THE JOURNEY FROM PHI TO RHI: USING CLINICAL DATA IN RESEARCH

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You are putting a study together and the data points are few. In order to know which patient is which, you only intend to use name and date of birth. Since neither is health information, it’s probably not covered under HIPAA.

true  false
Be Aware…

Being able to link any one of the 18 defined PHI data elements to a health care event means which is billed electronically means that the definition of PHI has been met as to the data created and HIPAA likely applies.
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
<table>
<thead>
<tr>
<th><strong>PII</strong> Personally Identifiable Information</th>
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<tr>
<td>→ PII is a term that is used in privacy law and it applies to all information privacy considerations.</td>
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<td>→ 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.</td>
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<td>→ PII comprises much of what is protected as PHI under HIPAA.</td>
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<th><strong>PHI (IIHI)</strong> Protected Health Information</th>
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<td>→ PHI is the information protected under HIPAA regulations.</td>
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<td>→ PHI is defined as identifiable information related to the physical or mental condition of an individual.</td>
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*In combination with that individual’s health care related information such as: |
Treatment, diagnosis, medications, billing details (health care events)

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<th><strong>RHI</strong> Research Health Information</th>
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<td>• PHI that has been properly released for use in research through one of the methods allowed by the HIPAA privacy rule.</td>
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<tr>
<td>• PII that is <strong>not</strong> associated with a health care event</td>
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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 (IRB waiver, HIPAA From B, etc.)
  
  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!!
Remember that Both PHI and RHI are Always Defined as Personal Information!

We have a duty to protect it

- 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.
- FIPA is the Florida privacy statute and requires security.
- FTC regulates via unfair and deceptive trade practices.
- 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.
You don’t consider studies that use de-identified data because de-identified data is tricky and does not provide much value for in-depth research.
WHAT IS DE-IDENTIFIED DATA?

Unlike a limited data set, protected health information that has been de-identified excludes all of the following identifiers of the individual or of relatives, employers, or household members of the individual.

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers (including license plate numbers)
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including fingerprints and voiceprints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, except as permitted by the re-identification rules
WHAT CAN BE INCLUDED?

- Covered entities may include the first three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
  - The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people
  - The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
- The year of the date of any medical testing may be included.
- The individual's age expressed in years, months, days or hours may be included except for individuals who are aged 90 years or more.
**PHI may be de-identified in one of two ways**

- **Safe Harbor Method** – Removing all 18 data elements
  - General disclaimer is always that remaining information cannot be used alone or in combination to identify individuals
  - Generally, negatively impacts utility of data

- **Statistical ("Expert") Method**
  - Use of statistical methods that may not require removal of all 18 identifiers
  - Direct identifiers (e.g. name, SSN) will still be removed or “masked”
  - Depending on data, some flexibility in handling of quasi-identifiers such as dates, ethnicity, eye color, etc.
  - Potentially provides “richer” de-identified data sets than Safe Harbor Method
Honest Broker

• Can “transform” PHI to de-identified data for use by researchers & others
  – No HIPAA authorization is required for use of de-identified data
  – IRB Review not precluded

• De-identification of both structured and unstructured data in to meet proposed regulatory changes for large scale sharing of information between institutions

• Facilitate precision medicine initiative which relies on de-identified data

Use of de-identified data, whenever possible, reduces data exposure risk of the institution
SCENARIO

You want to streamline the process to obtain consent and authorization. The standard informed consent for research has a long confidentiality paragraph but you realize that the Common Rule and HIPAA have two different standards. You use the informed consent but you also prepare a HIPAA authorization (HIPAA form B).
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 jail time for offenders are potential sanctions.
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 for which the use or disclosure is made (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 as a condition for receiving 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.
You’ve gone through the arduous process of creating a protocol and having it approved by the IRB (congratulations!), you’re ready to start recruiting ASAP. You’ve already identified prospective subjects so all you have to do now is give them a call to see if they are interested in participating.

true  false
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.

- ONLY treating physicians or staff may contact these patients to discuss with them the opportunity to participate in a research study.
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.
Exciting Initiatives to Aid in Subject Recruitment

Research Alerts in UChart

The UChart team will roll out a new tool which will allow researchers to identify subjects who fit criteria in UChart such that when they come in to their next visit with their regular treating physician a pop-up will alert the treating physician to the study. The physician can then ask the patient if they are interested in being contacted and notify the study team to reach out to the patient.

Consent to Contact Initiative

CTSI in collaboration with other key areas of UHealth is preparing to launch a program by whereby patients can take advantage of UHealth’s research offerings by consenting to be contacted for research studies that may benefit them. Researchers will have to apply to the program and their recruitment plan will have to be approved by a special committee.
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.
## 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 | **privacyoffice.med.miami.edu**  
| HIPAA Form B & other authorizations | 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](http://privacyoffice.med.miami.edu)

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