

# 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")

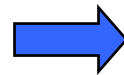


# HIPAA - Overview

- 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

# Waiver/Alteration of HIPAA 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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