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February 11, 2009

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 report of noncompliance involving research activities performed on frogs (*Huia cavitympanum*) prior to obtaining approval from the Chancellor's Animal Research Committee (ARC). This lab receives funding from various federal sources including National Institutes of Health (NIH) grants; however, the unapproved activities and travel accommodations related to the unapproved activities were funded entirely through a private foundation grant.

During Designated Member review of the investigator's application to add experiments to his approved protocol, it was noted that the investigator described animal activities which had been conducted by his graduate student in Borneo, but were not previously included in his approved protocol.

The investigator's protocol amendment request was brought before the full Committee on September 22, 2008. While the Committee appreciated that the investigator provided copies of permits for the field work, the investigator was reminded that UCLA's Assurance with OLAW states that "*all research, training, experimentation, and biological testing and related activities...involving live or dead, vertebrate animals which are conducted at this institution, or under the direction of any employee, student, or agent of this institution regardless of funding sources or location of the activity*" are covered by the assurance and, as such, must be reviewed and approved by the ARC prior to initiating work. As such, the investigator was asked to verify whether ARC approval was obtained prior to initiating field studies with *Huia cavitympanum* and who performed the studies.

He was also informed that further field work may not be conducted until he has obtained ARC approval for the proposed activities.

The investigator's response was reviewed at the convened ARC meeting of November 3, 2008. The investigator confirmed that the activities had indeed been conducted prior to ARC approval. These activities included observation of *Huia cavitympanum* in the animals' natural habitat in Borneo, collection of ten (10) live specimens, transport of the animals back to UCLA, and survival surgery performed on the animals in the investigator's laboratory at UCLA. The investigator stated that he "thought it was sufficient to obtain local permits and permissions" and was not aware that this work required ARC approval prior to initiation. During the November 3, 2008 meeting, the Committee voted to withhold approval of the amendment and suspend the investigator's protocol, pending completion of the following:

1. Complete revision of the protocol to accurately detail all research activities of this project, to be reviewed at a convened ARC meeting.
2. The ARC required that the investigator meet with the ARC Chair and Associate Director Kathy Wadsworth to review the applicable federal and local regulations and policies pertaining to his study, as well as his responsibility as Principal Investigator for ensuring compliance with the aforementioned regulations.
3. The investigator must provide a corrective action plan to ensure future compliance with the protocol and all applicable regulations.
4. Following ARC approval of the investigator's revised protocol, the ARC will conduct a protocol audit to ensure that the research activities are being carried out in accordance with the approved protocol.

The investigator was reminded that as Principal Investigator, he is responsible for upholding the federal, State and local policies and regulations governing the humane care and use of laboratory animals. As Principal Investigator, he is also accountable for ensuring that all personnel listed under his approved protocols understand all procedures described therein and perform their duties in accordance with the aforementioned regulations and policies. Continued noncompliance may lead to suspension of his privileges to conduct research involving animals at UCLA. He was also informed that in accordance with PHS Policy IV.C.7, the ARC, through the Institutional Official, must report this suspension to the NIH/OLAW.

The ARC Chair, Ms. Wadsworth, ARC Compliance Coordinator Rosa Harmon, and the Principal Investigator met on November 4, 2008. On November 6, 2008, the investigator and his entire lab staff met with Ms. Wadsworth and Assistant Director Andrew Perkins to review the regulations and policies for animal research at UCLA. The investigator also provided a corrective action plan to avoid future noncompliance, which included the aforementioned meetings, as well as weekly lab meetings to discuss animal

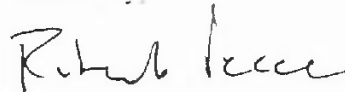
protocol issues, and use of checklists to ensure that all staff follow the protocol as written. The investigator also named a senior researcher in his lab who will be responsible for carrying out the research in the Principal Investigator's absence or illness.

The investigator also submitted a revised protocol, which was reviewed by the full Committee on November 12, 2008. The Committee determined that the investigator had adequately addressed their requests for clarifications and that the appropriate corrective actions are in process to address this matter. As such, the Committee voted to lift the suspension of the protocol.

The post-approval protocol audit is scheduled for March 3, 2009. The investigator and his lab staff are required to be present for the audit, which will be lead by Associate Director Kathy Wadsworth, and ARC Compliance Coordinator Rosa Harmon.

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: Assistant Provost Maryann Jacobi Gray  
ARC Chair William McBride  
Associate Director, Animal Subjects Research Kathy Wadsworth  
ARC Compliance Coordinator Rosa Harmon



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
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FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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February 24, 2009

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

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 February 11, 2009 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) determined that a PI and his graduate student were conducting animal activities that were not included in his approved protocol. Specifically, these activities included observation of frogs (*Huia cavitympanum*) in Borneo, the collection of ten live specimens and transporting them to UCLA, and the subsequent survival surgery on the animals. This activity was not funded by NIH.

Corrective actions consisted of: the ARC suspending the protocol; the ARC requiring complete revision of the protocol to accurately detail the activities, and; the PI meeting with the ARC Chair and the Associate Director for Animal Subjects Research to review applicable regulations, policies, and responsibilities. Also, the PI was required to provide a corrective action plan to ensure future compliance. It is understood the above mentioned training has taken place with the PI and with members of his laboratory. It is further understood that the PI's revised protocol was reinstated upon review by the ARC at a November 12, 2008 meeting and the revised protocol will be subject to a protocol audit scheduled for March 3, 2009.

OLAW believes that the actions taken by the UCLA ARC were appropriate for the incident. Although this protocol was not PHS funded, the establishment and application of policies and practices that are consistent with the provisions of the PHS Policy are commendable and avoid the perception of a double standard. We appreciate being informed of this matter and find no cause for further action by this Office.

Sincerely,

Brent C. Morse, DVM  
Animal Welfare Program Specialist  
Division of Compliance Oversight

cc: Dr. William McBride, IACUC Chair  
Ms. Kathy L. Wadsworth, Associate Director - Animal Subjects Research  
Maryann Jacobi Gray, Ph.D., Assistant Provost



## Full Assurance Agreement Printout

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

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**Dates:**      Conditional Data Due:      AAALAC Status: 1  
Effective: 07/11/2006      PHS Grant / Contract #:  
Expiration: 07/31/2010      Last Modified: 2/17/2009      By: th  
AR Reporting Cycle: 01/2009

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Chairman: William H. McBride, Ph.D.      Degree: Ph.D.  
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