Health Information Portability & Accountability Act

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HIPAA – Overview

HIPAA Act of 1996 ("HIPAA") and its regulations (the "Privacy Rule" and the "Security Rule")

- protect the privacy of an individual’s health information
- govern the way health care providers and benefit plans
  - collect
  - maintain
  - use
  - disclose

protected health information ("PHI")
HIPAA - Overview

- Expanded to include research
- Stanford determined the HIPAA covered entities to include:
  - Stanford Hospital and Clinics (SHC)
  - Lucile Packard Children’s Hospital (LPCH)
  - Stanford University Healthcare Components
  - Support Units
  - Office of Vice Provost and Dean of Research

All members of the workforce, business associates, trainees, researchers, volunteers, and service providers
HIPAA Authorization

- 45CFR 164.512 grants researchers ability to use and disclose health information
- Requires separate signature line / date on the authorization form
- Federal regulations allow for use of waivers and alterations.

IRB investigators can request one of the following:

- Waiver of Authorization
- Waiver of Authorization for recruitment
- Alteration of Authorization
In order to approve, IRB must determine that the following criteria are met:

1. involves **no more than minimal risk** to privacy by providing a plan or assurance that the researcher will:

   - protect subject identifiers,
   - destroy identifiers as soon as possible
   - give written assurances that PHI will not be reused or be disclosed
Waiver/Alteration of HIPAA Authorization

Criteria, cont.

2. Can’t *practically* be conducted without the waiver

3. Can’t *practically* be conducted without access to PHI

4. Will use the *minimum amount* of PHI necessary

5. Weigh the *risks vs. benefits*
Waiver of Authorization

- Researcher provides no information and does not obtain authorization from the participants.

Chart / retrospective records review
Waiver of HIPAA Authorization

For Recruitment

Granted to cover recruitment part of a study

However, HIPAA authorization will be required if participant is enrolled

e.g., a preliminary chart review for recruitment purposes
Alteration of HIPAA Authorization

Alteration of Authorization

- Omission of one or more of the required elements of authorization
  - e.g., study done over the phone where no signature can be obtained and a copy of HIPAA may not need to be sent
HIPAA Training

- New HIPAA training effective Aug. 2008
- Required to enroll in STARS; please take ASAP
- Additions being made to grey laminate
- Ask your training specialist for help anytime!

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