APPLICABILITY OF HIPAA TO RESEARCH AND CLIINICAL TRIALS

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by

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Overview of HIPAA Privacy Regulations

- HIPAA = Health Insurance Portability and Accountability Act of 1996
- HIPAA required Congress to enact comprehensive health information privacy law by August 21, 1999; if Congress failed to act by that date, U.S. Department of Health and Human Services (HHS) was required to issue regulations addressing privacy of health information
- Proposed regulations published November 3, 1999 (64 Fed. Reg. 59918); HHS received approximately 53,000 comments
- Final regulations published December 28, 2000 (65 Fed. Reg. 82462)
  - Preamble + regulations = 1,500 pages of double-spaced text!!!
- Comment period was reopened and additional comments were received until March 30, 2001
- Compliance by April 14, 2003
- NPRM issued 3/27/02 would modify some essential provisions, including those relating to research. New 30-day comment period.

HIPAA Privacy: The Basic Rules

- **Individually identifiable health information ("IHII"):**
  - **Is required to be disclosed by a "covered entity" (defined as health plans, health care providers, or health care clearinghouses) only to the individual who is the subject of that information and, in certain circumstances, to HHS**
  - **May not be used or disclosed by a covered entity without written consent or authorization from the individual subject except in limited circumstances where (i) the individual is provided with an opportunity to agree or object to the use/disclosure, or (ii) the use or disclosure is for an authorized purpose and meets certain requirements**

What Information is Covered by HIPAA Privacy Regulations?

- Protected health information ("PHI") is IIHI that is maintained or transmitted by electronic media or any other form or medium (45 C.F.R. § 164.501)
  - Includes virtually all IIHI held, created or received by covered entities, regardless of when or how it was created or obtained
    - IIHI that was electronically maintained or transmitted, and any paper records resulting from such electronic records;
    - oral communications of IIHI; and
    - paper records that were never in electronic form

HIPAA and Research

- HIPAA privacy regulations have many specialized rules and exceptions, including rules particularly applicable to research activities
- Under HIPAA, "'research' means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 164.501. Same definition as Common Rule.

Research Activities / Clinical Trials Under HIPAA

- HIPAA requirements for research are applicable regardless of source of funding - so if FDA and/or HHS regulations are not applicable to the clinical study at issue, entity is still bound by HIPAA privacy rules
- Research disclosure policies must be included in covered entity's "Notice of Information Practices"
  - E.g., if an institution allows its IRB to waive patient authorization for research involving retrospective chart reviews (which is permitted under HIPAA, provided that all the regulatory requirements are followed), then such practice must be disclosed in the notice given to all patients. 45 C.F.R. § 164.520
  - This requirement would be eliminated by the NPRM, which leaves contents of Privacy Notice to discretion of covered entity.

HIPAA: Patient Authorization for Research

- Without IRB or "privacy board" approval, HIPAA will generally require express patient authorization for use or disclosure of PHI in research activities (subject to exceptions discussed below)
- Patient authorization for research is not the same as informed consent; HHS specifically declined to equate the two, as purposes and requirements differ
  - E.g., authorization forms (unlike informed consent forms) must have an expiration – which may be satisfied by reference to an event, such as termination of the specific research study
  - NPRM: "end of the research study" is acceptable expiration event; "none" is acceptable for database authorization
  - Authorizations are solely for privacy issues – do not address risks of research treatment

HIPAA: Patient Authorization for Research (cont.)

- Cannot revoke authorization to the extent that action is taken in reliance on the authorization (i.e., no need to re-identify and separate out blinded information based upon patient's revocation) (
- NPRM broadens the interpretation of this reliance exception, if a subject revokes the authorization but the researcher needs the already-collected data for research integrity/accuracy purposes
- Covered entity must disclose in authorization if it will receive direct or indirect remuneration from a third party in exchange for the use or disclosure of the health information
- Patient research authorization form should include broad grant of access so that investigators may receive PHI from other covered entities who or which have treated the patient, when that PHI is required for the research

HIPAA: Patient Authorization for Research (cont.)

- HIPAA requires that study sponsors (such as pharmaceutical companies) and/or PI's research staff (and other sites in cases of multi-center trials) or related entities all be named in the authorization form approved by the IRB as parties to whom or to which PHI will be transferred
- NPRM would allow authorizations under HIPAA to be combined with research informed consent and any other permissions or consents necessary for study enrollment
- FDA regulations already require that FDA be named in patient consent form as party who may view medical information of study subjects

Research: Use Of PHI Without Authorization

- A covered entity may use or disclose PHI for research purposes WITHOUT an individual's authorization (or may use an authorization that varies from the otherwise applicable HIPAA regulatory requirements for an authorization):
  - In certain instances of use of PHI for purposes preparatory to research (i.e., to assess feasibility of research or formulate a research hypothesis), or in connection with research on decedents, upon certain representations of the researcher to the covered entity, OR
  - If the waiver of an authorization or an alteration of authorization is approved upon a signed, documented determination by either an IRB or by a "privacy board," in accordance with criteria set forth in HIPAA
    - Privacy board is similar to an IRB, but used only for privacy issues
    - Many of same membership/voting requirements under Common Rule for IRBs are applicable to a privacy board

IRB/Privacy Board Approval of Waiver of Authorization

- Determination by IRB or privacy board may be done on "expedited review" basis (in accordance with Common Rule or FDA requirements for expedited review by an IRB)
- Most likely to be used in cases of research involving retrospective chart reviews
- IRB or privacy board may waive or alter authorization to allow use of PHI to recruit study subjects
- IRB or privacy board written documentation must indicate that the waiver of patient's authorization satisfies these 8 criteria set forth in HIPAA privacy regulations:

IRB/Privacy Board Approval of Waiver of Authorization: 8 Criteria

1) Use or disclosure of PHI involves no more than minimal risk to the subjects;
2) Waiver or alteration of authorization will not adversely affect the privacy rights and welfare of the subjects;
3) Research could not practicably be conducted without the waiver of, or alteration to patient's authorization;
4) Research could not practicably be conducted without access to and use of the PHI;
5) Privacy risks to subjects are reasonable in relation to anticipated benefits if any, and importance of knowledge that may reasonably be expected to result from research;
6) Adequate plan exists to protect the identifiers (that link the medical information to the patient's identity) from improper use and disclosure;
7) Adequate plan exists to destroy the linking identifiers at the earliest opportunity unless there is health or research justification for retaining identifiers, or retention is legally required; and
8) Adequate written assurance exists that PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of project or other research for which used or disclosure would be permitted under the privacy regulations.

March 2002 NPRM would change these criteria, and reduce 8 to 3:

- Use or disclosure involves no more than minimal risk to privacy of the subject based on, at least: (a) adequate plan to protect the information from improper use and disclosure; (b) adequate plan to destroy identifiers; and (c) written assurances that the PHI will not be disclosed further than as set forth in the waiver
- The research could not practicably conducted without the waiver or alteration
- The research could not practicably be conducted without access to and use of the PHI

IRB/Privacy Board Approval of Waiver of Authorization

- Some of the 8 criteria (or 3 proposed criteria) track aspects of HHS Common Rule's requirements for waiving patient informed consent (minimal risk, no adverse effects, research not possible without waiver); in HIPAA, these criteria relate only to privacy (e.g., "minimal risk" refers to privacy risk only), NOT to all research risk
- Documentation of IRB/privacy board approval of the 8 criteria can be used to satisfy "minimum necessary standards" for disclosures that are done without patient authorization, if disclosures are in connection with research

IRB/Privacy Board Approval of Waiver of Authorization (cont.)

- Record of approval of waiver of authorization must be maintained for 6 years
- In Preamble to HIPAA privacy regulations, HHS encourages training of privacy board/IRB members regarding privacy, but it doesn't explicitly require it in the regulation - HHS notes that it reads current FDA and PHS requirements as already requiring IRBs to have some familiarity with privacy issues

HIPAA and Research Activities

- If anonymous or aggregated health information is being used in research instead of PHI, the institution must be certain that all such information is and will be adequately de-identified (unlinked to subject - i.e., no reasonable basis to believe that it could be used to identify the individual subject) in accordance with the HIPAA privacy regulations
- NPRM proposes some easing of the HIPAA de-identification standards for research purposes, and seeks input during comment period. ZIP code and address seem most troubling in this regard.
- HHS specifically rejected idea of requiring a written contract between researcher and covered entity regarding uses of PHI

Research: Impact on Providers

- Existing research policies, procedures and operations, and consent forms, should be reviewed to determine the extent to which PHI is currently used and disclosed in the facility's research activities. New consent and authorization forms should be carefully crafted to waive patient's rights of access to own record (for example, for placebo controlled studies), but to contain broad grant of access of PHI from other covered entities who or which have treated the patient to sponsors, other PIs, etc.

HIPAA Transition Provision

- If a covered entity obtains a consent, authorization or other legal permission prior to the effective date for mandatory compliance with the HIPAA privacy regulations (2003), the covered entity may use PHI that it created or received prior to or after 2003 for the research, provided that the covered entity complies with all limitations set forth in that consent, authorization or other legal permission:
  - This includes both general consents to participate in a research project, as well as more specific consents to use/disclosure of information for the purposes of a project
  - For research projects involving treatment of individuals for whom the researchers obtained an IRB waiver of informed consent under the Common Rule, the researchers must obtain a HIPAA-compliant individual authorization or waiver of authorization from an IRB or privacy board in accordance with HIPAA

NPRM and Transition Provisions

- NPRM would permit a covered entity to use or disclose for a specific research project PHI created or received before OR AFTER the compliance date, if the CE had obtained prior to the compliance date an authorization or other permission from the subject to use or disclose PHI for the research; a general informed consent form will suffice.
- If IRB has already waived informed consent requirement under applicable law, those studies "grandfathered" and no new authorization would be required

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