foreign, or Inter-institutional Assurance, as applicable) approved by the NIH Office of Laboratory Animal Welfare (OLAW), and valid IACUC approval. IACUC approval must be dated within the last three years in order to be valid. IACUCs are not authorized to administratively extend approval beyond three years. Foreign grantees receiving direct support are not required to provide IACUC approval, but must have a valid Foreign Assurance on file with OLAW (see <http://grants.nih.gov/grants/olaw/assurance/500index.htm> for list of foreign institutions with approved Assurances).

Policy

The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Assurance on file with OLAW.
2. The conduct of animal activities in the absence of valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval. Suspension is described in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) at section IV.C.6. (<http://grants.nih.gov/grants/olaw/references/phspol.htm>)

Institutions are required to report such situations to the Institute/Center (IC) supporting the award. NIH expects grantees to continue to maintain and care for animals during the periods described above. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.

Additionally, these situations constitute serious noncompliance with section IV.F.3. of the PHS Policy and as such must be promptly reported to OLAW in accord with the PHS Policy. See NOT OD-05-034, Guidance on Prompt Reporting to OLAW (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>)

Grantees are reminded that under consortium (subaward) agreements in which the grantee collaborates with one or more other organizations, the grantee, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grants funds by all parties, and all other obligations of the grantee as specified in the NIHGPS. The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects. The prime grantee is responsible for including these requirements in its agreements with collaborating

organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an appropriate Animal Welfare Assurance and that the activity has a valid IACUC approval. (see <http://grants.nih.gov/grants/olaw/assurance/300index.htm> for a list of domestic institutions with Assurances). If the prime grantee does not have an Animal Welfare Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Inter-institutional Assurance from OLAW. When the grantee is a domestic institution and there is a foreign performance site using animals, the grantee must ensure that the performance site has an appropriate Foreign Assurance and must provide verification of IACUC approval by the domestic grantee's IACUC, certifying to NIH that the activity as conducted at the foreign performance site is acceptable to the grantee. (See NIH GPS, Part II, Terms and Conditions of NIH Grant Awards, Consortium Agreements, http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251).

Inquiries

Questions concerning this Notice should be directed to:

Office of Policy for Extramural Research Administration
National Institutes of Health
Telephone: 301-435-0938
Email: grantspolicy@od.nih.gov

Questions about Assurances or IACUC approval of animal activities should be directed to:

Office of Laboratory Animal Welfare
Division of Assurances
National Institutes of Health
Telephone: 301-496-7163
Email: olawdoa@mail.nih.gov

Weekly TOC for this Announcement
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Department of Health
and Human Services



National Institutes of Health (NIH)
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