Guidance for Industry

IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations

FINAL GUIDANCE

This guidance is being distributed for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(3) without seeking prior comment because the agency has determined that prior public participation would not be feasible or appropriate. FDA made this determination because, without this guidance, some IRBs might halt enrollment in ongoing clinical investigations to review stand-alone HIPAA authorizations so as to comply with their written procedures. FDA invites comments on this document. Please submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that published in the *Federal Register*. FDA will review any comments we receive and revise the guidance document when appropriate.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner

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U.S. Department of Health and Human Services
Food and Drug Administration
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August 16, 2003

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IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations

This guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

I. INTRODUCTION

This guidance provides the current recommendations of the Food and Drug Administration (FDA) concerning Institutional Review Boards' (IRB) review and approval under 21 C.F.R. Part 56 of stand-alone authorizations that are created by covered entities (or by third parties), pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, and that are provided to research subjects prior to enrolling in clinical investigations after April 14, 2003, to obtain their permission to use and/or disclose their health information for research. A stand-alone HIPAA authorization (for research) is a document that is used to obtain permission from an individual for a covered entity to use and/or disclose the individual's identifiable health information for a research study, and that is not combined with an informed consent document to participate in the research study itself. The Privacy Rule refers to a HIPAA authorization that has been combined with an informed consent document as a "compound authorization." IRBs would be required to review the HIPAA authorization in a "compound authorization" because IRBs

are required, with certain exceptions, to review and approve informed consent documents. See 21 C.F.R. Part 56.

Because issues addressed in this Level 1 guidance require immediate resolution, it is not feasible or appropriate for FDA to seek comments before implementing it. See 21 C.F.R. §§ 10.115(g)(2) and 10.115(g)(3). This guidance is intended to encourage IRBs to permit the enrollment of subjects in clinical investigations without prior IRB review and/or approval of stand-alone HIPAA authorizations, since such review and/or approval is not required by the HIPAA Privacy Rule.

II. BACKGROUND

To improve the efficiency and effectiveness of the health care system, Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, which included "Administrative Simplification" provisions that required, among other things, the Department of Health and Human Services (HHS) to adopt national standards for certain electronic health care transactions. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated, into HIPAA, provisions that mandated the adoption of Federal privacy protections for certain individually identifiable health information.

In response to the HIPAA mandate, HHS published a final regulation, "Standards for Privacy of Individually Identifiable Health Information," generally known as the Privacy Rule, in December 2000. HHS subsequently amended the Privacy Rule on August 14, 2002. See 45 C.F.R. Part 160 and Part 164,

Subparts A and E. This Privacy Rule sets minimum national standards for the protection of certain individually identifiable health information. The Privacy Rule, however, applies only to three types of entities, known as covered entities: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with a transaction for which HHS has adopted a standard. As of April 14, 2003 (April 14, 2004, for small health plans), covered entities have been required to comply with the standards to protect and guard against the misuse and improper disclosure of individually identifiable health information. Failure to comply with these standards may, under certain circumstances, trigger the imposition of civil or criminal penalties. For a more complete description of the Privacy Rule, see www.hhs.gov/ocr/hipaa.

Health care providers who transmit health information electronically in connection with a transaction for which HHS has adopted a standard, such as most hospitals, are covered entities. In addition, clinical investigators who are health care providers but do not transmit health information in electronic form in connection with a transaction for which HHS has adopted a standard, but who are nonetheless part of the covered entities' workforce, must comply with the Privacy Rule in their work at or for the covered entity – unless they are workforce members of hybrid entities, and they are not part of the designated health care component. See 45 C.F.R. 164.105. Lastly, clinical investigators or other researchers who are not in either of the above categories are not covered by the Privacy Rule, but they should be aware of the Rule and its restrictions on the use and disclosure of protected health information.

Most IRBs are not covered entities under the Privacy Rule because they do not meet the Privacy Rule's definitions of health plan, health care clearinghouse, or health care provider who transmits any health information in electronic form in connection with a transaction for which HHS has adopted a standard. See 45 C.F.R. 160.103. However, IRBs interact with clinical investigators who might be, or who are employed by or are otherwise part of the workforce of covered entities under the Privacy Rule. In addition, IRBs may review research in which individually identifiable health information will be obtained from covered entities, and therefore, they need to understand how the Privacy Rule interacts with Federal informed consent requirements, including FDA human subjects protection regulations and regulations on institutional review boards (see 21 C.F.R. Parts 50 and 56).

The Privacy Rule provides that, unless the use or disclosure is otherwise permitted or required by the rule, the use or disclosure of the protected health information of an individual, such as a research subject, is permitted only if the individual signs an authorization for the use or disclosure. See 45 C.F.R. 164.508. For example, in the context of a clinical investigation conducted by a covered entity, a valid and properly executed HIPAA authorization is a permission from the subject for the covered entity to use and/or disclose the subject's protected health information for the clinical investigation. A HIPAA authorization is different than a subject's informed consent. A HIPAA authorization, when executed, is the subject's permission for his/her identifiable health information to be used and/or disclosed for a research purpose. An informed consent document, on the other hand, apprises potential research subjects of the possible risks and benefits associated with

participating in the clinical investigation and, when executed, indicates their willingness to participate. The Privacy Rule permits, but does not require, clinical investigators to combine a HIPAA authorization with informed consent documents; this combined form is known as a compound authorization under the Privacy Rule. See 45 C.F.R. 164.508(b)(3).

III. DISCUSSION

Prior to the April 14th, 2003 Privacy Rule compliance date, FDA and the Office for Civil Rights (OCR), which are both components of HHS, received requests for clarification of IRBs' responsibilities with respect to reviewing and approving stand-alone HIPAA authorizations under the Privacy Rule, Federal regulations governing human subjects protection and IRBs, including 21 C.F.R Parts 50 and 56, and international guidelines (see, for example, International Conference on Harmonisation (ICH) Good Clinical Practice: Consolidated Guidance (E6).[1] These requests expressed concern that, after the Privacy Rule's compliance date, clinical investigations might be impeded because IRBs could be backlogged with requests to review thousands of stand-alone HIPAA authorizations. The requests further stated that some IRBs would halt clinical investigation enrollment pending their review of these stand-alone HIPAA authorizations.

On April 15, 2003, OCR issued guidance entitled, "Privacy Guidance about Authorizations for Research and Institutional Review Boards" (OCR

[1] The IHC Good Clinical Practice: Consolidated Guideline (E6) states, for example, "Before initiating a trial, the investigator/institution should have written and dated approval/favourable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), *and any other written information to be provided to subjects.*"

Guidance, available at www.hhs.gov/ocr/hipaa/privguideresearch.pdf) addressing these issues. OCR clarified that IRBs are not required to review and approve stand-alone HIPAA authorizations under the Privacy Rule or the HHS Human Subjects Protection Regulations at 45 C.F.R. Part 46. Furthermore, pursuant to FDA's permission, OCR clarified that IRBs are not required to review stand-alone authorizations under the FDA regulations at 21 C.F.R. Part 56, so long as an IRB's written procedures, adopted pursuant to 21 C.F.R. 56.108(a), do not require such review and approval.

With FDA's permission, OCR also addressed, in further detail, IRBs' responsibilities under the ICH guideline entitled, "Good Clinical Practice: Consolidated Guideline" (1996), which some IRBs have misunderstood as requiring them to review all written materials provided to subjects, including stand-alone HIPAA authorizations. The OCR guidance clarified that the ICH guidelines are not legal requirements subject to enforcement by U.S. authorities. Furthermore, in adopting and publishing the ICH guideline, FDA's "Good Clinical Practice: Consolidated Guideline" states, as is true of all guidance, that "[i]t does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both." See 62 FR 25692, May 9, 1997. FDA is issuing this guidance to clarify that use of a stand-alone HIPAA authorization that an entity other than an IRB, such as an investigator or sponsor, has determined meets the requirements of FDA's "Good Clinical Practice: Consolidated Guideline" would be an acceptable alternative, so long as it is permitted by the IRB's

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(Emphasis added.) (See ICH E6 4.4.1.).

written procedures. Since the Privacy Rule does not require IRB review or approval of HIPAA stand-alone authorizations, the Privacy Rule would not affect the acceptability of this alternative.

FDA regulations governing IRBs require, in pertinent part, that IRBs follow written procedures they have adopted for reviewing clinical research. See 21 C.F.R. 56.108(a). Pursuant to this provision, IRBs that have written procedures requiring them to review all written materials provided to potential research subjects would have to review and approve stand-alone HIPAA authorizations, even though such review is not otherwise required under the Privacy Rule, FDA regulations governing IRBs, or international guidelines. Accordingly, if IRBs are backlogged in their review of stand-alone HIPAA authorizations, these IRBs might believe they have to halt enrollment in clinical investigations in order to complete their review in accordance with their written procedures.[2]

In order to ensure the continued enrollment of subjects in clinical investigations, and to encourage IRB flexibility with respect to handling possible backlogs, FDA is announcing its intention to exercise ongoing enforcement discretion with respect to the requirements of 21 C.F.R. 56.108(a) to the extent that IRBs' written procedures require the review and/or approval of stand-alone HIPAA authorizations because those written procedures require them to review all written materials provided to potential research subjects. FDA believes that enrollment in well-designed and well-conducted clinical investigations should not be interrupted for the purpose of IRB review and approval of stand-alone HIPAA authorizations. In exercising its enforcement

discretion, FDA does not intend to take enforcement actions against IRBs that decide not to review stand-alone HIPAA authorization even where an IRB's written procedures would otherwise require this review and/or approval. FDA's exercise of ongoing enforcement discretion with respect to 21 C.F.R. 56.108(a), along with OCR's clarification that IRBs are not required to review and approve stand-alone HIPAA authorizations under the Privacy Rule, HHS Human Subject Protection Regulations, or international guidelines, should allow important studies to proceed in the best interest of the public health.

[2] Alternatively, IRB's could modify their written procedures to exclude a requirement for review and/or approval of stand-alone HIPAA authorizations.