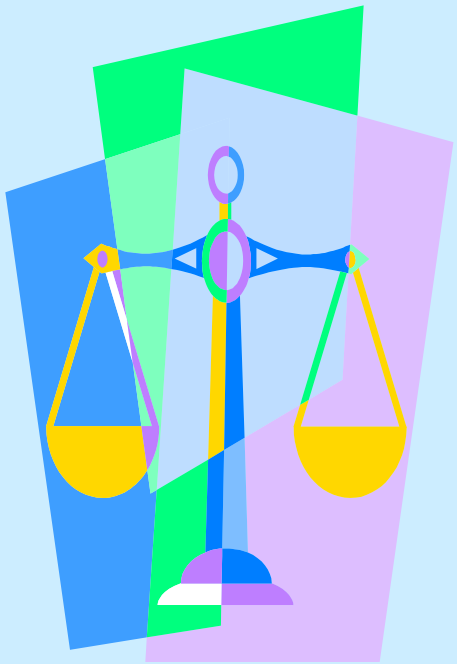

Research

United States Department of Health & Human Services

Research Provisions

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

45 CFR § § 164.508, 164.512(i)

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 <u>WITH</u>* 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

45 CFR § 164.508(c), (b)

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

45 CFR § § 164.512(i), 164.514(e)

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

45 CFR § 164.528(a), (b)

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.