



SEP 18 2015

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

Dear Dr. Carome:

Secretary Burwell has asked me to thank you for your letter expressing concern regarding the protection of human subjects participating in research at the University of Minnesota (U of M) and to respond to you directly.

As you know, the Office for Human Research Protections (OHRP) has reviewed the materials that you provided, as well as related reports from the U of M and the State of Minnesota Legislative Auditor's Office. U of M is implementing numerous corrective actions related to these matters and has suspended enrollment in all of its Department of Psychiatry interventional drug studies. OHRP is coordinating with the Food and Drug Administration on this matter and has requested and received several follow-up reports from U of M. Currently, OHRP is monitoring the implementation of the corrective actions by U of M through correspondence.

Thank you again for your interest in this matter. Please contact Dr. Kristina Borrer at 240-453-8132 if you have additional questions about this matter.

Sincerely yours,

A handwritten signature in black ink, appearing to read "K. DeSalvo", is written over a horizontal line.

Karen B. DeSalvo, MD, MPH, MSc
Acting Assistant Secretary for Health