



# MEMORANDUM

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS  
2107 Ueberroth Building  
169407

June 10, 2003

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

COPY

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

Dear Dr. Fahey,

Thank you for the April 29, 2003 letter regarding the above referenced complaint. As indicated in your letter, research conducted on samples brought to UCLA by Dr. Xiao Peng Chen from China for work in the Fogarty Program occurred in 1997. You question whether the current Medical Institutional Review Board (MIRB) decision was based on "requirements promulgated in 1998 and 1999."

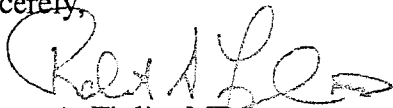
The MIRB previously acknowledged that you were not responsible for the conduct of the clinical trial that predated Dr. Chen's work with the samples in your laboratory. Rather, the Board determined you were responsible for the subsequent research performed on the samples at UCLA beginning in 1997. Our March 30, 2003 letter outlined the UCLA policies extant at the time of the research (testing of biological samples at UCLA) that were the basis for the MIRB conclusions. To reiterate: UCLA policies for human subjects research on existing human biological material or data related to human subjects were disseminated campus wide in 1996.

As background, the 1988 UCLA Multiple Project Assurance (MPA) was distributed in 1991 to all investigators as part of the UCLA Policies and Procedures for Research Involving Human Subjects.<sup>1</sup> The Policies and Procedures included instruction regarding exempt research, limiting exemption to work with biological material that is "publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." The 1988 MPA served as the basis for the 1996 policy. The Policy document was effective until replaced by the UCLA Investigator's Manual for the Protection of Human Subjects in April 1997, distributed campus wide, and the renewed MPA in 1998. The 1999 DHHS guidance was provided to you as further clarification of the policy and regulation.

<sup>1</sup> The 1988 UCLA Multiple Project Assurance (MPA) was distributed in 1991 as part of the UCLA Policies and Procedures for Research Involving Human Subjects, Human Subject Policy Committee.

On behalf of the MIRB, I appreciate your assurances that in the future you will seek IRB approval for such research. 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,

A handwritten signature in black ink, appearing to read "Robert A. Figlin, MD". The signature is written in a cursive style with a horizontal line extending to the right.

Robert A. Figlin, MD

Chair

On behalf of the Medical Institutional Review Board