



# Research





# Research Provisions

- ◆ Covered entities may use and disclose PHI for research:
  - with individual authorization, or
  - without individual authorization under limited circumstances



# What Research is Affected?

- ◆ Records research that uses existing PHI, such as:
  - Research databases and repositories
- ◆ Research that includes treatment of research participants, such as
  - Clinical trials



# Relationship to Other Research Rules

The Privacy Rule **does not** override the Common Rule or FDA's human subject protection regulations



# Common Rule vs. Privacy Rule

## Research WITH patient permission

Common Rule/FDA  
Regulated



IRB review of research  
and informed consent

Privacy Rule



Valid authorization



# Privacy Authorization

- ◆ Research participant authorization to use or disclose PHI is required for most clinical trials and some records research
  - May be no expiration date or event or may continue until “end of research study”
  - May be combined with informed consent to participate in research



# Common Rule vs. Privacy Rule

## Research WITHOUT patient permission

### Common Rule



- IRB Review—  
*4 waiver criteria*

### Privacy Rule



- IRB/Privacy Board Review—  
*3 waiver criteria*
- Preparatory research;
- Research on decedents; or
- Limited data set



# Use and Disclosure of PHI for Research *Without* Individual Authorization:

## Four Options:

- ◆ **OPTION 1:** Obtain documentation that an IRB or Privacy Board has approved an alteration to or waiver of authorization based on the following 3 waiver criteria:





## 3 Waiver Criteria

- 1) The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements...



# Minimal Risk Elements

- a. an adequate plan to protect the identifiers from improper use/disclosure;
- b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law; and
- c. adequate written assurances that PHI will not be reused/disclosed to any other person or entity, with certain exceptions.



## Waiver criteria...

- 2) The research could not practicably be conducted without the alteration or waiver
- 3) The research could not practicably be conducted without access to and use of the PHI



# Research Use and Disclosure of PHI *Without* Individual Authorization:

- ◆ **OPTION 2:** Obtain representation that the use or disclosure is necessary to prepare a research protocol or for similar purposes preparatory to research
  - No PHI removed from Covered Entity



# Research Use and Disclosure of PHI *Without* Individual Authorization:

- ◆ **OPTION 3:** Obtain representation that the use or disclosure is solely for research on decedents' protected health information



# Research Use and Disclosure of PHI *Without* Individual Authorization

- ◆ **OPTION 4:** Only use or disclose limited data set/“indirect identifiers” (e.g. zip codes, dates of service, age, death)
  - Requires a data use agreement



# Accounting for Research Disclosures

- ◆ Upon request, must provide accounting for research disclosures made without individual authorization (except for disclosures of the limited data set).
- ◆ For 50+ records:
  - List of protocols for which PHI may have been disclosed, and
  - Researcher contact information



# Covered Entity and Researcher Relationship

- ◆ **Researcher within Covered Entity**
  - Rule applies to entire entity; or
  - Elect Hybrid status
    - Must include clinical researcher in covered component if covered health care provider
    - May include clinical researcher in covered component even if not covered health care provider
    - May not include researcher that is not also providing health care
- ◆ **Researcher and Covered Entity are two separate legal entities**





# Ongoing Research at Time of Compliance Date (4/14/03)

- ◆ Grandfathers in use or disclosure of PHI as permitted by the following if obtained prior to the compliance date:
  - Legal permission for the use or disclosure PHI;
  - Informed consent for the research; or
  - An IRB waiver of informed consent under the Common Rule.