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May 23, 2002

Regis B. Kelly, Ph.D.
Executive Vice Chancellor
513 Parnassus Avenue
Room S-101
University of California
San Francisco, CA 94143-0407

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1169 and Federalwide Assurance (FWA) 000068

Research Project: M. A. Escamilla, et al. A minimalist approach to gene mapping: locating the gene for Acheiropodia, by homozygosity analysis. *Am J Hum Genet* 66:1995-2000; 2000.

NIH Project Numbers: K01 MH01453, R01 MH49499, and K02 MH01375

Dear Dr. Kelly:

The Office for Human Research Protections (OHRP) has reviewed your January 14 and May 2, 2002 letters regarding the above-referenced research that were submitted in response to OHRP's August 27, 2001 letter.

OHRP finds that the University of California, San Francisco (UCSF) has developed and implemented satisfactory corrective action plans to address the findings and required actions presented in OHRP's August 27, 2001 letter.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of UCSF to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Michael A. Carome, M.D. Director, Division of Compliance Oversight

- cc Dr. Reese T. Jones, Chairperson, IRB #1, UCSF
 - Dr. Susan H. Sniderman, Chairperson, IRB #2, UCSF
 - Ms. Sharon Friend, Director, Committee on Human Research, UCSF
 - Dr. John Mather, Director, Office of Research Compliance and Assurance, Veterans Health Administration

Commissioner, FDA

- Dr. David Lepay, FDA
- Dr. Greg Koski, OHRP
- Dr. Melody H. Lin, OHRP
- Dr. George Gasparis, OHRP
- Dr. Jeffrey Cohen, OHRP
- Dr. Kamal Mittal, OHRP
- Mr. Barry Bowman, OHRP