DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

MAR 15 2002

TO: Director, Office for Human Research Protections

FROM: Assistant Secretary for Health

SUBJECT: Correspondence From the Secretary's Advisory Committee on Genetic Testing - ACTION

The Secretary's Advisory Committee on Genetic Testing (SACGT) has asked me to convey its support for the development of guidance on informed consent of third parties in human subjects research and for the consideration of position papers on this topic developed by the National Human Research Protections Advisory Committee (NHRPAC) and the National Institutes of Health (NIH). A copy of recent correspondence from Dr. Edward McCabe, SACGT Chair, is attached for your information.

As you may recall, SACGT previously recommended that NHRPAC be asked to carry out a review of Federal policy in this area. At SACGT's February 13-14, 2002 meeting, the Committee was briefed about the NHRPAC statement by Dr. Mary Faith Marshall, NHRPAC Chair, and by NIH staff who were involved in the development of the NIH recommendations. Dr. McCabe's letter commends the processes that were employed to produce the position papers and found it noteworthy that the two documents are complementary and reach similar, though not identical, conclusions on the essential questions surrounding the third party issue. Dr. McCabe indicates that SACGT would like the Office for Human Research Protections to develop guidance based on the principles outlined in the NHRPAC and NIH papers, including specific illustrative examples that will help clarify when third parties are human subjects, and to seek public comment on the guidance.

I am aware that you are in the process of drafting such guidance. As you proceed, I would urge you to consider the positions taken on this issue by NHRPAC and NIH and to seek public comment on the resulting document.

Thank you for your attention to this matter.

/s/

Eve B. Slater, M.D., F.A.C.C.

Attachment