



FEB 20 2013

Michael A. Carome, M.D.
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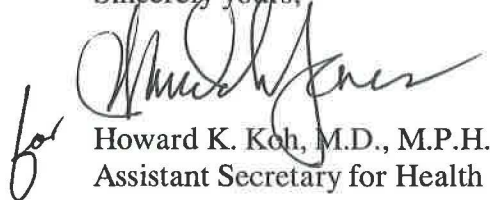
Dear Dr. Carome:

Secretary Sebelius has asked me to thank you for your letter regarding compliance oversight determinations made by the Office for Human Research Protections (OHRP), and to respond to you directly. We appreciate your interest in the protection of human subjects.

Please note that the OHRP evaluation you reference in your letter related to the study *Type 1 Diabetes TrialNet Protocol TN-14: Effects of Canakinumab on the Progression of Type 1 Diabetes in New Onset Subjects* is still ongoing and therefore we cannot comment on the particulars of this research or OHRP's evaluation. If you have any further questions or concerns, you may contact Dr. Kristina Borrer at 240-453-8132.

Thank you again for interest in this matter. I will also provide this response to Dr. Wolfe.

Sincerely yours,


for Howard K. Koh, M.D., M.P.H.
Assistant Secretary for Health