

May 23, 2009

Secretary Kathleen Sebelius
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

We are writing in support of the recommendations of the recent Institute of Medicine (IOM) report entitled, *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research (2009)*. The ongoing conduct of human subjects research requires a trusting relationship between scientists and participants. As scientific professionals, we are strongly committed to maintaining the privacy of research participants. We also are proud that the United States is a leader in health research.

The U.S. Department of Health and Human Services (HHS) developed a set of federal standards for protecting the privacy of personal health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A major goal of the Privacy Rule was to ensure that individuals' health information is properly protected while allowing the flow of information needed to promote high-quality health care. The Privacy Rule also sets out requirements for the conduct of health research.

The IOM committee that assessed the impact of the HIPAA Privacy Rule on research concluded that the HIPAA Privacy Rule does not protect privacy as well as it should, and that, as currently implemented, the Privacy Rule impedes important health research. The committee's first and foremost recommendation is that Congress should authorize HHS and other relevant federal agencies to develop a new approach (outlined in detail in the report) to protecting privacy in health research that would apply uniformly to all health research. When this new approach is implemented, HHS should exempt health research from the HIPAA Privacy Rule.

If national policy makers choose to continue to rely on HIPAA rather than adopt a new federal approach, the report suggested, among other actions, that 1) HHS should revise the HIPAA Privacy Rule in order to reduce variability in interpretations of the Rule by Institutional Review Boards (IRBs) and should revise and expand guidance and harmonization; 2) HHS should encourage greater use of partially deidentified data in order to enhance privacy in research by expanding use and usability of data with direct identifiers removed; 3) HHS guidance documents should simplify the HIPAA Privacy Rule's provisions regarding the use of personal health information (PHI) in activities preparatory to research; 4) HHS should develop guidance materials to facilitate more effective use of existing data e.g. clearly stating that individuals can authorize use of PHI stored in databases or associated with biospecimen banks for specified future research.

The Joint Policy Committee of the Societies of Epidemiology represents the combined expertise of scientists and practitioners in the field of epidemiology, the scientific basis for rational public health decision-making. Our organizations and members are conducting health research for the

benefit of public health. Our hegemony in science and innovation remains one of our most valued attributes as a nation. We ask that you act on the recommendations of the IOM report in order to protect citizen privacy while promoting our ability to advance the nation's health.

More detailed information can be provided by contacting Dr. Roberta Ness (Dean, University of Texas School of Public Health, Houston, TX; 713 500 9052; roberta.b.ness@uth.tmc.edu)

Thank you for your consideration of our letter.

Sincerely yours,

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