The Keys to HIPPA for Researchers: Protecting Human Subjects; Security and Privacy from a Regulatory Standpoint

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Learning Objectives

Summarize HIPPA highlights that are protected in the conduct of research.

Examine the Patient Rights defined in the regulation and enforcement requirements of HIPPA

Illustrate the application of HIPPA in the everyday practice of a PI conducting a clinical research trial

HIPAA for Research

- HIPAA 101 - Basic Reminders

  Health Insurance Portability and Accountability Act of 1996. **Federal Law** that regulates:

  - **Portability of insurance** from employer to employer
  - **Expansion of Fraud and Abuse** capabilities for Centers of Medicare and Medicaid
  - **Administrative Simplification that includes standards for transactions, secure technological systems, and privacy protections for patient health information**.
  - Standard Medical Record nomenclature and interoperability
  - NPI and other National Standard Identifiers

HIPAA HIGHLIGHTS

- **What is protected?**
  Private health information

- **Who is regulated?**
  Providers, payer and clearinghouses.

- Office of Civil Rights is the **Privacy Enforcer.** A complaint driven system. Serious fines and jail time for intentional abuse.

PHI – PRIVATE HEALTH INFORMATION

- What are we “protecting”? Personal, private, protected health information includes:
- Oral, written and electronic information
- Demographic and medical
- Past, present and future

PATIENT RIGHTS as defined in HIPAA

- **Notice of Privacy Practices** available for patients including grievance procedure. Handout

- Patient can request **restrictions on disclosures** of PHI but the organization does not have to comply with the request.

- Patient can request **alternate means of communications.**

PATIENT RIGHTS as defined in HIPAA

- Patient can **inspect their PHI and get copies**.
  - **Exceptions:**
    - **Psychotherapy notes**
    - **Ongoing clinical trials (when the patient has been notified that access will be limited during the research. In your Research Consent process, you can tell the participant that access to the Medical record will be limited so that information will not affect the trial outcome.)**
- Patient can **request amendments** to Medical Record. (Patient can have access, read, review, amend and copy)
- Patient must be given **full accounting of organization's disclosures** of PHI when they request. (And this disclosure listing will include disclosures for review in preparation for research.)

General HIPAA AUTHORIZATION

- Generally, the authorization for release of information relates to use and disclosure of information and is used by the hospital Medical Records department to send outbound records to requestors.

- HIPAA rules require an authorization for disclosure for requests other than payment, treatment and hospital operations that is covered under “consent”.

- **Hospital operations includes**: Quality assessment and improvement activities including outcome evaluation and development of clinical guidelines and related **functions that do not primarily aim to obtain “generalized knowledge”(i.e. research);** Population-based activities relating to improving health or reducing health care costs; Protocol development; Case management: Care coordination;Competence and performance reviews; Training accreditation, certification, licensing, credentialing, or other related activities; Underwriting and other insurance related activities; Medical review and auditing functions, including fraud and abuse detection ands compliance programs; Conduction or arranging for medical review, legal services, and auditing functions,Business planning and development, Business management and general administrative activities, Internal grievance resolutions, Creating de-identified health information, Fundraising for the covered entities benefit; and Marketing for which an individual’s authorization is not required in accordance with the regulation.

General HIPAA AUTHORIZATION

- ***RESEARCH IS EXCLUDED FROM HOSPITAL OPERATIONS***.
- Separate authorization is needed for research.

AUTHORIZATION FOR RESEARCH

- HIPAA Privacy rule permits covered entities to use PHI in connection with research **without patient authorization** if they comply with certain requirements:
  - IRB determines minimal risk to the subjects privacy
  - IRB agrees that the research could not be conducted without the waiver or modification
  - IRB agrees that the research could not be conducted without access to and use of PHI.

  - Example – obesity analysis by ZIP code

CONDITIONAL AND COMBINED AUTHORIZATIONS AND CONSENT

- Generally covered entities **can condition treatment based on the patient agreeing to signing Consent**, but **can not condition treatment on the patient agreeing to providing authorization.**

- **For research, however, there is an exception**. A researcher may condition treatment on the receipt of an authorization. If the treatment to be provided is part of a research protocol, the covered entity may withhold that treatment if the patient refuses to provide an authorization for use or disclosure of PHI in connection with that protocol.

- A covered entity may combine an authorization with any other legal permission (e.g, consent to treatment) **related to the research study.**

DE-IDENTIFICATION

- The final rule permits the creation and dissemination of a limited data set (that does not include directly identifiable information) for research, public health and some healthcare operations.

- Condition of the use of the limited data set is based on the covered entity and the recipient entering into a **data use agreement** where the recipient agrees to **limit the use of the data set** for the purpose which it was given and to **ensure the the security of the data** as well as **not to identify the information or use it to contact any individual.**

- **Aggregated data** is permissible without authorization if the identity of the participants can not be determined.

Business Associate Agreement

- BAA extends HIPAA to non-covered entities. They must provide security and privacy protections as we would.
- BAA was revised relative to the HITECH regulations to include breach notification rule
- “Step by Step” document and BAA Template on CNMC Intranet Compliance Department Website.
- You collect the information and we will review and answer your questions.
- Handout

Frequently asked Questions

- Q. I sometimes serve as the principal investigator on a clinical trial. **Can I still review my patient's charts to determine which patients are good candidates for a clinical trial?** Do I have to get authorization first? Can I allow other researchers to review the charts?

- A. HIPAA permits you to use and disclose protected health information for preliminary research activities such as developing hypotheses and recruiting research participants. Two restrictions apply: **The researcher can only record de-identified information;** and the researcher can not remove PHI from the organization.

Records in Transit

- During the transition to an electronic solution to Outpatient records, we have identified acceptable procedures to reasonably protect the records that are in transit between our main campus and our outpatient location

Records in Transit

- Records should be transported in locked briefcase or document box.
- Records should not be transported in a backpack or other similar unsecured manner.
- The container should be locked in the trunk of the car. Records should not appear on the seats or floor of the vehicle. The records should be attended at all times.
- Laptops should be stowed in similar manner while in transit to the patient care destination.
- If records are copied, they should be redacted, removing or blacking out the identifiable information.
- Once used, they should be shredded or placed in the HIPAA bins at the hospital and not left in rooms, on desks or any other location.

Frequently asked Questions

- Q. If a drug company asks me to help recruit patients for a clinical trial, **do I have to get authorization from patients before disclosing their names to the pharmaceutical company?**

- **Yes. You may not disclose protected health information to pharmaceutical companies for the purpose of clinical trial recruitment unless you have obtained their authorization.** You must also inform the patient if you are receiving any direct or indirect remuneration from a third party for the disclosure (such as a recruiting fee.)

Frequently asked Questions

- Q Can I allow researchers to **use my patient records for retrospective studies?**

- Privacy boards are specially constituted entities responsible for evaluating and minimizing the privacy risks of research. **HIPAA permits IRBs and privacy boards to waive authorization for the disclosure if the risk to the privacy of the individuals is minimal.**

- A. **Does this require patient authorization?** Under HIPAA, all research, regardless of the funding source (public or private), will **require either an authorization** to use and disclose protected health information from the patient **or a waiver of authorization from an IRB or privacy board.**

Frequently asked Questions

- Q. If I collect patient's **genetic information for research use**, is this information covered by the rule?

- A. HIPAA covers all individual identifiable information including genetic information. When information is de-identified it is not protected by the regulation, so if the genetic information can not be linked to the patient, it is possible it will fall outside of the protection of the rule. However, **on some level, genetic information is always identifiable. You should consider obtaining a waiver from the IRB.**

Frequently asked Questions

- What does the HIPAA requirement of “only the minimum necessary to conduct the research” mean?

  Throughout the regulation, minimum necessary means you have access to and use the information you need and not more.

- Do I need to tell the IRB in the IRB protocol submission the names of everyone on the research team who will come in contact with and handle PHI. Yes.

- What is the purpose of the HIPAA regulations? Who do they help? Do they present barriers? Purpose of HIPAA is to bring healthcare into 21century by encouraging electronic transactions. Purpose of Privacy and Security to allow for that goal. They protect citizens. And yes, as a result, some feel they limit research efforts.