



SCREENING PROCEDURES: WHAT IS COVERED BY A PARTIAL HIPAA WAIVER AND WHAT IS NOT?

IRB Webinar
March 12, 2015

BEFORE WE START...

Currently there is a lot of discussion at Emory on HIPAA and recruitment practices. The content of this presentation will be updated if any policies change or are clarified as a result of those discussions.

The information in this webinar is based on our P&Ps and 45 CFR 164.501, 164.508, 164.512(i) (See also 45 CFR 164.514(e), 164.528, 164.532. We also used this guidance :

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/research.pdf>

CONTENT OF PRESENTATION

- Basic Definitions
- What DO the regulations require?
- Physician Hat vs. Researcher Hat
- IRB Approval of Authorizations or Waivers
- Waivers of Authorization
- Preparatory to Research
- So, what would a Partial HIPAA waiver cover or not cover?
- New 'front-door' consent at EHC
- How can I screen people on phone or in person without HIPAA authorization?
- Questions

BASIC DEFINITIONS

HIPAA Privacy rule: established national standards to protect people's personal health information. It sets limits to the use of information without people's authorizations.

PHI: information that identifies the individual or there is a reasonable basis to believe the information can identify someone. See list of identifiers at

http://www.irb.emory.edu/documents/phi_identifiers.pdf

Note: HIPAA only applies when a "Covered Entity" is involved (Emory Healthcare, RSPH, SON, SOM, etc.). If your research or study team members are not part of a Covered Entity, then these HIPAA points do not apply.

WHAT DO THE REGULATIONS REQUIRE?

HIPAA allows for the use of PHI for research if certain requirements are fulfilled. Choices:

1. Obtain authorization from subject before accessing or collecting PHI for research
2. Obtain alteration (or “waiver”) from a Privacy Board (e.g. Emory IRB)
3. Use “Preparatory to Research” provision of HIPAA (e.g. for searching how many subjects may be eligible, based on review of MR; not done at Emory)
4. Have treating physician refer subjects (certain procedures must be followed)

“PHYSICIAN HAT” VS. “RESEARCHER HAT”

For the practice of medicine, a doctor is allowed to use PHI as part of healthcare operations.

HIPAA guidance suggests that additional protections come into play when looking at the same PHI but for research purposes

Treating physician/researcher should get partial HIPAA waiver and IRB review before looking at patient records for research eligibility

IRB APPROVAL OF AUTHORIZATIONS OR WAIVERS

Waivers need to be approved by Privacy Board

Emory IRB is the HIPAA privacy board for research use of PHI

We can approve Partial (PHW) or Complete HIPAA Waivers

- Partial waiver: allows for the use of the PHI during a part of the research where would be impractical to obtain authorization (e.g. recruitment). For example, looking at medical records or a database to identify potential subjects. Authorizations are eventually obtained when subjects enroll.
- Complete waiver: allows for the use/disclosure in a research study without ever seeking authorization, if fulfilling three criteria. For example, retrospective chart reviews approved by the IRB.

WAIVERS OF AUTHORIZATION

Criteria for all HIPAA waivers and alterations:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals; and
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.

PREPARATORY TO RESEARCH

Per the Privacy Rule, a covered entity may allow the use of PHI for activities deemed as “preparatory to research” if:

- There is representation from researcher (in writing or orally) that the PHI use is used for this reason
- Data will not be removed from covered entity
- Researcher accessing PHI is part of Covered Entity workforce

PREPARATORY TO RESEARCH

This does *not* apply if the activity is considered actual research, (for example, discussing PHI with a potential subject). The DHHS regulations at 45 CFR part 46 do not reference "preparatory to research" activities. All those uses would need to be approved by the Emory IRB.

NOTE: The Emory Medical Records Department has generally required IRB approval and a "partial HIPAA waiver" instead of allowing this provision.

SO, WHAT WOULD A PARTIAL HIPAA WAIVER COVER OR NOT COVER?

Will cover:

- Review of database with PHI to identify potential subjects
- Review of medical charts to identify potential subjects

At Emory, IRB review and approval required prior to accessing PHI

SO, WHAT WOULD A PARTIAL HIPAA WAIVER COVER OR NOT COVER?

Will not cover:

- Cold calling at Emory (other institutions may vary)
- Screening questionnaires with identifiers, where collected PHI is saved for research even if a person does not enroll
- Storage of data in database for research purposes (requires complete waiver)

SO, WHAT WOULD A PARTIAL HIPAA WAIVER COVER OR NOT COVER?

Will not cover:

- Collection of screening information via website/online form if there are any identifiers (including IP address) collected (not impracticable to display HIPAA authorizations before questions start)
- Screening or pre-visit procedures (e.g. blood labs, clinical exams done specifically for eligibility determination; fasting prior to visit)

NEW 'FRONT-DOOR' CONSENT AT EHC

Gets around the problem of “cold calling”: if patient gives front-door authorization, you may review their medical record and contact them if they appear to be eligible for your study.

No need for waiver

IMPORTANT: treating clinicians can still discuss studies with their own past or current patients, even if a patient did not sign the front-door authorization

HOW CAN I SCREEN PEOPLE ON PHONE OR IN PERSON W/O HIPAA AUTHORIZATION?

Ask screening questions without attaching identifiers to responses, e.g.:

- Verbally go through eligibility criteria and ask if person thinks they are eligible, then schedule visit.
- Fill out screen form, for your records, but do not record their name or linkable code on the form. Retain separate, unlinked list of eligible subjects and contact information. (Not feasible if you want to recall who you have already screened and why they failed screening.)

QUESTIONS?