





# 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















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





# 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.