



# MEMORANDUM

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS  
2107 Ueberroth Building  
169407

December 10, 2002

John Fahey, MD  
Department of Microbiology and Immunology  
12-262 Factor Building  
174718

**RE: Complaint About Human Research Collaboration on Malariotherapy**

Dear Dr. Fahey,

On behalf of the UCLA Medical Institutional Review Board (MIRB) I thank you for your response regarding allegations related to malariotherapy research. Your responses were reviewed during the meeting of November 6, 2002. The Board agreed that you do not appear to be engaged in human subjects research related to the allegations from "Dr. Bob Smith". The MIRB expressed concern that Dr. Heimlich posted information on his website that may imply your and UCLA's involvement in such research and welcomed your response that he is being asked to remove such references.

Though the MIRB determined after consideration of the information provided, you were not involved in the malariotherapy research, the Board noted additional issues. The MIRB requests your response to the following issues by January 3, 2003:

1. Your response indicates that Dr. Xiao Ping Chen came to UCLA in 1997 as part of the UCLA Fogarty International AIDS Training and Research program. Dr. Chen brought to UCLA anonymized blood samples from Chinese subjects who participated in malaria research. The samples were analyzed as part of Dr. Chen's immunology laboratory training. Please clarify for the Board whether Dr. Chen's analysis of the samples was intended to contribute or develop publication of any findings related to malariotherapy research or other research.
  - a. If so, please clarify whether Dr. Chen had UCLA IRB approval or a UCLA certified exemption from IRB review for the research use of the samples. If he had UCLA approval, please forward the approval number with your response. **PLEASE NOTE:** The UCLA Multiple Project Assurance with the DHHS-Office for Human Research Protections requires UCLA IRB approval or certified exemption for the prospective or retrospective use of human biological materials for research purposes.

- b. As noted above, research with biological materials obtained from living individuals requires UCLA IRB approval or Certification of Exemption. Please assure the Board that you will require UCLA IRB approval or Certification of Exemption from individuals who wish to work with human biological samples or data for research purposes and work in your laboratory or participate in scholarly programs under your supervision, such as the Fogarty International grant.
2. Your response to question #6 indicates that you supplied kits for immunological tests and establishing quality control procedures to Chinese investigators for in-country training. It appears that funding for the supplies was from Fogarty Training grant 5-T22-TW00003. Such grant awards are to the University and constitute UCLA funds. Please clarify whether the supplies were given to Dr. Chen as a Fogarty scholar or as a courtesy.
    - a. If the supplies were given to Dr. Chen as a courtesy, such distribution of material obtained through a Fogarty award may make the DHHS directly or indirectly engaged in the research. You should contact Grants Officer Martha Hansen, Office for Contract and Grants Administration regarding grant requirements. Please provide the Board with follow-up information regarding your discussions with Ms. Hansen regarding the above issue.

On behalf of the MIRB, I thank you for your commitment to the protection of the rights and welfare of human research subjects. Please contact Steven Peckman, Associate Director Human Subjects Research at 825-5344 or [speckman@oprs.ucla.edu](mailto:speckman@oprs.ucla.edu) if you have any questions.

Sincerely,

Robert A. Figlin, MD  
Chair  
On behalf of the Medical Institutional Review Board

**Please forward all requested responses to:**

Steven Peckman  
Office for Protection of Research Subjects  
2107 PVUB  
169407