Advanced Issues in HIPAA Research Compliance

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Presentation Agenda

- Privacy Rule and Human Subject Regulations
- Implications of Privacy Rule on Research
- Common Issues

- Questions and Discussion

Privacy Rule and Federal Human Subject Regulations

The HIPAA Privacy Rule does not preempt privacy and confidentiality requirements of federal Human Subject Regulations, i.e. Common Rule and FDA Human Subject regulations.

The Office for Civil Rights maintains that "[t]he Privacy Rule builds upon these existing Federal protections," while affording equal protections to privately funded research.

Regulation Comparison

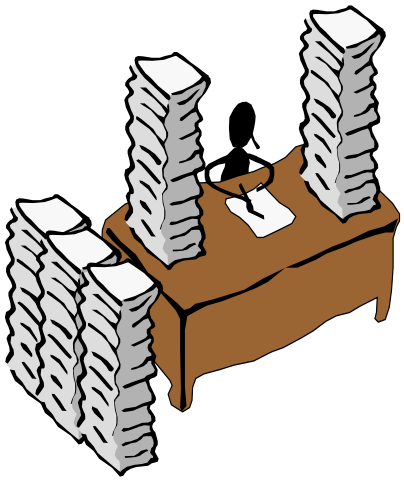
Human Subject Regulations	HIPAA Privacy Rule
Applies to *federally supported* or *FDA regulated* research	Applies to *all* research
Protects *rights* and welfare	Protects *privacy* rights and welfare
Human subject: A living individual about whom an investigator obtains (i) data through intervention/interaction or (ii) identifiable private information; or An individual who participates in research involving a test article	*Individual*: subject of information; a living or deceased person
Uses Institutional Review Boards (IRBs)	Uses IRBs or Privacy Boards
Board reviews all non-exempt human subject research	Board reviews only authorization waivers or alterations
Continuing review at least annually	*No requirement for continuing review*
Informed Consent	Authorization and Consent

Research Implications

- ***CON:***
  - –The regulations are Complex, Burdensome, and Costly

    IRB and Privacy Board waivers will increase paper work and IRB responsibilities; Estimated costs: $30 million in 2003, and up to $39 million by 2013.

  - – The regulations are Ambiguous at best
  - – Many in research industry Fear Liability from enforcement (potential suspension of research programs)



Research Implications

- ***CON:***

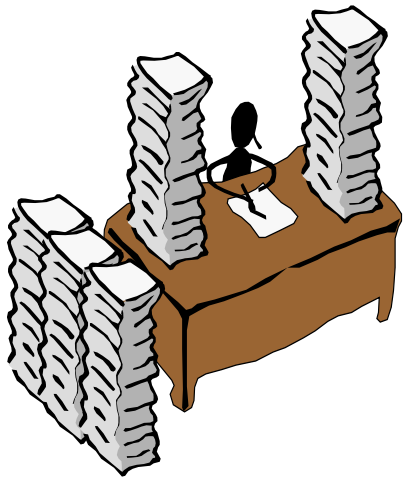
  – Many believe the rule is Unnecessary because of current federal research regulatory structure

  – Some are fighting for a New comprehensive health information privacy law.

  – Patient Recruitment hampered because authorization or waiver is required for disclosure to third parties

Research Implications

- ***PRO:***
  - Provides patient with more control, more information, and restores trust.
  - Relieves the increasing level of public concern about research and medical records.
  - More people will be willing to participate in confidence.
  - The HIPAA provisions do not impede research and are reasonable.
  - Further clarifications may be needed and provided by HHS.



Common Issues

Business Associates

- Are any of the following business associates of a covered research organization, requiring a business associate agreement?
  - Accreditations organizations?
  - IRB or Privacy Boards?
  - Researchers?
  - Contract Research Organizations?
  - Site Management Organizations?
  - Pharmaceutical Sponsors?
  - Device Manufacturers?

Common Issues

Minimum Necessary

- How does Minimum Necessary apply to research activities?
  - Researcher requests for PHI?
  - IRB/ Privacy Board Waivers?
  - Research Authorization?
  - Limited Data Set?
- Does minimum necessary limit ability to perform source document review?
  - Justification

Common Issues

Authorization Difficulties

- How do we obtain patient authorization if patient is in the hospital?
  - Preparatory to Research
  - IRB/Privacy Board Waiver
  - Authorization
- Should we combine research consent with authorization?
  - Most forms written on 1st year college or 10th grade level
  - Most patients read on 8th grade level

Common Issues

Authorization Difficulties

- Can we continue to use PHI after a patient has revoked authorization?
  - PHI created or during trial?
  - Data derived during the trial?

- Do we have to include the research sponsor in the authorization? What about if sponsor uses data for genetic research?

Common Issues

Authorization Difficulties

- If we do not have to state an expiration date in the authorization, can we use PHI indefinitely and for other research?

- If ¾ patients in a study consent to publication of research results but ¼ decline consent, can we publish results?
  - Identifiable information
  - Study results

Common Issues

External Researchers and Reviews Preparatory to Research

- Can we use the Preparatory to Research exception for feasibility studies?
  - Covered entity?
  - Physicians office?
- Can an external researcher use the Preparatory to Research exception to review PHI?
  - Privacy Rule – Yes
  - OCR Guidance – No
  - Why is there a discrepancy?

Common Issues

Statistician's Declaration of De-Identification

- Does the rule require the use of an external statistician to determine that information is not individually identifiable?
  - Knowledge of statistical methods
  - What about Bias?
  - Who needs to be convinced?
- Does a statistician have to prove that the information is not identifiable?
  - Very small chance of identification

Common Issues

Designated Record Set and Research Record

- We assign medical record numbers to research records of healthy volunteers. Is this a good practice?
  - Medical record is part of the DRS
- Is the research record part of the designated record set?
  - Clinical Trial
  - Records research

Common Issues

Current Research and Transaction Provisions

- What if a new patient is enrolled in a study after April 14, 2003?
  - IRB or Privacy Board Waiver
  - Authorization
- Do we have to obtain authorization for patients enrolled before April 14, 2003?
  - Not required
  - Does this

Common Issues

Individual Rights

- Notice of Privacy Practices
  - Should we mention research uses and disclosures in the Institutional Notice?
  - On-line?
- Restriction on Uses and Disclosures
  - Can a patient restrict use and disclosure of PHI in research?
- Alternative Communication
  - Do we have to accommodate a request for alternative communication?

Common Issues

Individual Rights

- Alternative Communication
  - Do we have to accommodate a request for alternative communication?
- Amendment of Information
  - Designated Record Set
  - May deny amendment

Common Issues

Individual Rights

- Access to Inspect and Copy
  - Does the patient have a right to access the research record?

- Accounting of Disclosures
  - Research Authorizations?
  - IRB or Privacy Board Waivers?*
  - Researcher Assurances?
  - Limited Data Set?
  - Prior Research?

Common Issues

Administrative Requirements

- Privacy Officer
  - Is a Research Privacy Officer required?
- Complaint Procedures
  - Are we required to have a separate complaint process for research-related privacy violations ?
- Sponsor Training
  - Should we provide additional training when the sponsor already trains investigators and staff?
  - Who should receive training?

Common Issues

State Law Preemption

- Covered Entity Status
  - Not a HIPAA covered entity
  - Covered under state law
- Decedent Information
  - Access limited
- Parents and Minors
- Registries
  - Regulated?
  - Voluntary?

HHS perspective on the use and disclosure of Private Health Information in Research

"Covered entities [should] be mindful of the often highly sensitive nature of research information and the impact of individuals' privacy concerns on their willingness to participate in research."

Standards for the Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule), 65 F.R. at 82520, December 28, 2000.

Questions and Discussion

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