



*Center for Interdisciplinary Research
in Immunology and Disease (CIRID)*

April 29, 2003

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Robert A. Figlin, M.D.
Chair, Medical Institutional Review Board
Office for Protection of Research Subjects
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RE: UCLA Medical Institutional Review Board Investigation of John L. Fahey, M.D., M.S.

Dear Dr. Figlin and Mr. Peckman,

This concerns Dr. Figlin's March 30, 2003 letter to me on behalf of the Medical Institutional Review Board ("MIRB"). As permitted by Dr. Figlin's letter, I wish to submit additional information relevant to the above-referenced matter and to have this additional information made part of the MIRB's file.

As you know, the conclusion of the MIRB was that there should have been MIRB approval for Dr. Xiao Ping Chen's analysis of blood serum at UCLA as part of the Fogarty Program in 1997. That blood serum had been collected three or four years earlier in China from HIV positive patients treated in clinical experiments using malariotherapy. Those experiments were in no way connected with me or with UCLA. In fact, I did not even know of Dr. Chen or his experiments at the time they were conducted. Nevertheless, the MIRB conclusion was that there should have been MIRB approval for Dr. Chen to analyze the blood samples in 1997 when he was at UCLA three or four years after those samples were collected. I have furnished the MIRB with multiple assurances that in the future I will seek MIRB approval for such research work.

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Mr. Steven Peckman
Robert A. Figlin, M.D.
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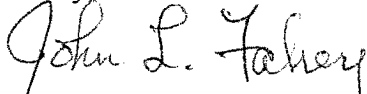
I wish to emphasize that in 1997, at the time that Dr. Chen analyzed the blood samples at UCLA, it was impossible for me to know that MIRB approval was needed. The best way to illustrate this is that in 2003, when the MIRB reached its conclusion that such approval was needed, it relied upon the following authorities which were promulgated after the 1997 event in question:

1. UCLA Multiple Project Assurance ("MPA") with the Department of Health and Human Services—Office of Human Research Protections ("DHHS-OHRP") dated May 1, 1998; and
2. The DHHS-OHRP January 26, 1999 Guidance, *Engagement of Institutions in Research*.

Given that these authorities which the MIRB relied upon in reaching its conclusions were only circulated one and two years after Dr. Chen conducted the blood serum analysis in question, it is understandable that I had not obtained the approval which the MIRB now has clearly required.

Thank you for your anticipated consideration of these points. Please include this letter with any materials which are forwarded to the DHHS-OHRP, the Fogarty International Program, UCLA administrators and any other funding or review source. While I question the apparent conclusion that in 1997 I was somehow responsible for knowing requirements promulgated in 1998 and 1999, I most emphatically assure you that I am complying with the procedures for MIRB approval which I now know apply to these matters.

Sincerely,



John L. Fahey, M.D., M.S.

