DEPARTMENT OF HEALTH & HUMAN SERVICES



Office for Human Research Protections The Tower Building 1101 Wootton Parkway, Suite 200 Rockville, Maryland 20852

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October 24, 2001

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 October 12, 2001 letter report regarding the above-referenced research that was submitted in response to OHRP's August 27, 2001 letter.

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

Furthermore, OHRP approves your request for an extension of the deadline for completion of required actions 2-4 stipulated by OHRP's August 27, 2001 letter. OHRP looks forward to receiving your next report regarding UCSF's implementation of these required actions by January 14, 2002.

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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. Jay H. Tureen, 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. James F. McCormack, 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