HIPAA Privacy and Research

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Theory of HIPAA Privacy

- “An individual’s rights and welfare must never be sacrificed for scientific or medical progress”. Comments page 974.

HIPAA Privacy Regulations

- Issued: Dec. 28, 2000
- Final: 04-15-01
- Effective: 04-15-03
- Location: 65 FR 82462-82829 OR www.hhs.gov/ocr/ because the Office of Civil Rights is responsible for implementation and enforcement.

Focus: Research

- Research with healthy normal volunteers not subject to HIPAA (but is covered by the Common Rule 45 CFR 46 (HHS); 21 CFR 50,56 (FDA).)
- HIPAA covers research combined with treatment because protected health information (PHI) is created.

Change from Proposed Regulations

- The Dec. 1999 proposed regulations covered all research including "research unrelated to treatment" but the final regulations only cover research that includes treatment.
- All research, "regardless of the source of funding" is covered. 164.512(i)

General Issues

- Research unrelated to treatment (not covered)
- Research associated with treatment (covered)
- Medical records review (covered)
- Medical registry review (covered)
- De-identified records review (exempt)

Quality Assurance Vs. Research

- 164.501 Definitions says “Health Care Operations” includes QA, outcome studies, so long as “obtaining generalizable knowledge is not the primary purpose of any studies”.
- Important because Health Care Operations can occur so long as they are listed in Notice and General Consent.

Research Defined

- 164.502: “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”
- Same as Common Rule 46.102(e) except for added underlined words.

Consent and Authorization

- “Consent” is required before creating or using PHI for treatment, payment, or health care operations. 164.506
- “Authorization” is required to use or disclose PHI for all other purposes. 164.508
- Consent for use/disclosure may be combined with research authorization under 164.508 (f).

Compound Authorizations

- Generally not allowed but can combine authorization for treatment with research
- 164.508(f) requires the authorization to contain: description of information to be used; who can use; expiration date; right to revoke; right to see information; disclosure if use will result in remuneration; signature.

Prohibition on Conditioning

- May not condition provision of treatment on signing authorization except may condition provision of research-related treatment on provision of authorization in accord with 164.508(f).
- NOTE: Comments say Secretary has authority to adopt standards relating to research but no specific authorization in HIPAA itself.

Use/Disclosure for Research

- 164.512(i) has the permitted uses rules.
- PHI may be used for research with:
- 1. subject consent; OR
- 2. IRB approval of an alteration or waiver.
- NOTE: Waiver not for mere convenience.
- Waiver approval by IRB (or Privacy Board) must be documented and signed by Chair or designee.

Use for Research 2

- Waiver criteria:164.512(i)(2)(ii)
- 1. No more than minimal risk to subject
- 2. Will not adversely affect privacy/welfare of subject
- 3. Could not practicably be conducted without waiver
- 4. Could not practicably be done without access to and use of PHI

Use for Research 3

- Waiver criteria continued:
- 5. Privacy risks reasonable vs. anticipated benefits and importance of knowledge reasonably expected to result
- 6. Adequate plan to protect identifiers
- 7. Adequate plan to destroy identifiers
- 8. Written assurances that PHI will not be reused/disclosed except for oversight of project.

Common Rule Waiver Criteria

- 1. No more than minimal risk.
- 2. Will not adversely affect rights of subject.
- 3. Could not practicably do the research.
- 4. Subject gets added information after participation (deception research).
- NOTE: Can waive documentation (but not consent process) under specific circumstances.

Use for Research 4

- IRB in granting waiver must follow Common Rule plus added waiver criteria using either full or expedited review.
- Reviews preparatory to research are allowed if researcher represents use of PHI is necessary to prepare a protocol; no PHI will be removed from the facility.

Use for Research 5

- Research on Decedent's information is allowed if researcher furnishes representation that PHI is sought solely for research and is necessary for research. Facility can require date of death. Note: Common rule (45 CFR 46.102 (f)) says human subject is living individual.

Use for Research 6

- Medical records contain PHI so they follow these rules. 45 CFR 46.102 (f).
- If study needs to look at “thousands of records” waiver may be allowable since it would be “impracticable” to do otherwise.
- For prospective data collection consent will be required.
- Rule: Imperative to assess privacy risks for research.

De-Identification of PHI

- 164.514 has 19 standards on how to de-identify.
- Once de-identified the data is not PHI.
- Consider de-identification for research; creation of registry data.
- Problem: Genetic or other longitudinal studies.
- Can use random generated number to de/re-identify. 164.514 (c)

De-Identification Elements

- Names
- All geographic subdivisions smaller than a State
- Zip Code
- All dates except year
- Phone numbers
- Fax number

De-Identification 2

- Electronic mail address
- Social security number
- Medical record number
- Health plan beneficiary number
- Account number
- License/certificate number
- Vehicle numbers

De-Identification 3

- Device identifiers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address number
- Biometric identifiers (finger/voice prints)
- Full face photographic images
- Any other unique identifier
- Note: Can assign a code to re-identify if code is kept secure.

Notice of Privacy Practices

- Facility must provide Notice. 164.520
- Notice must describe each purpose for which PHI will be used/disclosed including research.
- Notice must provide examples.

Disclosure to Subject

- 164.528 allows an individual to have an accounting of disclosures. (Need audit trail) 164.524 allows a right of access.
- But; 164.524(a)(2)(iii) says right of access is temporarily suspended as long as research is in progress provided the subject has agreed to the denial when consenting to participate and access is restored upon completion of the research.

Pre-Existing Consent

- 164.532(b)(3)(ii) allows for reliance on consent for research signed prior to April 15, 2003.

Other Stuff

- Certificates of Confidentiality are still effective. Comments page 825.
- Need to look at Preemption section 160.203 and your State laws.
- Rules may change if NBAC suggests changes. “This...is the first step in enhancing patients’ privacy...” Comments page 973 refer to NBAC.

Conclusions

- Include research activities in Notice and general consent.
- Educate IRB and faculty about medical records and registry research requirements. Consider de-identification.
- Create protocol for IRB review and revise IRB template consent to include required elements.

Case Study

- Ima Researcher wants to study how asthma was treated 1960-80. Her protocol says she will review all medical records of admissions to the hospital for acute asthmatic episodes. She requests a waiver of consent.
- Assume the regulations are in effect. Can the IRB approve a waiver?

Case Study 2

- The Michigan Cancer Center has always maintained a State wide registry of all cancer cases. There is a State law providing for the registry and granting it confidentiality. Post-HIPAA Privacy can the registry continue to exist? Can researchers use its data? Must they get IRB approval? Can the IRB grant a waiver of consent?

Case Study 3

- Near Lee There, a third year medical student presents at teaching rounds on current hospital patients with aspergillus.
- Issue: Need consent? IRB approval?
- The lecture goes so well that There now wants to publish a case report.
- Issue: Need consent? IRB approval?

Case Study 4

- Dr. Science wants to review treatment of HIV in 1980 versus today. She proposes a chart review of 100 records from the 80's and a comparison to the next 100 cases seen. She will follow all living subjects for 5 years.
- What should the IRB require?

Proposed Global Solution

- Most regulatory requirements can be eliminated or safely ignored simply by terminating all patient care treatment and concentrating strictly on basic science (without animal subjects) research.

Question and Answer

- Useful answers:
- It depends
- Why do you want to know?
- Can I get back to you on that?
- Useful question:
- Why didn’t I listen to my parents and marry money?