



UNIVERSITY OF CALIFORNIA,
LOS ANGELES

ROBERTO PECCEI
Vice Chancellor for Research

March 19, 2009

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

MAR 24 09 AM 7:25

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 the sampling of a significantly larger number of animals than originally approved by the ARC. This project involves sampling of a non-USDA covered species (birds), and is funded by the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID) Centers of Excellence for Influenza Research and Surveillance award #HHSN 266200700009C.

During pre-review of the investigator's continuation application, it was noted that the investigator had described a sampling of 20,000 birds per year, which is higher than the estimated 10,000 birds per year approved by the ARC during the original review of this project.

The investigator's continuation application was reviewed during the convened ARC meeting of February 23, 2009. Though it was noted that the NIH contract had been revised since the original version to increase the sample size to 20,000 birds per year, the investigator had not contacted the ARC about the change in scope for this project, nor had he obtained ARC approval for the increased sampling size.

The Committee acknowledged that as research proceeds, modifications to the approved protocol may be required in order to adapt to new developments and to ensure continued statistical significance. However, such changes must be reviewed and approved by the Committee prior to implementation.

Though this deviation may not have resulted in harm to animals sampled in the field, the investigator was reminded that implementation of any significant change to the ARC-approved protocol *without* prior approval as required by Public Health Service Policy

(PHS Policy) IV.B.7., constitutes a serious noncompliance with the aforementioned PHS policy¹. As such, the ARC, through the Institutional Official, is required to report this violation to the NIH Office of Laboratory Animal Welfare (OLAW).

The investigator was also reminded that the University, investigators, and the ARC share a collective responsibility for ensuring that animal research conducted under the auspices of UCLA, is carried out in compliance with all federal, State and local policies and regulations. Additionally, 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. Further, as Principal Investigator, he is also responsible for ensuring that procedures are in place to ensure that all persons participating in this study, including those from subcontracted institutions responsible for conducting sample collection in the field, comply with the aforementioned regulations, and with the approved protocol.

To avoid reoccurrence of this noncompliance, the investigator was asked to address the following:

1. The Committee required that the PI provide a corrective action plan to ensure future compliance with the ARC-approved protocol and all applicable policies and regulations. The plan was to include specifics about how, and how often, information is communicated to his staff and collaborators. He was also required to describe the procedures that will be used to ensure that requested changes to the research design are not implemented prior to ARC approval.
2. The ARC required that he meet with ARC Chair and Associate Director Kathy Wadsworth to review the applicable federal and local regulations and policies pertaining to his study, and his responsibility as Principal Investigator for ensuring compliance with the aforementioned regulations.
3. The PI was also directed to revise the protocol to reflect the revised sampling size, and revised justification for the requested number of birds.

The PI submitted the following corrective action plan to prevent reoccurrence of the noncompliance:

- 1) Yearly sampling plans from all participating institutions will be formulated prior to commencing surveillance work and be reviewed to verify that total the number of animals is not exceeded.*
- 2) Monthly teleconferences of the CRISAR Executive Committee (EC), which includes participants from all participating surveillance institutions, will review surveillance statistics and verify that the number of animals approved by the ARC is not exceeded.*

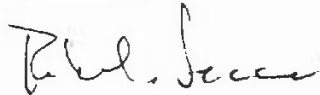
¹ NIH Guidance of Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. Guidance Document #NOT-OD-034, issued February 24, 2005, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>

- 3) *If monthly reviews indicate and/or project that the number of animals approved by the ARC could be exceeded (for example, due to a new project opportunity, outbreak and/or pandemic), an appropriately amended surveillance plan will be submitted to the ARC in advance of exceeding the approved number.*"

Additionally, a revised protocol was submitted as noted above and approved by the ARC on March 13, 2009. A meeting was also held March 13, 2009 with the investigator to review the regulations and his responsibilities as Principal Investigator.

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
Associate Vice Chancellor for Research Marcia Smith
Acting Director OCGA Virginia Anders
ARC Chair William McBride
Associate Director, Animal Subjects Research Kathy Wadsworth
ARC Compliance Coordinator Rosa Harmon



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 25, 2009

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

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 March 19, 2009 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- Los Angeles, following up on an initial telephone report on February 19, 2009. According to the information provided, OLAW understands that a field study consisting of obtaining samples from wild birds was approved for the use of approximately 10, 000 birds but twice that number was sampled.

The Institutional Animal Care and Use Committee /Animal Research Committee (IACUC/ARC) counseled the Principal Investigator (PI) on the requirement for prior IACUC approval of all proposed significant changes to a protocol. The corrective actions taken consisted of the PI developing yearly sampling plans to ensure that only the approved numbers of animals are sampled, conducting monthly reviews of numbers of animals sampled, and agreeing to submit protocol amendments prior to initiating a significant change. The PI submitted a revised protocol which was subsequently reviewed and approved by the IACUC.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. Although the NIH contract had been revised to account for the increase in sample size, please directly inform the contracting officer about the performance of an animal activity in the absence of IACUC approval.

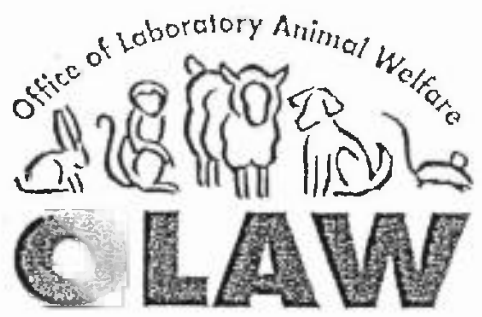
We appreciate having been informed about this matter and find no cause for further action by this Office.

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

A3196-4N



Initial Report of Noncompliance

Date: 2/19/09

Time: 12:00

Name of Person reporting: Kathy Wadsworth
Telephone #:
Fax #:
Email:

Name of Institution: VCLA
Assurance number: A3196

Did incident involve PHS funded activity? yes
Funding component: NIAID
Was funding component contacted (if necessary): _____

What happened?
10,000 more birds sampled than allowed in protocol (approved for 30,000)

Species involved: WILD BIRDS
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 # _____

