December 18, 2006

U.S. Department of Health and Human Services
Room 434 E
200 Independence Avenue, SW
Washington, DC 20201
Attention: Personalized Health Care RFI

Dear Secretary Leavitt,

On behalf of the Society for Women's Health Research, we are writing in response to the request for information on "Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genomic Information in Population- and Community-based Health Care Delivery Systems." The Society wants to take this opportunity to recommend to HHS that any transformation of health information technology leading to improved health and personalized care include the ability to research and analyze biological sex differences.

The Society for Women's Health Research is the nation's only not-for-profit organization whose mission is to improve the health of all women through research, education and advocacy. The Society advocates for increased funding for research on women's health; encourages the study of sex differences that may affect the prevention, diagnosis and treatment of disease; promotes the inclusion of women in medical research studies; and informs women, providers, policy makers and media about contemporary women's health issues.

The Society urges HHS to ensure that as part of its transformation of health information technology it include the study and examination of biological sex differences. There are many cases in which the benefit of a technology or service will be evident in a specific patient population. In order for specific patient populations, such as women, to benefit from the results of scientific research appropriate data collection and analysis must be performed to ensure that any important sex differences are revealed. Therefore, as HHS evaluates the quality of a proposed study design, we believe it is crucial that the health information technology system be designed to allow for analysis of demographic markers such as age and sex to enable the examination of sex differences.

Scientists have long known of the anatomical differences between the sexes, but only within the past decade have they begun to uncover significant biological and

physiological differences between the sexes. Sex differences have been found everywhere from the composition of bone matter and the experience of pain to the metabolism of certain drugs and the rate of neurotransmitter synthesis in the brain.

In April 2001, the Institute of Medicine (IOM) of the National Academy of Sciences released a report entitled, "Exploring the Biological Contributions to Human Health: Does Sex Matter?" The report, initiated and supported by the Society and released by the National Academy of Sciences, found that sex differences important to health and human disease occur in the womb and throughout the life span, affecting behavior, perception, and health.

According to definitions provided by IOM in the report, the term ***sex*** means "the classification of living things, generally as male or female, according to their reproductive organs and functions assigned by chromosomal complement." While ***gender*** is defined as, "a person's self-representation as male or female or how that person is responded to by social institutions on the basis of the individual's gender presentation. Gender is shaped by environment and experience." Sex is thus a scientifically acknowledged biomarker, whereas gender is not. This distinction is extremely important to biomedical research.

Currently, several government agencies apply these terms interchangeably, often using the word "gender" when "sex" is the correct term. It is the Society's recommendation that any research performed by the government use the definitions provided by the IOM. The quality of research results benefiting all patients depends on it.

Therefore, when HHS evaluates the quality of a proposed study design, it is crucial that all data be collected according to established scientific terminology, allowing for the ability to examine sex differences and the reporting of the research and analysis to HHS.

Thank you for providing this opportunity to comment on HHS's "Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genomic Information in Population- and Community-based Health Care Delivery Systems." We hope that you will take our comments into consideration.

Sincerely,

Phyllis Greenberger
President

Martha Nolan
Vice President of Public Policy