DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Health
Washington, D.C. 20201

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

Dear Dr. Carome:

Thank you for your letter to Secretary Burwell regarding the administrative process used by the Department of Health and Human Services (HHS) in drafting a notice of proposed rulemaking (NPRM) related to the HHS protection of human subjects regulation at 45 CFR part 46, subpart A. The Secretary has asked me to respond to your letter.

As you know, HHS is in the process of drafting an NPRM that, if published, would propose revisions to subpart A of the HHS protection of human subjects regulation. You express concern about the decision to have HHS components other than the Office for Human Research Protections (OHRP) participate in the drafting of this NPRM – in particular, the National Institutes of Health. No Federal statute, regulation, or policy prohibits the involvement of HHS components other than OHRP in the process of drafting this NPRM, and it is standard practice to involve multiple HHS agencies in developing regulations that have broad and overlapping impact. Furthermore, all significant regulations issued by HHS are reviewed within the office of the Secretary after an extensive internal review process involving all affected agencies. OHRP has played, and will continue to play, a central role in the development of the NPRM, including the opportunity to respond to suggestions from other HHS components.

Thank you again for your interest in the protection of human subjects. I also will provide this response to Dr. Sidney Wolfe, who co-signed the letter.

Sincerely yours,

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