



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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April 8, 2010

A. Eugene Washington, M.D., MSc
Executive Vice Chancellor
University of California, San Francisco
Office of Executive Vice Chancellor
513 Parnassus, S115
San Francisco, CA 94143-0400

RE: Human Research Protections Under Federalwide Assurance FWA-68

Research Project: A Prospective Randomized Multicenter Trial of
Amnioreduction vs. Selective Fetoscopic Laser for the
Treatment of Severe Twin-Twin Transfusion Syndrome
Principal Investigator: Timothy M. Crombleholme, M.D.
HHS Protocol Number: R01HD41149

Dear Dr. Washington:

Thank you for your April 2, 2010 email in response to our March 29, 2010 letter in which we asked the University of California at San Francisco (UCSF) institutional review board (IRB) to revise its plan for contacting the one subject who participated in the above-referenced research, but was not provided with the Eurofetus Trial preliminary or final results at the time that this one subject enrolled into the above-referenced study. In specific, we asked the UCSF IRB to revise the proposed letters that were to be sent to the subject. We reviewed the revised letters (dated April 2, 2010) and find the letters to be acceptable.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

Eugene Washington, M.D., MSc - University of California, San Francisco
April 8, 2010
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We appreciate the commitment of your institution to the protection of human subjects.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. John Heldens, Director, Human Research Protection Program, UCSF
Dr. Victor I. Reus, Chairperson, Parnassus Committee IRB #1, UCSF
Dr. Susan H. Sniderman, Chairperson, San Francisco General Hospital, IRB #2
Dr. Alan P. Venook, Chairperson, IRB #4, UCSF
Dr. Joe Ellis, Office of Extramural Research, National Institutes of Health (NIH)
Dr. Sherry Mills, Office of Extramural Research, NIH
Dr. Duane Alexander, Director, National Institute of Child Health and Human Development,
NIH