HIPAA Compliance in Medical Research: Practical Implementation

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Comments from the Field

Concerns in Implementing HIPAA in the Research Setting

- Additional delay in approval of research
- Additional burden on IRB
- Uncertainty regarding application of HIPAA to differing types of research

Privacy Rule Overview

Six Mechanisms	Minimum Necessary Standard	Accounting for Disclosures	Documentation Requirements
Authorization	**Does Not Apply**	**No**	**Patient-Subject Authorization(s)**
Waiver/Alteration of Authorization	**Applies**	**Yes, but simplified if 50 or more**	**Privacy Board (or IRB) Documentation**
Review Preparatory to Research	**Applies**	**Yes, but simplified if 50 or more**	**Researcher Representation**
Research Involving Decedent Info.	**Applies**	**Yes, but simplified if 50 or more**	**Researcher Representation**
Review of De-Identified Data	**Does Not Apply**	**No**	**Researcher Representation / Statistician's Determination**
Research Using Limited Data Set	**Applies**	**No**	**Researcher Representation & Data Use Agreement**

Submission Requirements

What to submit and to whom:

- Authorization Forms
  - IRB not required to review unless combined with the Informed Consent Document
  - IRBs prefer to review stand alone authorizations
- Waiver/Alteration of Authorization
  - Privacy Board (or IRB) must make document specific determinations
- Representations
  - Representation to the institution, but unclear as to whom
  - Representation is made to holder of the records

IRBs as Privacy Boards

Privacy Rule vs. Human Subject Protections requirements:

- Waiver of Authorization vs. Waivers of Informed Consent
- “De-Identified” vs. “Non-Identifiable” or “Anonymous”

Recommendations:

- Separate submission forms
- Separate reviewer checklists

Screening Records to Identify and/or Contact Prospective Subjects

Request a Waiver of Authorization

- Preferred mechanism
- Specify how and by whom prospective subjects will be contacted, and/or how and why the information will be disclosed

Representation of a Review Preparatory to Research

- Not a preferred mechanism
- More limited
- Recorded identifiers may not be removed from the covered entity
- Defining the “workforce”

Retrospective Studies Using Existing Health Information

Existing Identifiable Health Information

- Request a Waiver of Authorization (preferred)
- Representation that the information has been De-Identified
- Representation that the research involves a Limited Data Set

Existing De-Identified Health Information

- Representation that the research has been De-Identified

HIPAA Compliance: Essential Toolkit

Tools for Implementation:

- Comprehensive Manual on the Use and Disclosure of Health Information in Research
  - Overview of the regulatory mandate
  - Basic regulatory definitions
  - Institutional research privacy structure
  - Mechanisms for accessing PHI with and without an authorization
  - Disclosure of PHI for legal and regulatory purposes
  - Individual access to PHI

HIPAA Compliance: Essential Toolkit

Tools for Implementation (con't):

- Comprehensive set of research privacy forms
  - Set of sample authorization forms
  - Request for waiver or alteration of authorization
  - Set of investigator representations
  - Data use agreement for a limited data set
- Reviewer checklist
- Targeted "reference sheets"
- HIPAA Privacy Regulations

HIPAA Compliance: Additional Resources

Additional Resources:

- Developing “Frequently Asked Questions” for site specific issues
- Links to OCR & NIH Guidance

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