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March 19, 2009

Robinsue Frohboese, Acting Director
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHH Bldg.
Washington, D.C. 20201

Jerry Menikoff, MD, JD, Director
Office for Human Research Protections
U.S. Department of Health and Human Services
1101 Wootton Parkway
Suite 200
Rockville, Maryland 20852

Dear Ms. Frohboese and Dr. Menikoff:

The American Society of Clinical Oncology (ASCO) is the world's leading organization representing physicians engaged in cancer care and clinical research. ASCO has been actively engaged in efforts to assist its members in achieving compliance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule without unreasonable burden and without slowing the pace of cancer research. Moreover, we are considering the burden of Privacy Rule compliance in the future, as physician researchers become more actively engaged in research on personalized medicine, or the targeting of molecularly based cancer treatments on an individual basis.

We are writing to lend our support to last week's recommendation of the Secretary's Advisory Committee on Human Protections (SACHRP) to harmonize "those aspects of the Common Rule, the FDA regulations, and the provisions of the HIPAA privacy rule that govern access to and use of individualized health information and data." We urge your immediate action to address this issue that is critically important to advancing targeted cancer treatments. SACHRP correctly noted that personalized medicine hinges on our "scientific understanding of genomic and proteomic variation and susceptibility to disease." The burden on cancer clinical researchers who wish to use protected health information in biorepositories would be eased by your action to harmonize the Privacy Rule standards related to future uses to those contained in the Common Rule. The cancer patient would be the clear beneficiary of your efforts.

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Making a world of difference in cancer care



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More specifically, ASCO supports the recommendation contained in SACHRP's 2004 letter to the Secretary of Health and Human Services (HHS) proposing that the Privacy Rule apply the Common Rule standard of institutional review board (IRB) approval of a "research consent form that permits consent to certain future uses." The Institute of Medicine supported this same recommendation in its recent report entitled "Beyond the Privacy Rule: Enhancing Privacy, Improving Health Through Research."

Through a series of phone interviews with cancer clinical researchers and the compliance officers at their institutions, ASCO received significant information regarding the Privacy Rule standards that cancer researchers find most difficult to meet and those they believe could be modified to reduce research compliance burdens while still protecting the privacy of patients and research subjects. We found significant inconsistencies between leading academic institutions resulting in confusion and questions about the standards for obtaining authorization for future disclosures and uses contributed to inefficient reviews by some institutional review boards (IRBs) and frequently led to the abandonment of efforts to create certain databases or the curtailing of research projects that would use data in such repositories.

The ASCO interviews also revealed a diversity of approaches to the definition of a future research use. Some IRBs required a level of specificity about potential future uses that almost by definition precluded any future use. There was, however, significant agreement among researchers and compliance officers that cancer patients are willing to bank their specimens and clinical data for the purposes of future research and to have these data made available for research. According to researchers and compliance officials, these patients wish for no more than clear notice that their data will be maintained in a repository and used for future research according to the clear standards of the institution. With this level of information about future uses, patients believed they were able to grant an authorization without difficulty or reservation.

We believe the other recommendations contained in the 2004 SACHRP letter to the Secretary of HHS deserve your careful attention but we focus on the proposal related to future research uses and disclosures because we believe your action on this matter would yield immediate and significant improvement in our understanding of the molecular basis of cancer and benefit patients with cancer and those at risk for cancer. ASCO members are already reporting a negative impact of the future use authorization requirement on important cancer research efforts, and this will only intensify as physicians and researchers in the future rely on the study of banked biospecimens to inform personalized decisions about the use of molecularly based



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cancer treatments and the development of molecular diagnostic tools. The science and technology are poised to make important gains in our understanding of cancer.

Realizing this scientific promise would be greatly aided by streamlining regulatory requirements in a way that protects patient safety while providing clarity and efficiency. We are eager to work with you to address this important issue and urge you prompt attention.

Sincerely,

Richard L. Schilsky, MD
ASCO President

cc: Barbara Bierer, MD, SACHRP Chair
Julia Gorey, SACHRP Executive Director
Christina Heide, JD, OCR, Privacy Policy Specialist