



OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
BOX 951694
LOS ANGELES, CALIFORNIA 90095-1694

June 24, 2003

Michael A. Carome, MD
Associate Director-Regulatory Affairs
Office for Human Research Protections
Department of Health and Human Services
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

COPY

RE: Human Research Collaboration on Malariotherapy: John Fahey, MD
NIH grants TW 00003 and AI 36086

Dear Dr. Carome,

This letter serves as a final report regarding a violation of the University of California, Los Angeles (UCLA) Federal Wide Assurance (FWA) 00004642. As previously noted, the UCLA Institutional Review Board (IRB) conducted an inquiry into allegations about research collaboration between UCLA Professor John Fahey, MD and investigators in China on malariotherapy. The Board determined that Dr. Fahey, while not personally involved in the clinical trials, was involved in evaluating coded data and biological samples brought to UCLA from China by Dr. Xiao Peng Chen under the Fogarty International Program. Since Dr. Chen's work was performed as part of the Fogarty Program at UCLA and was under Dr. Fahey's supervision, the IRB determined that Dr. Fahey was engaged in human subjects research.

As noted above, the Board could not identify any information indicating Dr. Fahey's direct participation in clinical trials where malariotherapy was administered to Chinese subjects. The Board determined that Dr. Fahey and his laboratory participated only indirectly in the research by allowing the testing of Dr. Chen's coded samples. The IRB accepted Dr. Fahey's assurances that he will ensure that future Fogarty scholars and others under his direction will have appropriate UCLA IRB approval or certification of exemption prior to conducting any research activities at UCLA or using UCLA property, resources, material or funding.

Please do not hesitate to contact me or Steven Peckman, Associate Director-Human Subjects Research at 310.825.5344 if you have any questions.

Sincerely,



Judith L. Brookshire

Director

cc: Director Division of Compliance Oversight Kristina Borrer, OHRP
Executive Vice Chancellor Daniel Neuman
Vice Chancellor-Research Roberto Peccei
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Chairperson Robert Figlin, MIRB2
John Fahey, MD
Associate Director Steven Peckman