Access to Patient Information for Research Purposes: Demystifying the Process!

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“Administrative Simplification”? 

- Unfunded Mandate
- State Preemption
- Intersection with other Federal Laws
- ‘Reasonableness’ Test Determination
- Correlation between Intent, and Standard, and Implementation

The Privacy Rule is approximately 39,000 words long and requires 406,000 words to explain!
Not a “One Size Fits All Approach”!

The Privacy Rule is flexible and scalable to account for the nature of each organization’s culture, size, and resources.

Each organization must determine its own privacy policies and practices within the context of the Privacy Rule requirements and its own capabilities and needs.
Research and Health Care: The ‘Fit’ at SUNY Upstate?

1. Clinical Research may Involve Treatment
3. Co-Mingling of Research and Treatment Information
5. Dual Role of Providers: Health Care and Research
7. Research Supports Mission of Academic Medical Center
5. Consumer Expectations
Recognizing The Information Overlap ...

Hospital
- Treatment
- Payment
- Operations

-Workforce
-Medical Record
-Individual

Research
- Screening
- Protocol Development
- Recruitment
SUNY UPSTATE MEDICAL UNIVERSITY
HIPAA Organizational Structure

State University of New York
*Hybrid Covered Entity

Upstate Medical University
* Component of SUNY Hybrid

*Health Care Component

Provider Functions
- Research *
- Education *

Business Functions
- Univ. Counsel
- Public
- Institut. Compliance
- Diversity Aff. Action
- Emp/Labor Relations
- Safetly
- Media Relation
- Internal Audit
- IMT
- IMT
- Executive Council

*Organized Health Care Arrangement
- Faculty Providers (Full-time & Volunteers)

*Business Associate Relationships
- MSG
- RF
- Other Vendors

*Involving IIHI of University Hospital

*Non Health Care Components

Firewall
Information Flow Impact

Health Care Component
- Subject to HIPAA
  - Ex: Research Records
  - Authorization Required

Non-Health Care Component
- Not Subject to HIPAA
  - Ex: Employment Records
Navigating the Information Maze: Show Me the Way.....

1. Research or Health Care Operations?
2. PHI or Deidentified Information?
3. Subject Alive or Deceased?
4. Researcher a SUNY Workforce Member or External?
5. Privacy Education Completed and Confidentiality Agreement Signed?
6. Use and/or Disclosure of PHI?
7. IRB or Privacy Board Approval?
‘Research’?

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

45 CFR § 164.501
Or “Health Care Operations’?

- Health Care Operations includes conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, providing that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities....

45 CFR § 164.501
Protected Health Information?

- Protected Health Information ("PHI") is IIHI in any form (oral or recorded) that is:
  - Created or received by a covered entity; and
  - Related to the past, present, or future physical or mental health of an individual; the provision of health care to an individual; or the payment for the provision of health care to an individual; and
  - Either identifies the individual or is reasonably likely to allow identification of the individual

45 CFR 160.103, 160.501
Or De-Identified Information?

Health Information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.

45 CFR § 164.514 (a)
Individually Identifiable Data Elements

- Names
- Geographic subdivisions smaller than a state (see rule for details concerning use of zip codes)
- Dates of birth, admission, discharge, and death
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical Record numbers
- Health plan beneficiary numbers

- Account numbers
- Certificate/license numbers (e.g., of healthcare professionals)
- Vehicle identifiers
- Device identifiers (e.g. of pacemakers)
- URLs
- IP addresses
- Biometric identifiers
- Full face photographs
- Any other unique identifying number, characteristic, or code (e.g. blue-eyed, blond oriental who is 7 feet tall)
Subject Alive or Deceased?

The Common Rule protects the rights and welfare of human research subjects, defined as “living individuals”.

However
The Privacy Rule extends some limited privacy protection after death, permitting access to PHI based on obtaining certain reassurances from the researcher.

45 CFR § 164.512 (i) (1) (ii)
Researcher A SUNY Workforce Member?

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

45 CFR § 160.103
Workforce Member?
In or Out, No In Between!

- Authorization → IIHI may be used and disclosed regardless of status if denoted on Authorization

- No Authorization → IIHI may be used and disclosed if the following conditions are met:
  - Must be Workforce Members
  - Must Complete Privacy Education & Sign a Confidentiality Agreement
  - Must Have IRB or Privacy Board Approval Granted
  - Verification by Department Chair if Researcher is Voluntary Faculty
Use and/or Disclosure of PHI?

- **Use** \(\Rightarrow\) Employment, application, utilization, examination, or analysis of information within an entity that maintains the information.

- **Disclosure** \(\Rightarrow\) Release, transfer, provision of access to, or divulging in any other manner, information outside the entity holding the information.

45 CFR § 164.501
Research and Privacy Compliance: A Joint Effort

IRB
- Authorizations
- Waivers of Authorization
- Exemptions
  - LDU
  - De-id

Privacy Office
- Preparatory Reviews
- Decedent PHI
- Limited Data Use Agreements

Human Subject Research

Privacy Oversight & Compliance

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Unlocking The Door to PHI . . . .

De-Identification
Authorization
Waiver of Authorization
Transition Provision
Review Preparatory to Research
Decedent PHI
Limited Data Set
Deidentification of PHI

- Researcher must complete a *Deidentification Certification Form*
  - Removal of *ALL* 18 identifying elements
  - The information cannot reasonably identify the individual
  - If statistically de-identify, must provide attestation of qualifications and methodology of statistician

**REMEMBER:** Anonymous and Deidentified are not synonymous!
Authorization

- “Gold Standard” for disclosure of PHI
- May be combined with informed consent
- Revocation right balanced with ‘Reliance exception’
- Authorization specific to disclosure required for external research
- Subjects given a *Notice of Privacy Practices*
The Researcher must complete a *Waiver of Authorization Form*

- The use or disclosure involves no more than **minimal** risk to the privacy of the individual
- The research could not **practically** be conducted without the waiver
- The research could not **practically** be conducted without access to and use of the PHI
Permits the use and disclosure of PHI created or received before or after April 14, 2003 if one of the following was obtained prior:

- Authorization to use and disclose PHI for research
- Informed consent to participate in research
- Waiver of informed consent by IRB
Review Preparatory to Research

- Researcher must complete a *Review Preparatory to Research Request Form and submit to Privacy Office*
  - The PHI will be used *solely* to prepare a research protocol or similar purpose
  - The PHI is *necessary* for the research
  - The PHI is not to be *recorded* by the researcher
  - The review may only be performed by SUNY Upstate workforce members

*Does not provide a ticket to ride the research train!*
Decedent PHI

- Researcher must complete a Research on Decedents’ Information Request Form and submit to the Privacy Office
  - The use or disclosure is solely for research
  - The PHI is necessary to conduct the research
  - The individual is a decedent
  - The PHI of living person contained in decedents’ records will not be used or disclosed

In God we trust, all others need proof!
Limited Data Set

The Researcher must complete a Limited Data Set Form

- The data elements must be limited to those that could not be reasonably used to identify the individual

- The request is specific to the study/project

- Disclosures are made pursuant to a Limited Data Use Agreement executed by the Privacy Office

Must specify “what”, as well as “what not”!
Use and Disclosure of PHI for Recruitment?

- Treatment provider may discuss with patient
- Patient initiated contact with researcher
- Authorization permitting discussion with researcher
- Waiver of Authorization from IRB permitting discussion with researcher
- Researcher post flyers and advertises
Tissue, PHI or Both?

Neither blood nor tissue, in and of itself, is considered individually identifiable health information (IIHI); therefore, research involving only the collection of blood or tissue is not subject to the Privacy Rule requirements.

Unless

- Labeled with IIHI
- Results from analysis contain or are associated with IIHI

Impact: Information comes with strings attached!
# Requirements for Use & Disclosure of PHI

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<thead>
<tr>
<th>MINIMUM NECESSARY</th>
<th>ACCOUNTING</th>
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<tbody>
<tr>
<td>Authorization</td>
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<tr>
<td>Waiver of Authorization</td>
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<td>Preparatory Reviews</td>
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<td>Decedent PHI</td>
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<td>Limited Data Set</td>
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<td>De-identification</td>
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<tr>
<td>Transition Consent/Auth.</td>
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*Modified Accounting for Research Disclosures Tracking may be used for studies involving disclosures of 50 or more individuals.*
SUNY Upstate - Access To Research Data

1. Research Protocol Submission
2. Review by IRB/Privacy Office
3. Appropriate Use & Disclosure Method Approved
4. Determination Letter Issued
5. Submitted Data Request Form & Determination Letter Reviewed By Privacy Officer
6. Researcher Completes Data Request Form
7. PHI Provided to Researcher if Approved
8. Compliance Auditing

Approval or Denial Decision

Appropriate Department & Researcher notified

Denial
Monitoring & Oversight

Organizational Controls

Continuous Monitoring
- Data requests
- Systems Access
- Uses/Disclosures
- Protocol Review

Proactive Auditing
- User Activity Audits
- Audit Trails
- Role-Based Access
- Protocol Compliance

Triggered Reviews
- Patient Complaints
- Reported Breaches
- Violation of Protocols

Workforce Education Audits
- CITI Training
- Confid. Agreements
- HIPAA Privacy Rule

Management Reporting And Documentation
- Incident Occurrence
- Trend Identification
- Process Reviews
- Mitigation Findings

Implement

Remediation Process

Feedback
Don’t Surprise The Patient!

- Receipt of the Notice of Privacy Practices
- Ethical Recruitment Practices
- Permitted Use and Disclosure of PHI
- Accounting of Disclosures
Consequences of Inadequate Privacy Protections...

- Violate Individual’s Right to Privacy
- Loss of Public Trust
- Professional Misconduct
  [New York State Education Law § 6530(23)]
- Sanctions
- Suspension of Research Activities
“Covered entities [should] be mindful of the often highly sensitive nature of research information and the impact of individuals’ privacy concerns on their willingness to participate in research.”

Standards for the Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule), 65 F.R. at 82520, December 28, 2000
Who do I Call?

Contacting the Privacy Administrator:

- **E-mail**: Nappac@upstate.edu
- **Phone**: 464-6135
- **Hotline**: 464-6444

Visit the HIPAA Website at Upstate.edu/hipaa
CONCLUSIONS
&
QUESTIONS