IRB GRAND ROUNDS
UNLOCKING INFORMATION: FROM PHI TO RHI

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Overview

1. Basic HIPAA information: PII, PHI and RHI
2. Recruitment
3. Making RHI out of PHI
4. Record keeping requirements related to HIPAA

HIPAA Basic Information

- Health Insurance Portability and Accountability Act of 1996 was signed into law on August 21, 1996 and went into effect in 2003.

- HIPAA applies to: Healthcare Providers (Hospitals, Physician Practices, etc.), Healthcare Plans, Healthcare Clearinghouses and Business Associates

- Federal law that protects the privacy and security of an individual's health information held by a "**Covered Entity**." HIPAA regulations only apply to the Covered Entity functions.

- University of Miami is engaged in both Covered Entity functions and other activities that are not Covered Entity functions and is therefore considered a **Hybrid Entity**.

- Research is **not** part of the Covered Entity at the University of Miami both for legal reasons and practical concerns.

- Researchers must properly remove PHI from the University in order to use it for research (RHI).

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Protected Health Information (PHI)

- ❖ Name
- ❖ Postal address
- ❖ All elements of dates except year
- ❖ Telephone number
- ❖ Fax number
- ❖ Email address
- ❖ URL address
- ❖ IP address
- ❖ Social Security number

- ❖ Medical record number
- ❖ Health plan beneficiary number
- ❖ Device identifiers and their serial numbers
- ❖ Vehicle identifiers and serial number
- ❖ Biometric identifiers (finger & voice prints)
- ❖ Full face photo and other comparable images
- ❖ Any other unique identifying number, code or characteristic
- ❖ Account number
- ❖ License number

Be Aware…

Being able to link any one of the 18 defined PHI data elements to an identified diagnosis or medical condition connected to a health care event means that the definition of PHI has been met and HIPAA likely applies.

HIPAA Privacy Rule

•The Privacy Rule establishes the standard to protect the personal information of patients.

•It requires appropriate safeguards and also establishes limits and conditions on the uses and disclosures for patient information.

• **PHI used in research must be obtained from the Covered Entity in compliance with HIPAA.**

- ➢ With IRB approval under certain circumstances
- ➢ Reviews preparatory to research (with certification and IRB approval)
- ➢ Limited data sets accompanied by a data use agreement
- ➢ Express authorization from the research participant (HIPAA form B)
- ➢ Research that is solely on the protected health information of decedents (with certification and IRB approval)

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PII, PHI and RHI

PII Personally Identifiable Information

→**PII** is a term that is used in privacy law and it applies to all information privacy considerations.

→**PII** is any information which can be used to distinguish or trace an individual's identity *and* any other information that is linked or linkable to an individual.

→**PII** comprises much of what is protected as PHI under HIPAA.

PHI (IIHI)

Protected Health Information

→**PHI** is the information protected under HIPAA regulations.

→**PHI** is defined as identifiable information related to the physical or mental condition of an individual.

*In combination with that individual's health care related information such as:

Treatment, diagnosis, medications, billing details (health care events)

RHI

Research Health Information

- PHI that has been properly released for use in research through one of the methods allowed by the HIPAA privacy rule.
- PII that is **not** associated with a health care event

What is Protected Health Information (PHI)?

Protected Health Information (PHI) is any individually identifiable information that is transmitted or maintained in electronic medium, or in any other form by a covered function within UM or Jackson.

- ❑ **Medical Records**
  E.g. Medical History, Diagnosis, Treatment

- ❑ **Payment Information**
  E.g. Bills, Receipts

- ❑ **Ancillary Services**
  E.g. X-Rays, Labs

- ❑ **Demographic Information**
  (When maintained with health information or created as part of a health care event)
  E.g. Name, Date of Birth, Address, Social Security Number

What is Research Health Information (RHI)?

Research Protected Health Information (RHI) is any individually identifiable information obtained or generated through research activities exclusively for research purposes. RHI is either information that has been released from PHI status or generated as research only and not comprising of a health care transaction.

- ❑ **Information Obtained from Medical Records (EHR or Paper Chart) Via a HIPAA Compliant Method**
  E.g. Medical History, Diagnosis, Treatment

- ❑ **Information Obtained from Patients Recruited Outside the Covered Entity (no therapeutic intervention and no health event billed)**
  Recruitment via Community Notices, Call Centers, Existing Databases, etc.

- ❑ **Information Obtained from a Study in Which Information was Obtained Through a Community, Fitness, or Other Facility of Not Connected to or Associated with a designated component.**

- ❑ **ANY Identifying Information for Which a Participant has Given an Authorization**
  The HIPAA form B is your best friend!!

Sources of RHI

- Studies that recruit subjects through flyers and ads where no PHI was accessed and none is created during research

- Some interview studies and focus group studies

- Some non-treatment studies, testing done with no identifiers, use of aggregate data, diagnostic or genetic tests that do not go into the medical records

- Some questionnaire studies

- Studies that involve members of the Wellness Center or other community centers at the University which are not under the covered entity

- Databases with general (limited data sets) or no (de-identified) PII is used

PHI vs. RHI

- PHI is subject to all HIPAA rules and procedures for securing the information
- RHI is subject to best practices for maintaining confidentiality of research records and the Florida Privacy laws, but not subject to HIPAA.

RULE OF THUMB

Information is PHI and cannot be used for research without being released if:

- ❏ **it is obtained or generated as part of a health care service which**
- ❏ **is entered into a medical record or used to make treatment decisions and**
- ❏ **is used in connection with a standard transaction (billed).**

Remember that Both PHI and RHI are Always Defined as Confidential and Private Information

- Every effort should be made to use and maintain the information in accordance with the law and industry standards, in other words, the most responsible/secure way possible.

- Confidential Information is subject to UM policy for handling confidential data regardless of format/media: verbal, paper, or electronic.

- Authorization to access Confidential Information is granted by role-based need or specific authorization.

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Making PHI into RHI in a HIPAA Compliant Way

- Establish your research goals
- Obtain IRB approval for your study:
  - ❖ Review preparatory to research
  - ❖ Recruitment strategy
  - ❖ Language for ICF and HIPAA forms
- Get your forms together and review them to ensure that all necessary elements are addressed
- Talk to sponsors and other involved parties to make sure proper contracts are in place so that information can be shared in a compliant and responsible way
- Make sure you account for disclosures every time you or your team uses PHI prior to it being released to RHI

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HIPAA COMPLIANT RECRUITMENT PROCEDURES

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KEEP CALM
AND
PREPARE
FOR
RECRUITMENT

Recruiting and Screening

- The protocol **must** <u>clearly</u> describe the recruitment method **and** be approved by the IRB!!!

- Research recruitment techniques must meet HIPAA standards for privacy and confidentiality.

- Investigators must **separate** the roles of researcher and clinician and must not use their clinical access to search patient records for potential research participants.

  > **Note:** The minimum necessary rule restricts disclosures to the minimum necessary to carry out a function.

  > **Note:** University policy requires that the EHR be used <u>only</u> for a legitimate business purpose.

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Acceptable Means of Recruiting Research Participants

1. Recruitment by treating physicians or other health care providers:

- Physicians and other health care staff may review only their own patients' records, which includes the records of patients within their treatment group, to identify potential research subjects.

- Treating physicians or staff may contact these patients to discuss with them the opportunity to participate in a research study.

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Acceptable Means of Recruiting Research Participants

2. Recruitment by non-treating physicians or health care staff

- If the researcher is not involved in the treatment provided to patients, then the research submission **must** include a description of the plan for recruitment in the research protocol submitted to the IRB.

- These plans are reviewed by the IRB to ensure appropriate contacts are made to the patients regarding the research study opportunity.

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Acceptable Means of Recruiting Research Participants

3. Screen for eligibility

- If health information will be requested from potential research subjects as part of the screening process, then researchers, before the screenings, **must** obtain either (1) a signed authorization from the potential research subject or (2) a partial waiver of authorization from the IRB to allow the solicitation.

Acceptable Means of Recruiting Research Participants

4. Request that interested individuals contact the research staff

- Researchers may recruit research subjects by using IRB-approved flyers, advertisements, and other means of communication.

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AUTHORIZATION ELEMENTS

INFORMED CONSENT
V.
HIPAA AUTHORIZATION FORM

❖ The informed consent is an individual's consent to participate in the research study, generally. It is governed by regulations directed at human subject protection. The ICF requirements are less stringent than the HIPAA requirements.

❖ The HIPAA Authorization is an individual's permission to disclose their PHI to specific individuals, for a certain purpose. It is governed solely by the HIPAA and HITECH regulations. Violations will also be governed by the HIPAA rules, thus fines, penalties and even <u>jail time</u> for offenders are potential sanctions.

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BASIC ELEMENTS OF THE AUTHORIZATION

✓ Description of the PHI to be used (specific)

✓ Identification of person or class of persons authorized to disclose the PHI

✓ Identification of person or class of persons who may receive and use the PHI

✓ Description of each purpose of the use or disclosure (study-specific; if future research contemplated must specify the nature of the research and give a reasonable expectation of what the information may be used for)

✓ Authorization expiration date (cannot be indefinite)

✓ Signature and date

✓ Mental health records, HIV/AIDS, substance abuse, sexual assault information and sexually transmitted diseases **must** be specifically authorized (checked boxes consistent with study and IRB approval)

REQUIRED STATEMENTS

✓ Inform the patient of (1) his or her right to revoke the authorization in writing, (2) how to revoke the authorization and (3) any exceptions to the right to revoke.

✓ State that UM cannot require the patient to sign the authorization in order to receive treatment or payment or to enroll or be eligible for benefits.

✓ State that information disclosed pursuant to the authorization may be re-disclosed by the recipient and no longer protected by the federal privacy regulations

RECORD KEEPING REQUIREMENTS

Record keeping requirements

- **Chart review at UM or JHS**

  - Submit IRB approval letter and watermarked data collection sheet to the Office of HIPAA Privacy & Security, PAC 409, Locator M-879, telephone: 305-243-5000.

  - If chart review will occur at Jackson Health Systems, contact the Jackson Privacy Office at 305-585-6854 for further information.

General Rules For Use and Disclosure of PHI for Research:

Accounting for Disclosures:

Disclosures made pursuant to an IRB *waiver of authorization*
Any chart review, review preparatory to research, research on PHI of decedents, disclosures to public health authorities or law enforcement

Accounting Required →

Authorized disclosures (Authorization from subject) (HIPAA form B!!)
PHI furnished in limited data sets
PHI disclosed for medical billing, internal auditing, quality assurance

Accounting NOT Required →

Record keeping requirements:

Disclosures made pursuant to an IRB *waiver of authorization* → **Accounting Required**

Investigators must complete an accounting for disclosures (HIPAA Attachment 45) and submit to Office of Privacy and Security.

Disclosure forms must be completed for **each** subject participating in the study.

Record Keeping Requirements

1. **Limited Data Set**

    - Provide IRB approval letter, business associate or other
    agreements (s) and watermarked data collection Sheet to
    the Office of HIPAA & Security , PAC 409, Locator M-879,
    telephone: 305-243-5000

2. **HIPAA Authorization (Form B)**

    - Send a copy of each signed authorization form to the
    Office of HIPAA Privacy & Security, PAC 409, Locator
    M-879, telephone: 305-243-5000.

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Record Retention

- If a study involves the collection of identifiable health information, records must be retained for a minimum of **six (6)** years following study closure. This retention period is consistent with the HIPAA Privacy Rule under which subjects may ask investigators for an accounting of all uses and disclosures of their study information for a period of 6 years after their participation is completed (c.f. *45 CFR 164.528*).

Contact Information

Office of HIPAA & Privacy Security	[Office of HIPAA Privacy & Security](#) 305-243-5000
HSRO	[Human Subject Research](#) 305-243-3195
Office of HIPAA & Privacy Security Web Resources **HIPAA Form B & other authorizations**	[privacyoffice.med.miami.edu](#) All forms to make the necessary HIPAA requests, disclosures and authorizations. Policies also
HSRO Web Resources	[hsro.med.miami.edu](#)
Report any issue anonymously	['Cane Watch](#) 877-415-4357

The institution has policies and procedures that serve to protect our patient information in oral, written, and electronic form. These are available on the Office of HIPAA Privacy & Security website: http://privacyoffice.med.miami.edu

Additionally, University-wide Information Technology policies regarding proper Use of Computer Systems are also applicable.

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