

April 25, 2002

The Honorable Tommy G. Thompson  
Secretary, U.S. Department of Health and Human Services  
Office of Civil Rights  
Attention: Privacy 2  
Hubert H. Humphrey Building  
Room 425A  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Secretary Thompson:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the March 27, 2002 proposal to modify the federal medical privacy rule. FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people.

We recognize that the US Department of Health & Human Service (DHHS) has made diligent efforts to modify the privacy regulations issued under the Health Insurance Portability and Accountability Act of 1996 to accommodate the concerns previously voiced of the research community. The proposed changes go a long way towards correcting the unintended consequences of the privacy regulations that threatened biomedical research. However, we reiterate our strong conviction that research subject to IRB oversight under the Common Rule<sup>i</sup> should be exempt from the privacy rule.

The protection of human research participants is a paramount concern to both the public and researchers. The Institutional Review Board (IRB) system, which was established to protect the rights and welfare of human research participants, is overburdened, understaffed and under great strain, primarily due to increased caseloads. Essentially, the Common Rule and FDA regulations already instruct IRBs to determine all risks of research, including the risk of a violation of privacy. We believe that in general the privacy of medical records is well respected and protected by the IRB system. In fact, a 1997 report by the National Committee on Vital and Health Statistics recognized that IRB privacy safeguards work.<sup>ii</sup> It would be duplicative and burdensome to also have the IRB consider risks to research subjects under a second set of criteria and would imperil the protection afforded to human subjects by IRB review. While the proposed Privacy Regulations contemplate the alternative of a Privacy Board independent from the IRB, it is difficult enough to get qualified members to serve on IRBs and a Privacy Board would simply set up a dual structure with competing demands for qualified members. Alternatively, to simply add Privacy Board responsibilities to those currently required by IRBs would, we believe, further distract these essential review committees from their principal responsibilities for patient protections of all types to further attentions to details of paperwork.

If, however, specific modifications of the IRB system for protection of the privacy of patient records were thought to be warranted, we strongly believe that such modifications to existing regulations under the Common Rule and/or FDA regulations would be a far more effective and cost-efficient mechanism to accomplish any such changes. We recommend this approach as a far better alternative to the creation of administratively cumbersome and burdensome

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processes for establishing a separate bureaucracy within our research institutions with largely redundant responsibilities.

Notwithstanding our position that the privacy regulations should exempt research carried out under the Common Rule, we offer the following comments to several of the proposed changes to the research provisions:

### **De-identification Alternative**

In a November 20, 2001 letter to you, FASEB joined with 180 research universities, medical schools, teaching and community hospitals, and medical specialty and scientific societies to petition the Department to reopen the research provisions to further rulemaking and comment. Among other recommendations, we expressed our concern that the Rule's standard for de-identification of medical information would render data useless for much epidemiological, health services and other population-based research. We are pleased that our concerns have been heard and considered.

Instead of a formal proposal to modify the de-identification provisions of the Rule, the NPRM posits an alternative that would delineate a set of "direct" identifiers that would be removed to create a modified de-identification standard for medical research purposes. Data sets that do not include *directly* identifiable information, but which contain certain identifiers such as admission, discharge and service dates; date of death; and a 5-digit zip code, would not render the data *identifiable*. These characteristics are often necessary in conducting medical research. The alternative suggested by the NPRM conditions the disclosure of this limited data on the entity obtaining an agreement from the recipient to 1) limit the use of the data to the specified purpose in the Privacy Rule; 2) limit who can use or receive the data; and 3) agree not to re-identify the data or contact the individuals.

FASEB strongly supports the use of this alternative approach to the de-identification standard and we encourage the Department to implement the standard. This alternative will protect privacy with fewer burdens to vital medical research than those inherent in the unmodified Rule.

### **Authorization**

There are several proposed modifications to the authorization requirements set forth in §164.508 of the Rule. First, the modification provides for the use of one authorization form for all purposes, which could be combined with the consent form for participation in research. This greatly simplifies the process of obtaining authorization, lessens confusion and eliminates redundant paperwork.

Further, the NPRM recognizes that there are circumstances in which a research participant intends that the participant's private health information (PHI) be available for an indefinite period of time without being subject to a termination date or terminating event. The NPRM would allow an authorization to approve permission for disclosure of PHI to a repository or database maintained for research purposes *without* a termination date or terminating event. Since much medical research is dependent on data stored in a repository or database, we applaud this proposed modification.

The NPRM further provides that the authorization contains certain core elements and that it contains certain notifications. We are concerned with one required notification that would oblige the party holding the PHI to state the potential for redisclosure by the recipient. This requirement calls for an estimation of the risks of disclosure by a recipient who is typically beyond the control of the party authorized to disclose the information. We urge that the Department clarify in guidance that it would be sufficient to meet the requirements of proposed §164.508(c)(2)(iii) with a notification that researchers are only permitted to use or disclose the protected health information for purposes that have been authorized by the

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RB or as required by law or regulation. However, the notification would also state: "There is always a risk of unplanned redisclosure by the recipient."

### **Waiver Requirements**

Another proposed change announced in the NPRM concerns the assessment of requests for waivers of authorization. The Department has acknowledged the concerns of the research community that the criteria for waivers of authorization were confusing and internally inconsistent. The Department's proposed modifications address these concerns by eliminating certain criteria and by describing the standards that an Institutional Review Board or Privacy Board should consider when evaluating whether the use or disclosure of PHI involves no more than a minimal risk to the privacy. We commend the effort of the Department to make the waiver of authorization provisions as they relate to research more workable.

### **Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required**

We ask that DHHS correct an oversight in Section 164.512 (h) by adding the phrase "or anatomical instruction" at the end of the following sentence so that it reads: 'A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, tissues OR WHOLE BODIES for the purpose of facilitating WHOLE BODY ORGAN, eye or tissue donation and transplantation OR ANATOMICAL INSTRUCTION.' This would enable the continued use of anatomical donations in medical education.

In conclusion, FASEB believes research undertaken with IRB protection under the Common Rule quite effectively affords research participants privacy protections and that consequently, such research should be exempt from the Privacy Rule. Nonetheless, we appreciate the consideration that DHHS gave to our initial expression of concern and we applaud the efforts of DHHS in making the Privacy Rule much more workable for the research community. We welcome the opportunity to meet with your representatives to further elaborate our views on these issues should you find it helpful.

Sincerely,

Robert R. Rich, M.D.  
President

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<sup>i</sup> 45 C.F.R. Sec 46.111(a) (7)

<sup>ii</sup> Health privacy and confidentiality recommendations of the National Committee on Vital and Health Statistics Washington, D.C.: National Committee on Vital and Health Statistics, June 27, 1997.