



Federation of American Societies for Experimental Biology

— *Quality Life Through Research* —

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American Federation for Medical
Research

June 17, 2010

Christine K. Cassel, MD
Health Information Technology Working Group
President's Council of Advisors on Science and Technology
Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Dear Dr. Cassel:

The Federation of American Societies for Experimental Biology (FASEB) is pleased to share its thoughts with the Presidents Council of Advisors on Science and Technology on how health information technology (HIT) can be employed to improve public health through biomedical research. FASEB is composed of 23 societies with more than 100,000 members, making it the largest coalition of biomedical research associations in the United States. Our mission is to advance health and welfare by promoting progress and education in the biological and biomedical sciences. As such, FASEB is deeply interested in ensuring the accessibility of electronic health record data to biomedical researchers.

The Administration has recently initiated a considerable effort to increase electronic health record (EHR) adoption by health care providers across the country, while increasing investment in the development of the National Health Information Infrastructure. This is a golden opportunity to connect clinical care and biomedical research on a national scale to meet several of the Administration's grand challenges and would significantly enhance the ability of scientists and engineers to develop new therapeutic treatments that lead to enhanced quality of care, better health outcomes, and improved public health.

The aggregate EHR data of hundreds of millions Americans would represent the largest health information data resource in the world and would arm researchers with unique tools to fight disease and illness. First, the large number of participants would dramatically enhance researchers' ability to detect medically relevant trends and contributions to risk with regard to complex disease. Knowledge of specific underlying causal gene mutations can allow for more personalized therapeutic intervention. The identification of appropriately qualified candidates for clinical trials would also be greatly enhanced by the inclusion of research among the nation's health information technology strategic goals. Particularly for rare diseases, having patient-consented access to health information from a broad segment of the American public could result in increased participation among affected individuals in biomedical research studies. Similarly, this would facilitate the inclusion of minorities and other groups underrepresented in biomedical and clinical research. In addition, researcher access to patient-consented EHR information would support the real-time, post-marketing surveillance of pharmaceuticals and medical devices. Because pharmaceuticals and medical devices are approved on the basis of results of

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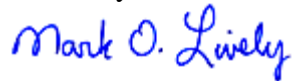
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clinical trials carried out among controlled groups of study participants, those results are not always representative of the general population.

The integration of clinical care and scientific research is absolutely critical to the rapid realization of many of the Administration's biomedical grand challenges. Because EHR data represents a unique resource, we strongly urge PCAST to advise the Administration to maximally leverage emerging EHR usage by integrating biomedical research into the broader strategic goals of the nation's health information technology initiatives. As part of this initiative, FASEB recommends modifying the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. A number of 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 by limiting researchers' access to and utilization of protected health information. The administration could facilitate biomedical science by exempting research from the Privacy Rule and working with the scientific and information security communities to develop and implement improved methods to insure that the privacy of study participants and the confidentiality of their data are protected. Additional information on FASEB's recommendations with regard to HIPAA are enclosed.

We are pleased to have been able to share our thoughts on some of the opportunities enhanced implementation of HIT could create with respect to improving health through biomedical research and look forward to working with PCAST and the Administration on these issues.

Sincerely,



Mark O. Lively, Ph.D.
FASEB President

cc: John Holdren Ph.D., Harold Varmus M.D., Eric Lander Ph.D., Deborah D. Stine, Ph.D.

enc: FASEB Statement on the HIPAA Privacy Rule and Research

**Federation of American Societies for Experimental Biology (FASEB)
Statement on the Health Insurance Portability and Accountability Act (HIPAA) Privacy
Rule and Research**

The Federation of American Societies for Experimental Biology (FASEB) affirms that the ethical conduct of research and the protection of human research participants are of paramount importance. Consistent with this view, we believe that researchers and research institutions have an obligation to protect the privacy and confidentiality of study participants and their clinical data. FASEB is concerned, however, with the process by which human subjects research and the data generated through that research, are regulated. Of particular concern is the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which a number of reports indicate impedes research vital to improving human health. In the interest of advancing health science and ensuring the protection of study participants, FASEB recommends that research be exempted from the Privacy Rule and that data privacy and security protections be strengthened through the Department of Health and Human Services (HHS) Common Rule, which currently regulates most federal funded human subjects research. These and other recommendations are described below in greater detail.

- **Research should be exempted from the HIPAA Privacy Rule.** Since its implementation in 2003, the HIPAA Privacy Rule has had a significant, negative impact on health research. A recent report conducted by the Institute of Medicine (IOM)¹ concludes that the Rule has made it more difficult to design consent forms that participants can understand, increased the cost and time associated with recruiting research subjects, caused delays in institutional review board (IRB) approval, and contributed to selection bias, among other impediments to research. Such obstacles slow the progress of research critical to developing treatments for human illness and disease. FASEB believes that research should be exempted from the HIPAA Privacy Rule. Such an exemption is not without precedent: HIPAA does not restrict the use and disclosure of sensitive health information collected in the course of public health and quality improvement activities. If research is to be exempted from the Privacy Rule, FASEB would recommend that the Common Rule be extended to non-federally funded research currently regulated by the Privacy Rule.

- **HHS should strengthen data privacy and security protections.** The HHS Common Rule and Food and Drug Administration regulations provide mechanisms for protecting research participants. Both require that IRBs determine that risks to research participants are minimized, that adequate provisions are in place to protect the privacy of subjects and confidentiality of their data, and that researchers provide participants with a statement describing the extent to which the confidentiality of records identifying them will be maintained. These measures are an important component of our human subjects protection process. Nonetheless, HHS should do more to protect the privacy and security of data. FASEB recommends that HHS work with the research and information security communities to identify and implement improved data security methods. We suggest creating a process to certify as “safe harbors” institutions that adhere to sound security and privacy practices and that establish standards for investigators with respect to ethical research practices. In addition, we recommend that HHS establish and enforce appropriate penalties for the intentional breach of privacy.

FASEB recognizes that exempting research from the Privacy Rule, extending the Common Rule, and enhancing data security measures will be challenging; thoughtfully implementing these recommendations will take time. In the interim, we urge HHS to make the following modifications to the Privacy Rule in order to mitigate the negative impact it has on health research.

- **Consistent with the Common Rule, the Privacy Rule should allow individuals to authorize the use of stored protected health information (PHI) for future unspecified research.** The Common Rule allows participants to consent to future research with biological samples or information stored in databases if such future uses are reviewed by an IRB and described in sufficient detail to allow informed consent. However, HHS has indicated that under the Privacy Rule, each purpose of the requested use or disclosure described in the authorization form must be study specific, meaning that unspecified future research is not permitted. To conduct further studies with stored data, researchers are required to re-contact individuals for every project for which the samples could be used in order to obtain consent. This is the case even if participants have consented to those future uses via an IRB-approved consent form. Impractical, at best, this process could be impossible for research involving a large number of samples. In addition, it adds confusion to already complicated authorization forms.² Indeed, a number of studies report that language added to the authorization forms as a result of HIPAA has made the forms more difficult for participants to understand.^{3,4,5}

FASEB believes that the Privacy Rule should allow individuals to authorize the use of their PHI for future unspecified research if those uses are reviewed by an IRB and described in sufficient detail to allow informed consent. Such uses are already permitted under the Common Rule. Harmonizing these regulations would facilitate the conduct of IRB-approved research and allow research participants to exercise greater control over how their data could be used.

- **HHS should create a modified deidentification standard for research purposes.** Neither the Privacy Rule nor the Common Rule applies to health information that has been deidentified. However, the standards for deidentification under the two rules differ significantly. The Privacy Rule specifies that data can be deidentified by stripping 18 direct identifiers from data sets (i.e., the “safe harbor” method). It also permits the creation of limited data sets, allowing covered entities to disclose data with only 16 direct identifiers removed provided that they enter into a data use agreement with the recipient. Under the Common Rule, data is considered to be deidentified if data or specimens have been coded in such a way that investigators cannot readily ascertain the identity of the individual to whom the information pertains. In practice, therefore, some information is considered individually identifiable under the Privacy Rule, but not under the Common Rule, adding to confusion regarding what is permissible under current regulations.

The Privacy Rule standards also make it difficult to conduct certain kinds of vital health research. The safe harbor method requires the removal of so much important health information that it diminishes the utility of the data for many research projects. For example, one study of pharmacy, administrative, and financial files of patients discharged from a

hospital system found that creating a deidentified data set via the safe harbor method resulted in a 31% loss of unique data elements compared to creating a limited data set of that information. Much of the information lost was important to research.⁶ While limited data sets provide greater flexibility to researchers, it is not always possible to link data sets from multiple sources, making it difficult to generate a complete record of a participant's health history.

Moreover, the strict deidentification process mandated by the Privacy Rule does not guarantee that PHI will be protected. One study shows that even after deidentifying data via the safe harbor method, individuals could be reidentified with a moderately high expectation of accuracy by applying only diagnosis and medical combination information.⁷ Advancements in technology and the availability of large public data bases are likely to make it even easier to reidentify anonymized data. FASEB appreciates that HHS is currently reviewing the Privacy Rule deidentification standards. We hope this review will result in the creation of a modified deidentification standard for research purposes that is more closely aligned with the Common Rule.

- **HHS should require Privacy Board/IRB approval for research activities conducted preparatory to research by all researchers.** The Privacy Rule permits covered entities to use and disclose PHI without authorization for activities that are preparatory to research. However, according to current HHS guidance, only internal researchers (that is, employees or members of a covered entity's workforce) are able to contact potential subjects regarding enrollment. External researchers, or those affiliated with but not part of a covered entity's workforce (e.g., those in an organized health care arrangement), must either enter into a business associate agreement with the covered entity or obtain a waiver of authorization from an IRB/Privacy Board in order to do so. This distinction is made even though internal and external researchers may be subject to the same institutional rules and regulations and the jurisdiction of the same IRB. At the same time, the Common Rule requires that activities preparatory to research, including record review and participant recruitment, be reviewed and approved by an IRB regardless of the investigator's relationship to the covered entity.

FASEB agrees with the Secretary's Advisory Committee on Human Research Protections (SACHRP)⁸ that the confusing guidance on this topic and the lack of harmonization between the Privacy Rule and the Common Rule undermines rather than enhances the attention that must be paid to the protection of research participants during the recruitment process. Consistent with SACHRP's recommendation, FASEB urges HHS to eliminate the distinction between internal and external researchers with regard to conducting activities preparatory to research. We also recommend that HHS harmonize the Privacy Rule with the Common Rule by requiring Privacy Board/IRB approval for all of a covered entity's researchers prior to contacting potential subjects regarding study recruitment.

- **The accounting for disclosures requirement should be eliminated for research.** Under the Privacy Rule, individuals have the right to request that a covered entity provide them with a comprehensive list of the disclosures of their PHI made in the six years⁹ preceding the request. The accounting must include the date the disclosure was made, the identity of the individual receiving the information, a description of the information disclosed, and a

statement of the purpose of the disclosure. Disclosures for research pursuant to a waiver of authorization, research on decedents' information, and reviews preparatory to research are all subject to this accounting requirement. Although HHS created an exception for research involving groups of 50 more subjects—allowing covered entities to provide a general list of all protocols for which their PHI may have been disclosed—reports indicate that tracking and storing the details of each disclosure is extremely costly for institutions. As a result, some healthcare providers are reluctant to provide patient data to researchers.¹⁰

The time and expense expended in compliance with this regulation is not offset by added privacy protection since the accounting is made after the information has been disclosed. In addition, the Privacy Rule already requires that investigators demonstrate that they will protect patient privacy before being granted a waiver of authorization or access to information for review preparatory to research. FASEB recommends that the accounting for disclosures requirement be eliminated for research. Instead, institutions should focus on fully investigating reports that PHI was inappropriately disclosed and taking appropriate action if wrong doing is confirmed.

¹ Institute of Medicine. 2009. *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. Washington, DC: The National Academies Press.

² Secretary's Advisory Committee on Human Research Protections. 2004. *Letter to Secretary Thompson*.

³ Greene SM, Bennett B, Kirlin KR, Oliver R, Pardee R, and Wagner E. 2008. *Impact of HIPAA Privacy Rule in the HMO Research Network*. Seattle, Washington: Group Health Cooperative Center for Health Studies.

⁴ Breese P, Burman W, Rietmeijer C, and Lezotte D. 2004. *The Health Insurance Portability and Accountability Act and the informed consent process*. *Annals of Internal Medicine*. 141: 878-898.

⁵ National Committee on Vital Health Statistics, Subcommittee on Privacy and Confidentiality. *Susan Ehringhaus's testimony on behalf of the Association of American Medical Colleges*. November 19, 2003.

⁶ Clause SL, Triller DM, Bornhorst CPH, Hamilton RA, and Cosler LE. 2004. *Conforming to HIPAA regulations and compilation of research data*. *American Journal of Health-System Pharmacy*. 61(10):1025-1031.

⁷ *Ibid*.

⁸ Secretary's Advisory Committee on Human Research Protections. *Ibid*.

⁹ The HI-TECH Act modified the accounting for disclosures requirement such that covered entities will be required to provide individuals with a list of all disclosures made within 3 years of the request. This modification will go into effect in 2011 or 2014 depending on when the entity adopted electronic health records.

¹⁰ National Committee on Vital Health Statistics, Subcommittee on Privacy and Confidentiality. *Ibid*.