Secretary's Advisory Committee on Genetic Testing
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
http://www4.od.nih.gov/oba/sacgt.htm

March 4, 2002

The Honorable Eve E. Slater, M.D., F.A.C.C.
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Slater:

On behalf of the Secretary's Advisory Committee on Genetic Testing (SACGT), I am writing to request that you convey to the Office for Human Research Protections (OHRP) our support for the development of guidance on informed consent of third parties in human subjects research. In developing such guidance, SACGT urges OHRP to consider position papers (enclosed) that have been developed on this topic by the National Human Research Protections Advisory Committee (NHRPAC) and the National Institutes of Health (NIH).

In 2000, after preliminary analysis of the issues in consultation with a number of experts, SACGT concluded that the issue affected all areas of research, not only research related to genetics and genetic testing, and recommended that NHRPAC be asked to carry out a review of Federal policy in this area. NHRPAC took up the issue last year, deliberated for several months, and finalized a consensus statement in January 2002. In addition, NIH, at the invitation of OHRP, has made recommendations on this issue.

At SACGT's February 13-14, 2002 meeting, we were briefed by the Chair of NHRPAC, Dr. Mary Faith Marshall, about the NHRPAC statement and by NIH staff who were involved in the development of the NIH recommendations. We were impressed with the processes that were employed to produce these 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. We commend NHRPAC for coming to consensus as a committee on the matter and for its efforts to involve all interested parties in its deliberative process. We also commend NIH for the careful and comprehensive approach it took in the analysis of the issue.

We understand that OHRP is currently reviewing the NHRPAC and NIH documents. We would like to see OHRP develop guidance based on the principles outlined in these documents, including specific illustrative examples that will help clarify when third parties are human subjects, and seek public comment on the guidance.

Thank you for your attention to this matter.

Sincerely,

Edward R.B. McCabe, M.D., Ph.D.
Chair

Enclosures