



Federation of American Societies for Experimental Biology

— *Quality Life Through Research* —

Member Societies

The American Physiological Society
American Society for Biochemistry and
Molecular Biology
American Society for Pharmacology and
Experimental Therapeutics
American Society for Investigative
Pathology
American Society for Nutrition
The American Association of
Immunologists
American Association of Anatomists
The Protein Society
Society for Developmental Biology
American Peptide Society
Association of Biomolecular Resource
Facilities
The American Society for Bone and
Mineral Research
American Society for Clinical
Investigation
Society for the Study of Reproduction
Teratology Society
The Endocrine Society
The American Society of Human
Genetics
Environmental Mutagen Society
International Society for
Computational Biology
American College of Sports Medicine
Biomedical Engineering Society
Genetics Society of America
American Federation for Medical
Research

President

Mark O. Lively, Ph.D.
Professor of Biochemistry
Wake Forest University
School of Medicine
Medical Center Blvd.
Winston-Salem, NC 27157
Telephone (336) 716-2969
Fax (336) 777-3242
mlively@wfubmc.edu

9650 Rockville Pike
Bethesda, MD 20814-3998
Telephone (301) 634-7090
<http://www.faseb.org>

May 18, 2010

Ms. Georgina Verdugo
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building
Room 509F, 200 Independence Avenue SW
Washington, DC 20201

VIA ELECTRONIC SUBMISSION TO: <http://www.regulations.gov>

Dear Ms. Verdugo:

Thank you for the opportunity to comment on the Department of Health and Human Services request for information on Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health (HITECH) Act. FASEB is the largest coalition of biomedical research associations in the United States, representing 23 societies and over 100,000 scientists and engineers. We strongly believe that researchers and research institutions have an obligation to protect the privacy and confidentiality of study participants and their clinical data. FASEB is, however, very concerned with the adverse impact that the HIPAA Privacy Rule has had on health research.

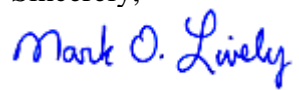
Recent reports, including a study by the Institute of Medicine, indicate that the implementation of the Privacy Rule impedes research vital to improving human health. FASEB has also reviewed this issue and agrees that requiring covered entities to provide individuals with an accounting of disclosures of their protected health information places a prohibitive burden on institutions. Tracking, storing, and communicating the details of each disclosure is costly, and some healthcare providers are reluctant to provide patient data to researchers for this reason. The time, expense, and harm to research associated with this regulation are not offset by added privacy protection, since the accounting is made after the information has been disclosed. Moreover, the Privacy Rule currently requires that investigators demonstrate that they will protect patient privacy before being granted a waiver of authorization or access to patient information for review preparatory to research. These matters are also governed by the Common Rule, which mandates that access to patient data for research purposes be approved by an independent, institutional review board.

Insofar as the accounting of disclosures provision has a negative impact on research and does not enhance the protection of study participants, FASEB recommends the institutions not be required to account for disclosures made for research through an electronic health record or any other means. FASEB believes that both research and study participants would be better served if institutions focused on fully

investigating reports that protected health information has been inappropriately disclosed and taking appropriate action if wrong doing is confirmed.

Thank you for in advance for considering FASEB's comments. Please do not hesitate to contact me if I can provide you with any additional information.

Sincerely,

A handwritten signature in blue ink that reads "Mark O. Lively". The signature is written in a cursive style with a blue color.

Mark O. Lively, Ph.D.
FASEB President

