



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

January 13, 2014

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 to Dr. Howard Koh and me regarding revised guidance issued by the Department's Office for Human Research Protections (OHRP) about financial compensation of human subjects for their participation in research. As you know, OHRP issued a revised response to the frequently asked question (FAQ) "When does compensating subjects undermine informed consent or parental permission?" and sent out a listserv announcement to that effect on September 23, 2013. You expressed concerns about the content of, and process for making, those revisions.

OHRP bears oversight responsibilities for the Department of Health and Human Services (HHS) Protection of Human Subjects regulations which require investigators to obtain the informed consent of subjects for participation in research only under circumstances that minimize the possibility of coercion or undue influence, and this requirement remains unchanged. OHRP has not interpreted this requirement to mean that subjects cannot receive an appropriate level of remuneration for research participation but rather has interpreted this to mean that the level of compensation cannot be so high as to unduly induce a subject to participate. We understand, however, that there may have been some misunderstanding in the research community about how to apply OHRP's interpretation of this requirement in determining an appropriate level of remuneration for research participation, specifically regarding whether the risks of the research may be considered in this determination.

The revisions to the cited FAQ clarify OHRP's prior guidance on the issue of remuneration to subjects that may constitute undue influence. The revised FAQ is not a change in policy but rather a clarification explaining that the regulations do allow subjects to receive an appropriate level of remuneration for accepting research risks. As explained in OHRP's September 23, 2013, listserv announcement regarding the revised FAQ, the change was intended to clarify that OHRP does not consider all levels of remuneration based on research risks to be unacceptable. Determining when the amount or type of remuneration creates undue influence for prospective subjects remains an important consideration for investigators and institutional review boards, based on the nature of the research and the subject population.

Because this revised FAQ does not represent a change in policy, OHRP did not seek public comment before publishing the revised response. OHRP does not plan to seek public comment specifically on the revised FAQ, but OHRP welcomes comments on its guidance at any time. Again, thank you for your interest in this matter. I will also provide this response to Dr. Sidney Wolfe, who cosigned your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathleen Sebelius". The signature is written in a cursive style with a large initial "K" and a distinct "S" at the end.

Kathleen Sebelius