



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary  
Office of Public Health and Science

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

Telephone: 240-453-8120  
FAX: 240-453-6909  
E-mail: Lisa.Rooney@hhs.gov

March 29, 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 March 4, 2010 email in response to our November 9, 2009 letter in which we asked the University of California at San Francisco (UCSF) institutional review board (IRB) to develop a 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.

We find that, in general, the proposed procedures for contacting and debriefing the subject are acceptable. We are concerned, however, that the text of the proposed letters may lead to confusion and may not explain why the institution is providing the subject with specific information approximately 6 years after study participation. As a result, we recommend that the proposed letters to the subject be revised as follows:

- (1) Provide an explanation as to why the institution is notifying the subject of this information approximately 6 years after study participation. In short, insert the following language at the end of the first paragraph in both draft letters: "We were required by

federal regulations to provide this information to you before you made a decision about participating in the UCSF study.”

- (2) Delete the last sentence in the second paragraph in both letters. We believe that this sentence may confuse the subject.

Please note that any revised letters should be reviewed and approved by the appropriate UCSF IRB. By April 27, 2010 please submit to our office copies of the final drafts of the proposed letters.

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