
ITHS
Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.
NED 2020
Networking to Enhance Development
A Conference By and For Research Coordinators
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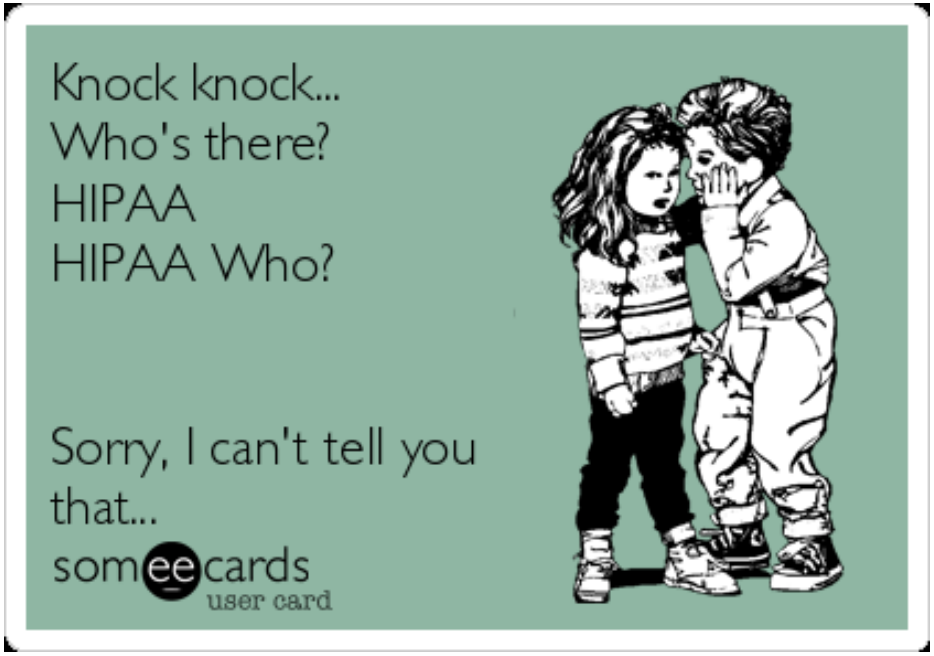
HIPAA and Scenarios for Critical Thinking



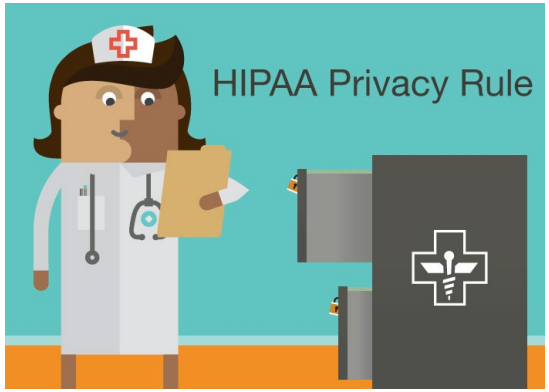
Presented by: Sheila Ganti

Learning Objectives

1. Describe two similarities and two differences between clinical HIPAA consent and research authorization

2. Identify two challenges HIPAA presents for researchers

What is the Health Insurance Portability and Accountability Act (HIPAA)?



Intended to:

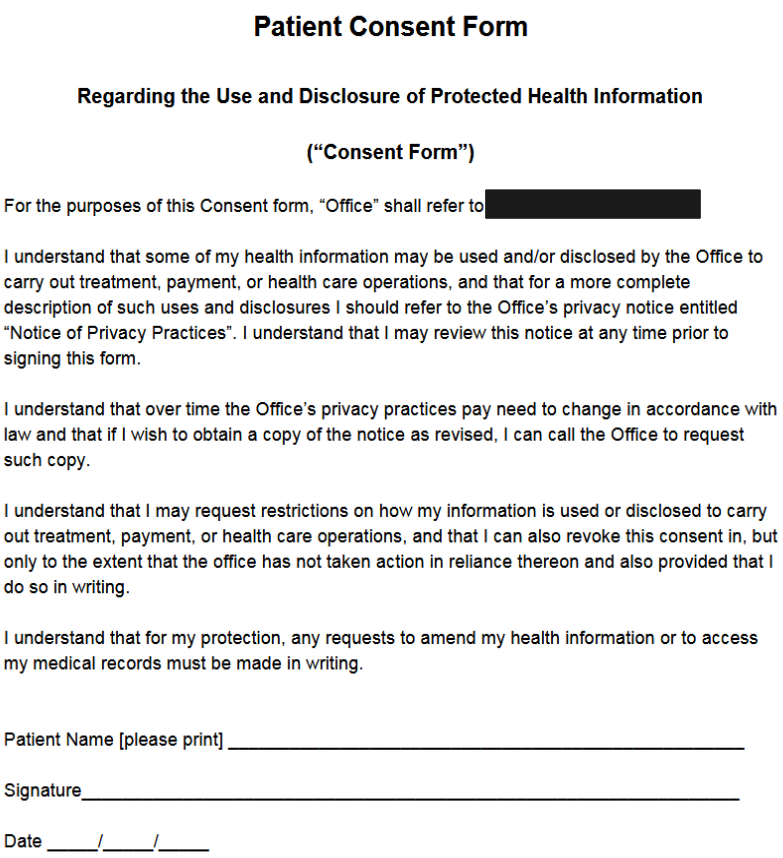
- Help patients' health insurance move with them and streamline transfer or medical records (Portability)
- Protect health-related data, confidentiality, and availability (Accountability)
- Simplify healthcare claims, paperwork, and health records

It is a(n):

- Federal law
- Agreement between the institution (covered entity) and the individual

Clinical HIPAA Consent

"Consent for Care"



Patient Consent Form

Regarding the Use and Disclosure of Protected Health Information

("Consent Form")

For the purposes of this Consent form, "Office" shall refer to [redacted]

I understand that some of my health information may be used and/or disclosed by the Office to carry out treatment, payment, or health care operations, and that for a more complete description of such uses and disclosures I should refer to the Office's privacy notice entitled "Notice of Privacy Practices". I understand that I may review this notice at any time prior to signing this form.

I understand that over time the Office's privacy practices pay need to change in accordance with law and that if I wish to obtain a copy of the notice as revised, I can call the Office to request such copy.

I understand that I may request restrictions on how my information is used or disclosed to carry out treatment, payment, or health care operations, and that I can also revoke this consent in, but only to the extent that the office has not taken action in reliance thereon and also provided that I do so in writing.

I understand that for my protection, any requests to amend my health information or to access my medical records must be made in writing.

Patient Name [please print] _____

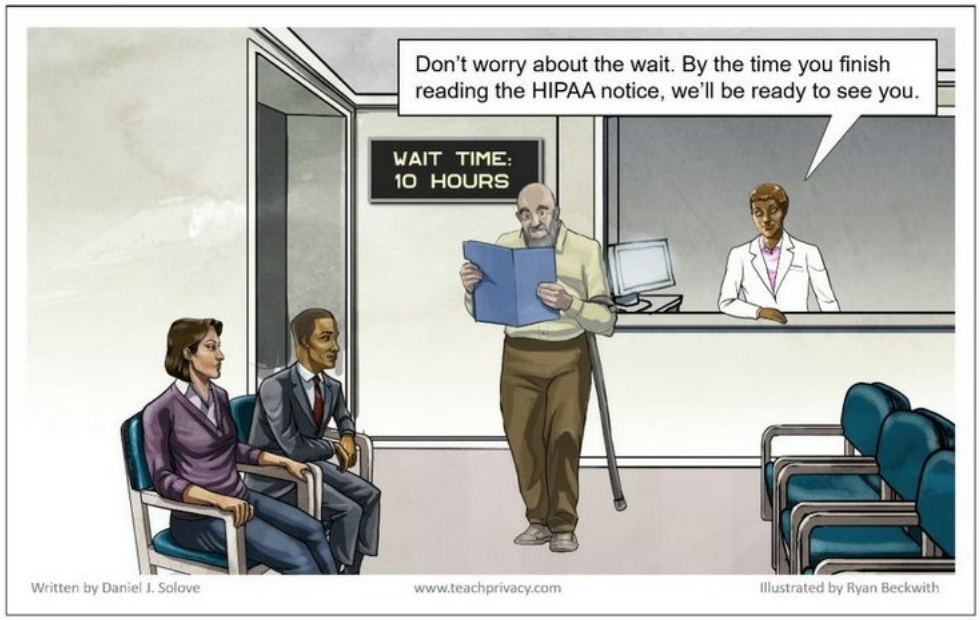
Signature_____

Date _____/_____/_____

- One consent may cover all uses and disclosures indefinitely
- The document may not specify the information to be used or disclosed
- The document may not specify the recipients of the receiving PHI information

Research HIPAA Authorization

Signature required for participation in a study (unless there is a waiver)

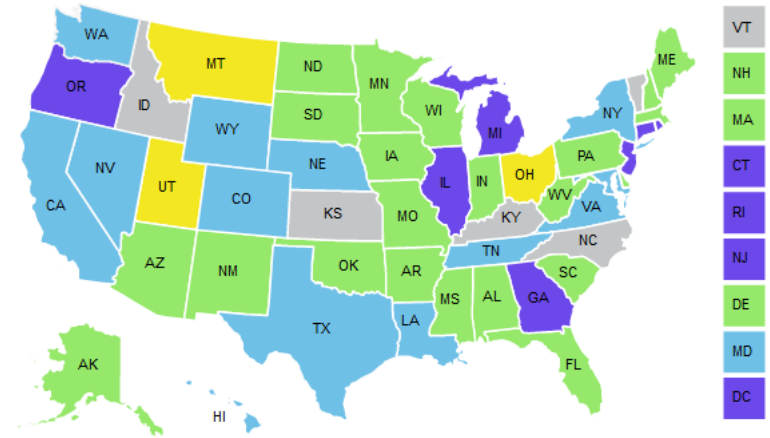


- What information will be created/used/shared
- With whom information will be shared
- The purpose of the requested disclosure
- Timeframe for how long the authorization is valid
- A statement regarding the right to revoke authorization
- About whom the information will be collected
- Signed and dated with copies given to the participant
- IRB/Office of Research Compliance oversight


List of
PHI
(Protected Health Information)
Names
Dates
Addresses / Zip Codes / Geocodes
Phone Numbers
Fax Numbers
Email Addresses
Social Security Numbers
SSN
Medical Record Numbers
Health Plan Beneficiary Numbers
Account Numbers
836
AB·12 34
Certificate /License Numbers
Device Identifiers
Vehicle Identifiers
www
URLs
IP Addresses
IP
Biometric Identifiers
Facial Images
Any Other Unique Identifiers
IRI
Total Data Management

Scenario One

Multisite studies with a single IRB



*Click on a state to see more information on **Medical Records Collection, Retention, and Access** in that state*

State Medical Record Access Requirements Compared to HIPAA

Stronger than HIPAA | Same as HIPAA | Preempted by HIPAA

No law specifically granting individual access right; HIPAA applies

HIPAA applies to covered entities, and state has additional requirements for entities not covered by HIPAA

You are working on a large NIH funded multisite study with a single IRB. The IRB is not part of your institution. The IRB approved the use of a single consent form for all sites with the HIPAA language incorporated into the consent form.

What elements of HIPAA should be considered?

Scenario One: Multisite studies with a single IRB

HIPAA is a federal law that supersedes state law, but some states have stricter regulations than others

HIPAA authorization should come from the institution who "generated" the data being collected

Consider submitting a standalone HIPAA authorization form to your IRB for approval

The central IRB doesn't take on the responsibility for any HIPAA requirements applicable to your institution (compliance, accounting for disclosures of PHI, etc.)

Scenario Two

Research in community-based clinics

You are working on a survey study talking to women who have recently given birth to understand how differences in socioeconomic background and race/ethnicity affects experience during delivery and in the baby's first 6 months.

Pediatricians in several community clinics have agreed to let you approach their patient population during clinic appointments and do the survey in their clinics. Moms will be discussing their own health and their infants' overall health with you. You will also be reviewing information from the kids' chart.

How does HIPAA apply?

Scenario Two: Research in community clinics

Are you collecting PHI? From whom?

Clinics usually do not have their own HIPAA authorization forms for research. What documents would you use?

Scenario Three

Storage of data in an electronic portal (eCRFs) for retrospective studies

You are working on a large single site retrospective study. You will be accessing medical records generated at your institution and entering the data into a central database (REDCap, for example). Because this is a retrospective study, the IRB has approved your request for a waiver of HIPAA authorization.

What elements of HIPAA do you need to consider?

Scenario Three: electronic databases for retrospective studies

No written permission has been obtained from the participant to use, create, or share their identifiable information, so you may need to track your disclosures

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Consider where exactly the data are being stored. For example, REDCap is administered by UW. Are data leaving your institution?

For these studies, consider 18 HIPPA identifiers

Scenario Four

Sharing research results with PCPs

You are working on a drug trial where a central lab is running tests on samples from consented participants. The central lab is contracted with the sponsor.

Your site's PI wants to share some results with the participants' PCP. Participation has ended for some participants (screen fails or early withdrawals).

What is the best way to release results to the PCP?

Scenario Four: sharing research results with PCPs

Results were not generated at your site, so your institution would not be releasing the result

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Original HIPAA form signed as part of consent likely came from your site, and so would not be applicable in this situation. Likely that the central lab also does not have appropriate paperwork

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Documenting authorizations is important, even if the appropriate form does not exist.

Scenario Five

Accessing clinical data from multiple sources

MyChart is a system that allows patients to see medical records from participating institutions (Swedish, Everett Clinic, UW, etc.) using a single login. Patients can make appointments with providers electronically, view lab results, request referrals, and pay bills.

On the backend, users from any of the intuitions at which medical records have been created can also see all medical records across the participating institutions.

What impact does this have for research?

Scenario Five: accessing clinical data from multiple sources

Consider the source of the data – which institution "created" it?

Implications for retrospective studies with waivers: if you were a participant, would you want researchers to have access to these data?

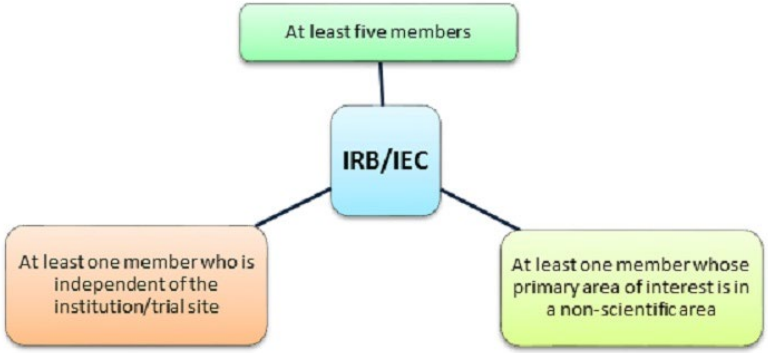
Not all information from a medical record may be put in MyChart. Research consent forms could be excluded

Scenario Six

Independent IRBs versus Institutional IRBs

- Independent IRBs:
  - Examples: WIRB, Quorum, CIRB
  - Fees for service
  - Oversee approximately 70% of all US drug and device clinical trials (2016)
  - Faster turnaround
- Institutional IRBs
  - Usually free for members of that institution
  - Intimate knowledge of local customs and practices/laws

What are some of your experiences with independent and institutional IRBs?



https://www.statnews.com/2016/07/06/institutional-review-boards-commercial-irbs/

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Questions?

Thank You


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