Advanced Issues in HIPAA Research Compliance

The Sixth National HIPAA Summit

March 27, 2003
Washington , D.C.

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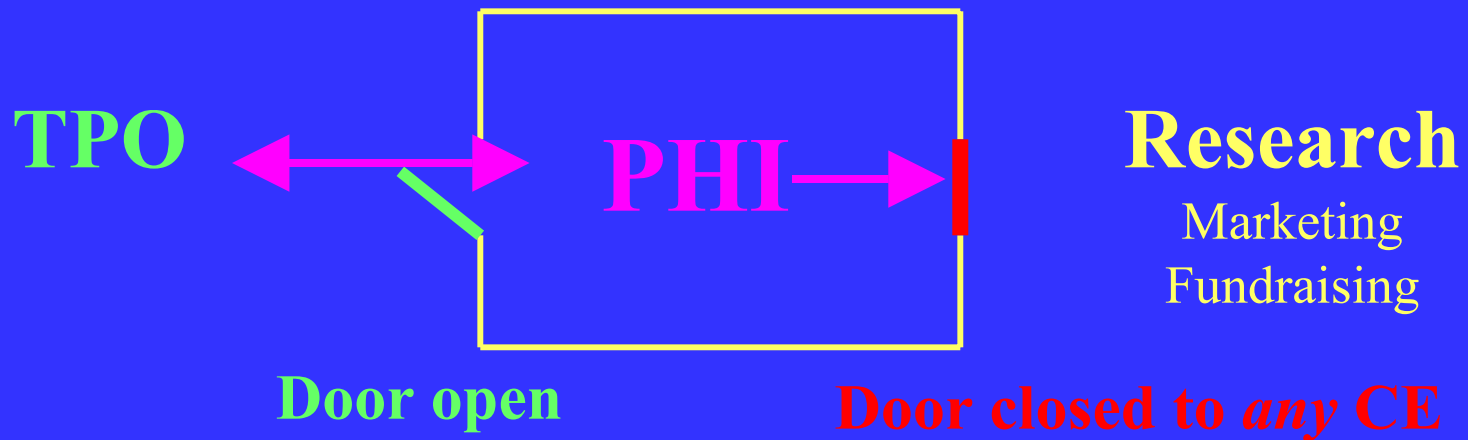
Default HIPAA Rule For Research: The Door To PHI Is *Closed* and *Locked*



Need a HIPAA key to open the door to PHI for research

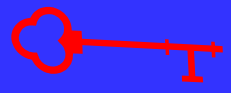
What Are the HIPAA Keys For Research?

1. Authorization
2. Grand-fathered authorization
3. Waiver of authorization
4. Representations
   - Review Preparatory to Research
   - PHI of decedents
5. Limited Data Set
6. Permitted disclosures
7. Disclosures to business associates

Requirements Associated With HIPAA Keys

HIPAA Key	Minimum Necessary	Track Disclosures
Representations	Yes	Yes
Limited data set	Yes	No
Business associate	Yes	Yes
Authorization	No	No
Waiver	Yes	Yes

Which HIPAA Key Applies to Your Research Activity?

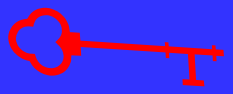
Research + CE + PHI = HIPAA 

1. **Is the use/disclosure for research?**
2. **Is a covered entity involved?**
3. **Is PHI involved?**
4. **If yes to 1 - 3, which HIPAA key applies?**

Which HIPAA Key Applies to Your Research Activity?

- Examples
  - Subject screening
  - Protocol development
  - Subject recruitment

HIPAA Keys For Research Activities



Review Preparatory to Research (RPR)

- A covered entity (CE) may
- *Use* or *disclose*
- PHI for research
- Without an authorization
- If the CE obtains from a "researcher"
- A "representation" that
  - PHI will be reviewed solely "to prepare a research protocol or for a similar purpose,"
  - The PHI is necessary for the research purpose, and
  - The PHI *will not be removed* from the CE's site

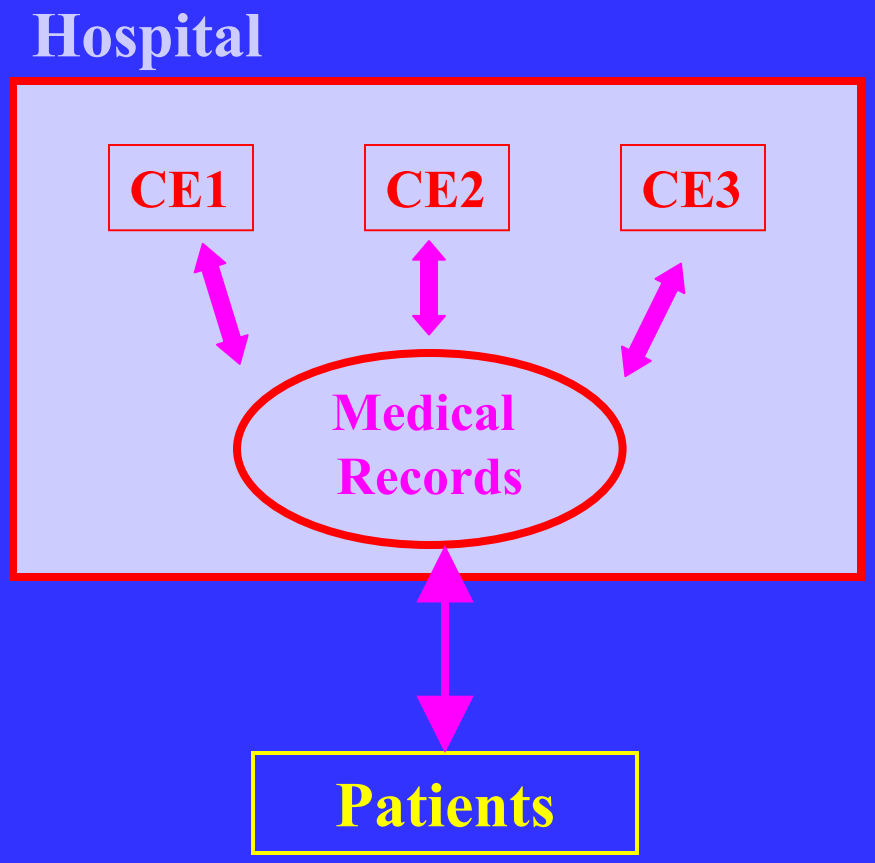
Representations For Reviews Preparatory to Research

- What procedural requirements apply to Representations?
- HIPAA does not specify anything other than the content of Representations
- Representations:
  - Do not have to be reviewed or approved
  - Do not have to be in writing
- BUT disclosures made under a Representation must be tracked by the CE holding the PHI
  - HIPAA gives individuals a right to an accounting of all disclosures of their PHI made by the CE in the previous 6 years
  - How to track disclosures if Representations are not in writing?

Representations For Reviews Preparatory to Research

- How may PHI be used by researchers under an RPR representation?
- "To prepare a research protocol or for a similar purpose"
  - Subject screening
  - Protocol development
  - Subject recruitment
    - "The preparatory research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment." (OCR Guidance, 12/4/02)
    - But the PHI may not leave the CE's site
    - How may a researcher *outside* of the CE recruit subjects if the PHI may not be removed from the CE's site?

RPR Representations: Researchers *Within* the Covered Entity

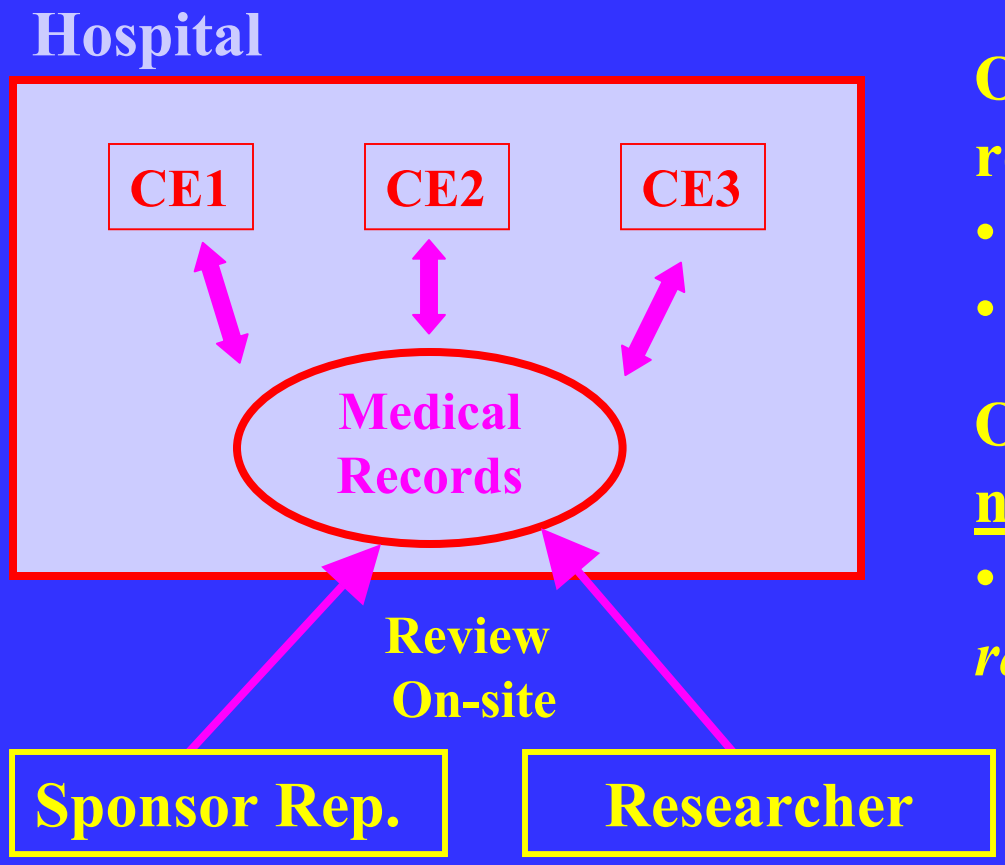


Researchers within the CE may use PHI to:

- **Screen subjects**
- **Protocol development**
- **Recruit subjects**

1. **PHI remains on-site**
2. **Disclosure of PHI by CE to the patient is permitted for any purpose (164.502(a)(1)(i)).**

RPR Representations: Researchers *Outside* the Covered Entity



Outside researchers <u>may</u> review PHI *on-site* to:

- **Screen subjects**
- **Protocol development**

Outside researchers may <u>not</u> take PHI *off-site*:

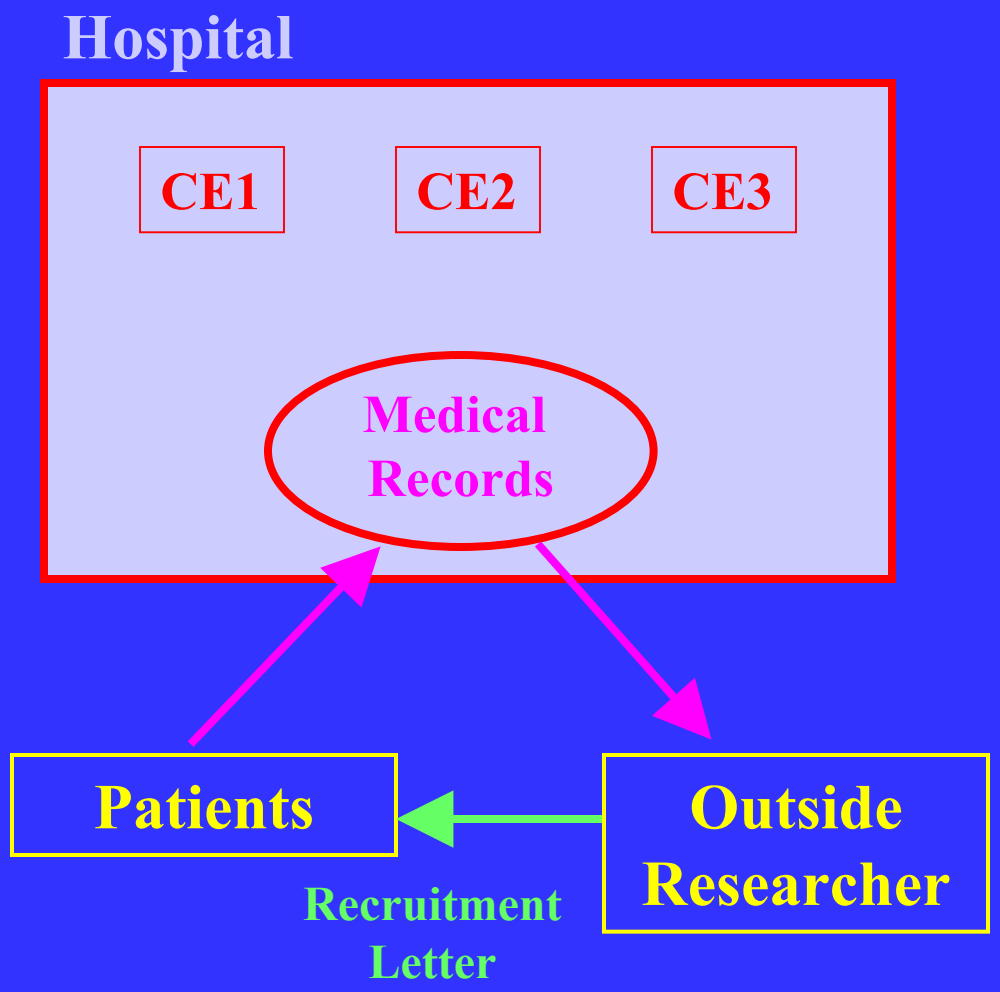
- **Cannot obtain PHI to *recruit* subjects**

What HIPAA Keys May Outside Researchers Use to Recruit Subjects?

Office of Civil Rights, HIPAA Guidance, 12/4/02

- **"[A] researcher who is not a part of the covered entity *may not use the preparatory research provision to contact prospective research subjects*. Rather, the outside researcher could obtain contact information through a partial waiver of individual authorization by an IRB or Privacy Board ***."**
- **"For example, even if an IRB does not waive informed consent and individual authorization for the study itself, it may waive such authorization to permit the disclosure of protected health information as necessary for the researcher to be able to contact and recruit individuals into the study."**

What HIPAA Keys May *Outside* Researchers Use to Recruit Subjects?



Outside researchers may obtain PHI to *recruit* subjects with a:

1. **Waiver of authorization**
2. **Authorization**

Common Rule Requirements For Subject Recruitment

- Recruitment of subjects is part of the informed consent process
- Procedures for recruiting subjects must be:
  - Included in the research protocol
  - Reviewed and approved by an IRB
- Different procedures under HIPAA and the Common Rule for researchers within a CE:
  - HIPAA: May screen and recruit under an RPR Representation
  - Common Rule: Need IRB review and approval for recruitment

HIPAA Keys For Subject Screening and Recruitment

	Common Rule	HIPAA	
		Within CE	Outside CE
Screening	——	RPR	RPR*
Recruit	IRB	RPR +IRB	Waiver* + IRB
Enroll	IRB	IRB	IRB

* Disclosure must be tracked by the CE

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Questions?