The 21st Century Cures Act: Changes on the Horizon for Research Privacy Protections

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Overview

- The legal landscape
  - HIPAA Regulations
  - The HITECH Act
  - The Common Rule
  - The 21st Century Cures Act
- Ethical and Policy Considerations
- An Alternative Approach: Rejecting the 21st Century Cures Act in favor of an opt-out approach to records research

Records Research Regulation

HIPAA: 45 CFR §164.506

- A covered entity may use or disclose protected health information for treatment, payment, or health care operations *without patient authorization.*
- Healthcare operations: Administrative, financial, legal, and quality improvement activities.

Section 1124 of 21st Century Cares Act

- Would relax HIPAA's patient authorization requirement by including RESEARCH in the definition of "healthcare operations."
- Includes studies whose purpose is to obtain generalizable knowledge.

Effect

- If this provision is passed by the Senate, covered entities may be able to share data for general research purposes with other covered entities without any individual authorization or IRB waiver.
- Loosening of human subject research protection and HIPAA privacy protection.

The Golden Age of Records Research on the Horizon?

Promotes Records Research

- Regulatory Incentives for EHRs: HITECH Act
- Enhanced Technological Capacity: Interoperability
- Unparalleled Access to Ready Made Data Sets

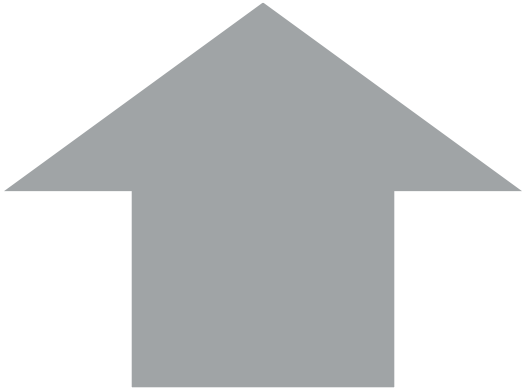
Hinders Records Research

- Regulatory Hurdles
  - HIPAA (PHI Protections)
  - The Common Rule (Human Subject Research Protections)

Balancing Competing Interests

Protecting individual privacy interest

Realizing societal benefits from research



HIPAA OVERVIEW

Privacy Rule	• Establishes national standards to protect individuals' PHI • Covered entities may disclose PHI without patient authorization to other covered entities/business associates for "treatment, payment, and healthcare operations"
Patient Health Information (PHI)	• Includes clinical, financial, and demographic information about an individual's past, present, or future health condition, health care services, or payment for services that is created or received by a covered entity
Covered Entity	• Includes health plans, health care clearinghouses, and health care providers that engage in HIPAA standard electronic transactions • Includes some, but not all, researchers
Business Associate	• Includes entities that provide services to covered entities involving PHI or assist in any HIPAA-regulated activity on behalf of a covered entity • Include contractors and subcontractors

Exceptions to Prior Authorization Under HIPAA

1. Research involving a decedent's information
2. Preparatory research prior to conducting actual research
3. Waiver of informed consent by a privacy board or IRB
4. Limited data with a data use agreement pursuant
5. De-identification of the data

Common Rule (45 CFR 46)

The Common Rule requires IRBs to review and approve research involving human subjects in federally funded research studies, considering all risks of harm related to research participation, including potential privacy harms and breaches of confidentiality.

- **Human Subject** - A living individual from whom an investigator obtains “identifiable private information” in the course of research.
- **Informed Consent** - Requires that researchers provide potential research subjects with information about the anticipated benefits and risks of each research study so that potential participants may make educated decisions about whether to enroll (45 CFR §46.116). IRBs may grant a waiver of informed consent.

Informed Consent Waivers

1. The study must be minimal risk

(1) “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (2) “The risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge may reasonably be expected to result.”

2. The researcher must demonstrate that it is not practical to conduct the research without the waiver or alteration.

3. The waiving of the informed consent must not adversely affect subjects’ rights and welfare.

4. The research must determine whether pertinent information be provided to subjects later, if appropriate. Information about the study and its aims should be made available upon legitimate request.

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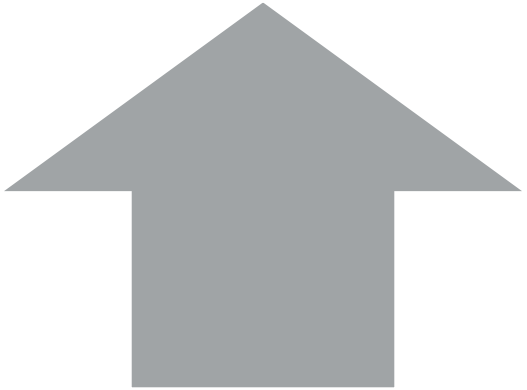


A Proposed Solution: 21st Century Cures

Research
"including studies whose purpose is to obtain generalizable knowledge"

= "Healthcare Operations"

Section 1124 relaxes HIPAA authorization requirements by allowing covered entities to use and disclose PHI to other covered entities or business associates for research without individual authorization or IRB waiver.

Theories and Policy Concerns

Against Loosening Standards

(1) Potential for Material Harm: stigma, discrimination, violence, losing jobs, higher insurance premiums, identity theft.

(2) Physiological harm

(3) Individuals may be deterred from seeking care.

(4) Unique nature of genetic information

(5) Undermines patient autonomy

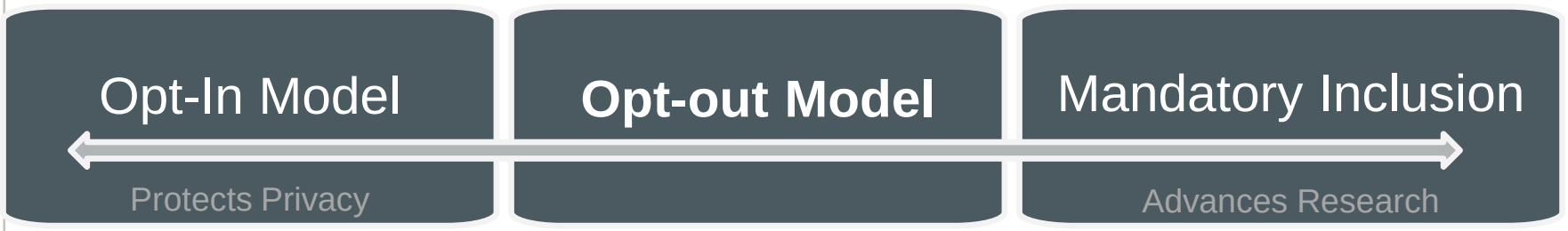
(1) Utilitarian Theory: HIPAA privacy protections over-emphasize individual rights at the expense of research progress and overall societal good

(2) Historical Perspective: HIPAA was created at a time in which policymakers considered large databases and the technological capacity to process data very rapidly

(3) Practicality: HIPAA compliance is administratively burdensome and costly

For Loosening Standards

Developing an Optimal Consent Model for Records Research



- An opt-out approach:
  - Presumes patients' data may be used, unless the patients take affirmative steps to exclude it
  - Requires the disclosure of the uses of the data and an explanation of risks and benefits of participation
  - Data quality concerns surrounding selection bias may persist

Conclusion

Ensuring strong privacy and confidentiality protections in the realm of human subject research is essential to gain public confidence and to ensure continued participation in clinical research.

Under an opt-out model, an individual is not unknowingly turned into a research subject from whom information is collected, analyzed, or published by researchers without their knowledge or consent.

An opt-out model helps advance research more readily than the current opt-in model, but has more protections to ensure that the privacy and autonomy of subjects in such studies are not being unduly compromised by the 21st Century Cures Act.

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