



DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Assistant Secretary for Health

Office of the Secretary

Office for Human Research Protections
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December 28, 2011

Douglas A. Bingham, J.D.
Executive Vice President, COO
The Scripps Research Institute, TPC8
10555 North Torrey Pines Road
La Jolla, CA 92037

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) - 411

Dear Mr. Bingham:

Thank you for your October 5, 2011 report in response to our September 11, 2011 questions and concerns letter. We have determined that the responses provided in your October 5, 2011 report adequately addressed our questions and concerns.

At this time, there should be no need for further involvement by our office in this not for cause evaluation. Please notify us if you identify new information which might alter this determination.

We appreciate your institution's continued commitment to the protection of human research subjects.

Sincerely,

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

Cc: Mr. Thomas E. Northrup, Chief Business Counsel, Scripps Research Institute
Dr. Ronald Simon, IRB Co-Chair, Scripps Health
Dr. Margaret Hamburg, Commissioner, Food and Drug Administration (FDA)
Dr. Joanne Less, FDA
Dr. Sherry Mills, Office of Extramural Research (OER), National Institutes of Health (NIH)
Dr. Joe Ellis, OER, NIH