Basics of HIPAA and Research

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Human subjects research (HSR) must be conducted in compliance with HSR regulations and HIPAA regulations

HIPAA applies whenever you use protected health information (PHI) for research purposes. Does it apply in these cases?

You record research data from the clinical record	**YES**
You check to see if any of tomorrow's clinic patients are eligible for a research study	**YES**
You conduct research visits in the clinic	**YES**
You eyeball the patient board to figure out which patients to approach about a research study	**YES**

HIPAA applies whenever you use protected health information (PHI) for research purposes. Does it apply in these cases?

You conduct a survey at a local community center and ask subjects to provide their date of birth	**NO**
You conduct a survey in the clinic waiting room and ask subjects to provide their date of birth	**YES**

Treat all research in a clinical setting as subject to HIPAA

Watch out for HIPAA identifiers like dates and zip codes

http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/

Keep HIPAA obligations in mind at each point in the research process

Just because you have access,
does not mean you have authorization

Use of PHI for research purposes requires:

- A signed HIPAA authorization from the subject or
- A documented waiver of HIPAA authorization

Keep HIPAA obligations in mind at each point in the research process

Just because you have access, does not mean you have authorization

Will there be enough subjects ?

How do I find my subjects ?

What data do I need ?

What do I have to account for ?

What do I have to keep or destroy ?

Waiver ?

Waiver or Authorization ?

Accounting of Research Disclosures under waiver

HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations

http://www.umassmed.edu/ccts/irb/investigator-guidance/
http://www.umassmed.edu/ccts/human-research/privacy-and-security/

Will there be enough subjects?

Just because you have access,
does not mean you have authorization

- A HIPAA waiver is likely required **before** you check unless
  - You are using UMMS IT de-identified data (http://www.umassmed.edu/it/cdp/)
  - You are estimating without going into records (e.g., based on experience)
  - You are using records from patients to whom you provide direct patient care

How do I find my subjects?

No waiver or authorization required

- Potential subjects contact you in response to flyer
- You provide direct patient care and recruit your own patients (these may be referrals)
- Providers alert you to a potential subject without sharing HIPAA identifiers

Signed HIPAA authorization required

- Providers pass patient identifiers to you with written patient permission

Waiver required

- You access/receive identifiers for people you do not provide direct patient care for without their signed authorization
- Examples include (1) searching patient records, logs, boards, etc., and (2) getting HIPAA identifiers from providers who alert you to an eligible subject

How do I find my subjects?

ATTN PIs: Getting pre-screening help from research staff may require a HIPAA waiver

Are research staff accessing records of their own patients?
If yes, no waiver needed

Are research staff helping you assess whether you should offer the research to your patient as part of a discussion of treatment options?
If yes, no waiver needed
NB: Compare an investigational drug/device study versus an observational registry

Let's look at a waiver more closely…

UMass Memorial Medical Center
HIPAA IRB WAIVER OF AUTHORIZATION***

Principal Investigator:
IRB Study ID #: H
Protocol Title:

Remember to complete the header

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1. Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study.

To find potential subjects

To conduct the entire study

Other? Explain

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1. Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study.

To find potential subjects

2. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. List the PHI to be collected and its source(s).

Sample 1:
Weekly OR schedule: Name, DOB, gender, surgery type, date of surgery

Allscripts/Meditech: Address, phone number

3. Explain why the research could not practicably be conducted without this PHI.

Sample 1:
We are conducting a study of adult men undergoing surgical removal of belly buttons. The inclusion and exclusion criteria depend on age, gender, surgery type, and date of surgery. Name, address, and phone number are required to contact potential subjects.

4. Describe the plan to protect identifiers from improper use or disclosure. Be sure to indicate where PHI will be stored, who will have access (researchers must list all of the entities that might have access to the study's PHI such as IRB, sponsors, FDA, data safety monitoring boards, and any others given authority by law), and the procedure used to destroy them. (Note that identifiers must be destroyed at the earliest opportunity, unless there is a justification for retaining the identifiers or retention is required by law.)

11/30/16	**12-1pm**	**HIPAA and Data Storage, Handling, and Destruction**

5. Explain why the research could not practicably be conducted if you had to obtain permission from the individuals to access their PHI for research purposes.

Sample 1: Because belly button removals are rare, we may miss eligible subjects and be unable to complete the research if we rely on them to self-identify. Prior attempts to recruit with flyers have failed.

Convenience is not an appropriate justification

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1. Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study.

To conduct the entire study

2. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. List the PHI to be collected and its source(s).

Sample 2:
Clinical Data Portal*: MRN, DOB, date of myocardial infarction, STEMI or Non-STEMI, date of admission, date of discharge, LV ejection fraction, medications at time of MI…

*http://www.umassmed.edu/it/cdp/

3. Explain why the research could not practicably be conducted without this PHI.

Sample 2:
We are conducting a retrospective chart review of the relationship between prior medication (recorded as meds at time of MI) and MI severity using adult patients seen prior to January 1, 2016. We require MRN, DOB, and date of MI to identify unique adult patients prior to 1/1/16. We require type of MI, length of stay, and LV ejection fraction as measures of severity…

4. Describe the plan to protect identifiers from improper use or disclosure. Be sure to indicate where PHI will be stored, who will have access (researchers must list all of the entities that might have access to the study's PHI such as IRB, sponsors, FDA, data safety monitoring boards, and any others given authority by law), and the procedure used to destroy them. (Note that identifiers must be destroyed at the earliest opportunity, unless there is a justification for retaining the identifiers or retention is required by law.)

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Sample 2: The research requires a large sample size extending back several years. Subjects may have moved or died, and contact information will be incomplete.

Convenience is not an appropriate justification

What do I have to account for?

REMINDER: The PI is ultimately responsible for completing the required accounting of research disclosures for any PHI released under a waiver. The relevant forms are available on the IRB website and additional information regarding these obligations is available by contacting the Office of Clinical Research, UMass Center for Clinical & Translational Science (UMCCTS), or the UMass Memorial Medical Center Privacy Officer.

http://www.umassmed.edu/ccts/human-research/privacy-and-security/

200+ individual patient records = Complete summary accounting

199 or fewer individual patient records = Complete the individual forms with Name, MRN, and DOB (make sure included in waiver)

Always check websites for current forms and requirements

What do I have to keep or destroy?

With some exceptions, identifiers can and should be destroyed to minimize the risk of breach of confidentiality

http://www.umassmed.edu/ccts/irb/investigator-guidance/

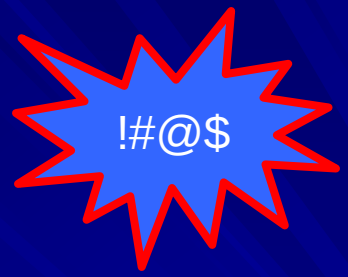
2.22. Retain research records (including signed consent documents) for the greater of:

2.22.1. Three years after completion of the research

2.22.2. Maintain signed and dated consent documents for at least three years after completion of the research.

2.22.3. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research.

I think I need an authorization for an existing study. What do I do?



- Stop
- Contact the IRB
- Submit a Modification with a plan to obtain the necessary authorizations or waiver

Take these steps to facilitate review of HIPAA Authorizations

1. Use a stand-alone HIPAA authorization (not merged with a consent)
2. Modify the form to get the information you need – the template allows UMass Memorial Medical Center (and no other places) to disclose PHI
3. Select only the PHI you need; otherwise explain in the study plan why you need statutorily protected records or (nearly) every box in the General Records section
4. Use everyday language in the purpose of disclosure
5. Remove the section for parent or legal representative if you are only enrolling adults who are able to consent for themselves

Take these steps to facilitate review of HIPAA waivers

1. Make sure the list of PHI is consistent across the waiver, study plan, and data collection sheet (it's ok to reference the data collection sheet)
2. If using the waiver to find potential subjects before asking them to be in the research, take only what you need to assess eligibility
3. Have a plan for someone familiar to the patient to make the first introduction to the research, e.g., send a letter from someone they recognize as having rightful access to their PHI before you call
4. Have a plan to destroy identifiers when someone declines

HIPAA FAQs

Q: What is the difference between a waiver and authorization?

A: You must have a signed HIPAA authorization from subjects before using their PHI for research purposes. A HIPAA waiver waives this requirement.

Q: I use a HIPAA waiver to find eligible subjects. I obtain consent from subjects in person, but my study has a waiver of written documentation of consent. Do subjects still have to sign a HIPAA authorization?

A: Yes

HIPAA FAQs

Q: The PI has changed on a clinical trial. Do subjects need to sign a new HIPAA authorization?

A: It depends. Active subjects should sign a new HIPAA authorization. Subjects in long-term follow-up with no interaction do not need to sign a new HIPAA authorization.

Q: Subjects signed a HIPAA authorization when they enrolled in our research. We would like to invite some of these subjects to enroll in a new study. Do we need a HIPAA waiver or authorization for this new study?

A: It depends. You do not need a waiver to recruit from existing subjects. You may need a HIPAA authorization depending on whether the new study collects new PHI.

HIPAA FAQs

Q: I need a HIPAA waiver to get records from another site. Can UMMS grant the waiver?
A: Yes, but check first with the site for any requirements it may have.
Q: Do I need a HIPAA waiver to access records for my own patients?
A: No, but they must be <u>your</u> patients, not the clinic's, not the department's, etc.

HIPAA FAQs

Q: I need a waiver for an activity that is not human subjects research (e.g., a case study, research on individuals who are all deceased). Who do I contact?

A: Contact the UMMS Privacy Officer (Loren Maloney). The IRB only grants HIPAA waivers in the context of human subjects research.

Questions?

HIPAA	Loren Maloney, JD, CHC, CHPC	Senior Privacy Officer, UMMS	Loren.Maloney@umassmed.edu Office: (508) 856-6960
IRB	Allison Blodgett, PhD, CIP	Director of IRB Operations	allison.blodgett@umassmed.edu Office: (508) 856-4271