# HIPAA & RESEARCH

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# HIPAA

**Health Insurance Portability & Accountability Act**

# Major Purposes/Components of HIPAA Statute

- **Health insurance portability**

- **Funding of DHHS/OIG Fraud & Abuse Enforcement**

- **Administrative Simplification**
  - **Standardization of E-Transactions (e.g. claims)**
  - **Security of E-Health Information & E-Signatures**
  - **Privacy of Personally Identifiable Health Information**

# DHHS HIPAA Privacy Regulations a/k/a "The Privacy Rule"

- **Title:** "Standards for Privacy of Individually Identifiable Health Information"
- **Citation:** 65 FR 82462
  45 CFR Parts 160 and 164
- **Promulgated:** December 28, 2000
- **Effective Date:** Original 2/6/01
  Revised 4/14/01
- **Compliance Date:** Original 2/6/03
  Revised 4/14/03
- **Deadline for Comments:** 3/30/01

# General Concepts & Requirements of Privacy Rule

1. **Rule governs the use and disclosure of "protected health information" by "covered entities"**

   - **"Covered Entities"**
     - **Health Plans**
     - **Health Care Clearinghouses**
     - **Health Care Providers (e.g. hospitals) that transmit health information electronically**

# General Concepts & Requirements of Privacy Rule

1. **Rule governs the use and disclosure of "protected health information" by "covered entities" (cont.)**
   - **"Protected Health Information" ("PHI")**
     - **relates to person's physical or mental health or condition or the provision/payment of health services**
     - **identifies or could identify person**
     - **created or received by Covered Entity**
     - **transmitted in any form (electronically, paper, oral)**

# General Concepts & Requirements of Privacy Rule

2. **Rule permits providers to use/disclose PHI as follows:**

   **- With Consent for treatment, payment or health care operations**

   **- With Prior Notice (and Opportunity to Object) for marketing, fundraising and directory functions**

   **- Without Consent, Authorization or Prior Notice/OTO for listed "public policy" purposes such as law enforcement, public health and research**

__ **- With Authorization for all other purposes**

# General Concepts & Requirements of Privacy Rule

**3. Some general provisions that may implicate research are:**

- **"Minimum Necessary" Rule**
- **Psychotherapy Notes**
- **State Law**
- **De-Identified Data**
- **Notice of Privacy Practices**
- **Accounting of Disclosures**
- **Individual Rights**
- **Administrative Requirements**
- **Enforcement & Penalties**

# Research Provisions of Privacy Rule

1. **Definition of "Research" same as under Common Rule:**

   **"a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"**

# Research Provisions of Privacy Rule

**2. Individual Authorizations for use/disclosure of PHI**

**A. Patient authorization required for all research uses/disclosures except:**

**- Certain studies meeting HIPAA criteria (e.g. patient authorization not practicable) approved by an IRB or Privacy Board**

**- Reviews "preparatory to research"**

**- Research on decedent's information**

**B. Authorization may be combined with:**

**- HIPAA consent for treatment/payment/hco**

**- Consent to participate in research**

# Research Provisions of Privacy Rule

**2. Individual authorization for use/disclosure of PHI (cont.)**

**C. Required elements of a valid authorization include:**

**- specific/meaningful description of PHI to be used/disclosed to researcher**

**- specific identification of persons/class to whom CE may disclose PHI**

**- specific identification of persons/class to whom researcher can disclose PHI**

**- expiration date/event**

**- notice of patient rights to revoke**

**- statement about possible re-releases by researcher and limits of protections of Privacy Rule**

**- signature of patient**

# Research Provisions of Privacy Rule

**2. Individual authorizations for use/disclosure of PHI (cont.)**

**D. Additional required elements of authorizations for "Treatment" Studies:**

**- descriptions re intended use/disclosure for treatment, payment, health care operations**

**- description re any restrictions on use/disclosure for other permitted purposes**

**- if consent or notice is also used/provided, a reference to them, with a statement re binding effect of representations in authorization**

# Research Provisions of Privacy Rule

**3. Researcher access to PHI without individual authorization**

**A. By waiver/alteration of authorization by IRB or Privacy Board**

**(i) Composition/Status of Board**

**- IRB established in accordance with Common Rule, e.g. 45 CPR 46.107**

**- Privacy Board that:**

**- Has members with varying backgrounds and appropriate professional competency**

**- Includes at least 1 unaffiliated member**

**- Has no members w/ a conflict of interest**

# Research Provisions of Privacy Rule

**A. By waiver/alterations of authorization by IRB or Privacy Board (cont.)**

**(ii) Procedure for Board Approval**

- **IRBs must follow "normal" or "expedited review" procedures of Common Rule**
- **Privacy Boards may approve**
  - **by a majority vote of a majority of the Board that includes 1 unaffiliated member,**

    **or**
  - **through expedited review and approval by Chair or Chair's designee**

# Research Provisions of Privacy Rule

**A. By waiver/alterations of authorization by IRB or Privacy Board (cont.)**

**(iii) Criteria for Approval**

**- Boards may approve waiver/alteration of authorization if 8 criteria are satisfied**

- **no more than minimal privacy risk to subject**
- **no adverse effect on subject's privacy rights and welfare**
- **research not practicable w/out waiver/alteration**
- **research not practicable without PHI**
- **risks reasonable vs. benefits to individual/society**
- **adequate plan to protect PHI**
- **researcher plan to destroy identifiers asap if possible**
- **written researcher assurance of confidentiality**

# Research Provisions of Privacy Rule

**A. By waiver/alterations of authorization by IRB or Privacy Board (cont.)**

**(iv) Documentation of Board Approval**

**- Board must prepare and send to Provider the following documentation signed by Chair or Designated Member:**

**- statement identifying Board and approval date**
**- statement certifying approval by appropriate process**
**- statement that Board determined that 8 criteria are satisfied**
**- brief description of PHI necessary for research**

# Research Provisions of Privacy Rule

**A. By waiver/alterations of authorization by IRB or Privacy Board (cont.)**

**(v) Responsibility of Provider (CE)**

- **Prohibit researcher access until all required documentation is received from IRB**
- **Provider probably may "rely" on IRB findings and representations, including "minimum necessary" findings**
- **Retain documentation for 6 years**

# Research Provisions of Privacy Rule

**B. For "Reviews Preparatory to Research"**

**- Provider may permit access to PHI upon written representation from researcher that:**

**- purpose is to prepare a protocol or for a "similar purpose preparatory to research"**

**- PHI won't be removed from Provider**

**- PHI is "necessary" for research**

**- Provider probably may rely on reseracher's representations, at least when "reasonable under the circumstances"**

# Research Provisions of Privacy Rule

**C. For Research on Decedents' Information**

- **Provider may permit access to PHI upon receipt from researcher of:**
  - **representation that access is solely for research on decedents**
  - **documentation (at provider's request) of proof of subject's death**
  - **representation that PHI is necessary**
- **Provider probably can rely on researcher's representations, at least when "reasonable"**

# Research Provisions of Privacy Rule

**4. Relationship of Privacy Rule and Common Rule**

- **Rules are separate and distinct**
- **Both must be complied with**
- **4 Common Rule Waiver criteria not the same as first 4 of 8 criteria in HIPAA Privacy Rule**
- **Research "exempt" from Common Rule may still require IRB review under HIPAA (e.g. chart reviews with no identifiers recorded)**
- **Advisable to make/document approvals separately**
- **Need to coordinate HIPAA Compliance with IRB policies and procedures - e.g. "Preparatory" research activities may still require IRB approval under IRB policies**

# Research Provisions of Privacy Rule

**5. Summary**

- **Reviews Preparatory to Research and Research on Decedent's Information**
  - **- Required documentation given to Provider**
  - **- No Board review required**
- **Studies not involving patient contact or treatment**
  - **- Board approval required**
- **Studies including patient contact or treatment**
  - **- Authorization required**
  - **- Possibly Board approval of access to PHI for initial "case identification"**

# Research Provisions of Privacy Rule

**6. State Law Issues**

- **Many states prohibit access to sensitive information (e.g. HIV/AIDS information) without specific approval**
- **Stricter state laws must still be complied with**
- **Some state laws (e.g. WA) have HIPAA-like provisions requiring IRB approval for unauthorized researcher access**
- **At least one state (MN) prohibits researcher access (to records created after 1996)without patient authorization**