



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

November 13, 2013

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street NW
Washington, D.C. 20009

Dear Dr. Carome:

Thank you for your letter regarding the Transfusion of Prematures (TOP) Trial. I appreciate your interest in the protection of human subjects. The Office for Human Research Protections (OHRP) is carefully reviewing information related to the TOP Trial.

As you know, HHS held a public meeting on August 28, 2013, to seek public input and comment on how certain provisions of the federal policy for the protection of human subjects should be applied to research studying one or more interventions which are used as standard of care treatment in the non-research context. OHRP will develop draft guidance on these matters and seek broad public input before finalizing the guidance.

If you have any further questions or concerns, you may contact Dr. Kristina Borrer, Director, Division of Compliance Oversight, OHRP at (240) 453-8132.

Thank you again for interest in this matter. I will also provide this response to the cosigners of your letter.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is written in a cursive style.

Kathleen Sebelius