The Impact of HIPAA on Ongoing Research Studies

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HIPAA and Research In a Nutshell

- Individual authorization generally is required to use or disclose PHI for “research”
  - Systematic investigation
  - Designed to develop or contribute to generalizable knowledge
- Health care operations vs. research
  - Quality assurance and improvement; outcomes evaluation - not research if the *primary* objective is other than to develop or contribute to generalizable knowledge
  - Population-based activities to improve health or reduce costs
  - Protocol development
- Exceptions
  - No PHI (de-identified data sets)
  - HIPAA waivers (different criteria from Common Rule)
  - Reviews preparatory to research
  - Research on decedents
  - Limited data sets with data use agreements

HIPAA vs. Common Rule

	HIPAA	Common Rule
Application	Health information	Human subjects (not deceased)
Focus	Privacy rights	Protection of subjects
Permission	Authorization	Informed Consent
Alteration or Waiver Criteria	• Minimal risk to subjects' privacy –Protect identifiers –Destroy identifiers/ break links –Written assurances • Impracticable without waiver • Impracticable without use of PHI	• Minimal risk to subjects • No adverse effect on subjects' rights • Impracticable without waiver • Information to subjects when appropriate *Note special rules for waiver of documentation*
Other	Accounting requirement	N/A

Priorities in a HIPAA world

- Covered Entities
  - Regulatory compliance
    - HIPAA
    - State privacy laws
  - Limitation of liability
  - Public perception/PR

Priorities in a HIPAA world

- Researchers
  - Individual researchers
    - Perform research
    - Publish results
  - Academic institutions
    - Regulatory compliance
      - Common Rule
      - State research laws
    - Research/publication by faculty
    - Limitation of liability
    - Public perception/PR

Priorities in a HIPAA world

- Sponsors
  - Even if not a CE:
    - Other regs (e.g., FDA)
    - Subject recruitment
    - Access to detailed data (for AE reporting, drug/device approval, etc.)
    - Limitation of liability
    - Public perception/PR

Continuing Studies

Section 164.532 transition provision:

- A covered entity may use or disclose PHI pursuant to an authorization or other express legal permission obtained from the individual
- Applies to PHI created/received before April 14
- Does not apply if authorization is sought from any individual participating in the research

Continuing Studies
Challenges to Researchers

- Subject recruitment
  - Pre-HIPAA
    - OK to recruit using CE records subject to IRB approval (see IRB Guidebook, Ch. 4, Section I)
    - Investigator must otherwise be allowed access by the record holder (institution or doc) and must accept responsibility for confidentiality
  - Post-HIPAA
    - [Partial] waiver of authorization
    - Review preparatory to research

Continuing Studies
Challenges to Researchers

- Protocol Changes
  - Protocol revisions: additional IRB or institutional review may be required
  - Contract revisions where research is sponsored or data is obtained under written agreement (negotiations, etc.)
  - Need for HIPAA waiver/authorization
  - Biased results

Continuing Studies
Challenges to Researchers

- Informed consent/authorization
  - Pre-HIPAA
    - Written informed consent usually required
    - Exceptions: exempt research or waiver of consent or documentation of consent by IRB
    - Elements: focus on nature of study, risks/benefits of participation, voluntariness; some discussion of confidentiality
  - Post-HIPAA
    - Written authorization usually required
    - Exceptions: waiver, review preparatory to research, decedents, limited data set, de-identified data
    - Elements: all of the above (when research is governed by Common Rule) PLUS significant focus on privacy rights

Continuing Studies
Challenges to Covered Entities

- Need for additional data
  - Pre-HIPAA
    - CEs routinely accessed, used or released PHI to authorized researchers without significant constraints
    - No issues vis. mandatory AE and other public health reporting
  - Post-HIPAA
    - CEs' ability to access, use or release PHI is constrained absent appropriate authorization
    - Public health reporting is permissible but subject to constraints (e.g., accounting requirement)
    - Use of data about deceased individuals

Continuing Studies
Challenges to Covered Entities

- Accounting
  - Imposition of accounting requirement on CE for disclosures to researchers without authorization and for public health reporting
  - Does not apply if use limited data set
  - Special accounting for research uses involving data on more than 50 individuals

Data Use Agreements

HIPAA Requirements	CE Considerations	Researcher Considerations
▪ Establish permitted uses/disclosures ▪ No further use/disclosure if a HIPAA violation for CE ▪ Who can receive or use the LDS ▪ No further use/disclosure except as required by law ▪ Safeguards ▪ Report noncompliance ▪ Subcontractor compliance ▪ No efforts to identify or contact subjects	▪ Impose additional safeguards (e.g., standard contractual protections) ▪ Address additional compliance issues (e.g., Common Rule)	▪ Simplify process ▪ Facilitate access to data needed for studies ▪ Minimize Common Rule issues where feasible

Helpful Sites

- for more information on the Privacy Rule generally: www.hhs.gov/ocr/hipaa
- for HHS's Q&A's: http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/std_alp.php

Helpful Sites

- for the NIH brochure on the Privacy Rule and Research: http://privacyruleandresearch.nih.gov/
- OCR on HIPAA research authorizations: http://www.hhs.gov/ocr/hipaa/privguideresearch.pdf

Helpful Sites

- Research FAQ's: www.hhs.gov/ocr/hipaa/guidelines/research.pdf and/or www.hhs.gov/ocr/hipaa/assist.html

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