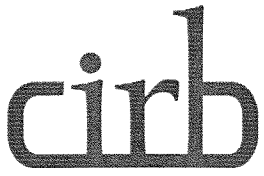

CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

August 1, 2011

VIA www.regulations.gov

U.S. Department of Health and Human Services
Office of Civil Rights
Attention: HIPAA Privacy Rule Accounting of Disclosures
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue
Washington, DC 20201

Re: Comments on Notice of Proposed Rulemaking entitled "HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act – RIN 0991-AB62

Dear Sir or Madam:

The Consortium of Independent Review Boards ("CIRB®") appreciates the opportunity to comment on the Office of Civil Rights, Department of Health and Human Services' ("DHHS") proposed rule entitled "HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act." See 76 Fed. Reg. 31,426 (May 31, 2011) ("Proposed Disclosure Accounting Rule" or "Proposed Rule"). CIRB is a consortium of independent institutional review boards ("IRBs") located in the United States and Canada that provide IRB services to institutions external to their individual member institutions. Independent IRBs have review responsibility for a majority of the FDA-regulated clinical research conducted in the United States. Because the Proposed Rule will modify the privacy regulatory provisions under the Health Insurance Portability and Accountability Act ("Privacy Rule") as set forth in 45 C.F.R. Part 164, the individual CIRB members have a significant interest in the Proposed Disclosure Accounting Rule, particularly as it impacts the research community.

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DHHS' Proposed Rule is part of its implementation of the Health Information Technology for Economic and Clinical Health Act's ("HITECH") requirement that covered entities and business associates should provide individuals with an accounting of disclosures of protected health information to carry out treatment, payment, and health care operations when such disclosures are through an electronic health record. Id. Among other things, DHHS requested comments on whether certain disclosures associated with research should be exempt from the accounting requirements. CIRB will primarily focus its comments on this issue.

As DHHS understands, under the current Privacy Rule, entities are required to make available an accounting of certain research-related disclosures of an individual's protected health information. See 45 C.F.R. § 164.528. This accounting requirement includes disclosures for research purposes in accordance with 45 C.F.R. § 164.512(i),[1] which involves "research where an Institutional Review Board ("IRB") or Privacy Board has waived the requirement for individual authorization because, among other reasons, it determined that the study poses no more than minimal risk to the privacy of individuals and the waiver is needed to conduct the research." See 76 Fed. Reg. 31,426, 31,432 (May 31, 2011).[2] In the Proposed Rule, DHHS is considering exempting such disclosures from the accounting requirements. Id. However, it requested information on the regulatory burdens associated with such an accounting in support of such an exemption. Id.

CIRB highly supports the exemption of disclosures associated with 45 C.F.R. § 164.512(i)(1)(i). While CIRB does not have the ability to provide DHHS with actual data reflecting the current regulatory burden on covered entities, it agrees with the Secretary's Advisory Committee on Human Research Protections and the Institute of Medicine's conclusions that the current accounting provisions for research disclosures place a "heavy administrative burden on health systems and health services research, but achieves little in terms of protecting privacy." Id. at 31,433.

Pursuant to 45 C.F.R. § 164.512(i)(1)(i), an IRB or Privacy Board must consider a number of factors, and assure that several safeguards are in place, before allowing a covered entity to use or disclose an individual's protected health information for research purposes in the absence of subject authorization. These steps provide a heightened level of privacy security to the subject, and CIRB does not believe that there is any added human subject protection benefit in requiring covered entities to account for such disclosures. Thus, under

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[1] Research disclosures associated with either limited data sets or disclosures pursuant to a participant's authorization currently are exempt from the accounting requirement, and would remain exempt under the Proposed Rule. See 45 C.F.R. § 164.514(e).

[2] 45 C.F.R. § 164.512(i) also exempts from the accounting requirement disclosures associated with reviews preparatory to research and disclosures of research on a decedent's information. See 45 C.F.R. §§ 164.512(ii) and (iii). CIRB supports these exemptions as well.

these circumstances, where the regulatory burden associated with the accounting is understood to be extremely high, CIRB recommends against requiring accounting of disclosures under 45 C.F.R. § 164.512(i).

As a separate matter, CIRB understands that, regardless of the exemption of disclosures under 45 C.F.R. § 164.512(i) from the accounting requirement, individuals will be able to obtain an "access report" for these types of disclosures if the disclosures are in electronic format. Id. DHHS should consider whether the burden associated with providing access reports for such disclosures is indeed "reasonable" as suggested in the Proposed Rule preamble or whether research disclosures such as those associated with 45 C.F.R. § 164.512(i) also should be exempt from this requirement. See 76 Fed. Reg. at 31,437.

CIRB thanks DHHS for the opportunity to comment on these significant modifications to the Privacy Rule and its application to research disclosures. While CIRB supports an individual's access to information about protected private health information disclosures, such access should be considered in light of the added benefit to the individual, and the regulatory burden on the covered entity. Where added subject protection is neglible, and the cost burden is high, CIRB recommends exemption from the accounting requirements.

Sincerely,

Cami Gearhart by SH

Cami Gearhart