Are you in the correct place?

This is a training module on the HIPAA Privacy and Security rules.

- Did you access this module through Mlearning?
  - If yes: Continue with this module
  - If not: If you are associated with UMHS (University of Michigan Health System), and did NOT access this course through MLearning, you will not get credit unless you log into MLearning, and enroll in the course - [Log into Mlearning](#), search for “HIPAA” and enroll in course PRIV-10012, HIPAA for Clinicians & Non-clinicians with Research Responsibilities.

- If you DID access this through MLearning OR you are NOT associated with UMHS, continue with this module.
HIPAA Learning Module: Basic

HIPAA Privacy and Security Rules...
For Clinicians and Non-Clinicians Involved in Research

University of Michigan
Updated 09/23/2013
Our Commitment to Privacy

- The University of Michigan and the University of Michigan Health System are committed to protecting the privacy and integrity of our patients’ health information.

- The HIPAA Privacy and Security Rules recognize the importance and value of this commitment.

- Protecting Patient Health Information is the responsibility of all of us.
Learning Objectives

• Key things for you to know:
  ✓ Just Ask! Check with your supervisor or the UMHS Compliance Office *whenever* you have a question or concern
  ✓ HIPAA key terms and general rules you can apply
  ✓ When you can share patient information and when there are limits to what can be used or shared
  ✓ UMHS’ *Notice of Privacy Practices (NPP)* explains patients’ rights regarding the use of their health information
  ✓ Your role in protecting patient information stored electronically
Reporting Concerns

- Report through Supervisor/Manager
- Otherwise, Compliance Office:
  - By Phone: 615-4400
  - By Email: Compliance-Group@med.umich.edu
  - Website: [http://www.med.umich.edu/compliance/index.htm](http://www.med.umich.edu/compliance/index.htm)
- Anonymous Compliance Hotline or Online Reporting:
  - Phone: (866) 990-0111

Not sure? ....Report it anyway.
Too late? ....Report it anyway.
Already told us? ....Report it again!

You cannot be retaliated against for reporting a concern in good faith!
The privacy rule gives patients more control over their Protected Health Information (PHI). So you need to know…

- Patients’ rights regarding the use of their PHI;
- Key terms and general rules that you can apply; and,
- When you can share patient information and when there are limits to what can be used or shared.
The Privacy Rule gives patients the right to:

- have their PHI protected;
- inspect and copy their records;
- request that PHI in their records be corrected or changed;
- ask for limits on how their PHI is used or shared;
- ask that they be contacted in a specific way, such as at work and not at home;
- get a list of disclosures made of their PHI.
Notice of Privacy Practices (NPP)

- Providers and Health Plans must have a Notice of Privacy Practices (NPP) - it provides a detailed description of the various uses and disclosures of PHI that are permissible without obtaining a patient’s authorization.

- You can access the UMHS’ NPP [here].

- In general, anytime you release patient information for a reason unrelated to treatment, payment (e.g., billing) or healthcare operations (TPO), an authorization is required.
Patients are asked to acknowledge receipt of the Privacy Notice on their first encounter at UMHS, to note in writing that they received a copy of the Notice.
Covered Entities

- A Covered Entity is a health care provider or a health plan that submits bills electronically.
  - Examples include: Health Systems such as the University of Michigan Health System; Hospitals; Physicians; Health Plans such as Blue Cross Blue Shield of Michigan; etc.

- All Covered Entities, along with their Business Associates and any subcontractors of their business associates, that use or access patient information on the Covered Entity’s behalf are subject to HIPAA.

- The University of Michigan is a Hybrid Covered Entity. Click here for more information.
Protected Health Information (PHI)

- PHI is health information about a patient created or received by health care providers and health plans. PHI includes information:
  - Sent or stored in any form (written, verbal, electronic);
  - That identifies the patient or can be used to identify the patient;
  - That is about a patient’s past, present and/or future treatment and payment of services.

PHI is any health information that can lead to the identity of the individual or the contents of the information can be used to make a reasonable assumption as to the individual’s identity.
HIPAA Learning Module: Basic Key Terms

**PHI includes one or more of these identifiers:**

- Names
- Addresses including Zip Codes
- All Dates
- Telephone & Fax Numbers
- Email Addresses
- Social Security Numbers
- Medical Record Numbers
- Health Plan Numbers
- License Numbers
- Vehicle Identification Numbers
- Account Numbers
- Biometric Identifiers
- Full Face Photos
- Any Other Unique Identifying Number, Characteristic, or Code
Question:
If you have a document or an electronic device such as a thumb/flash drive that contains patient initials and medical record number(s), does your document or device contain PHI?
Test Yourself

Answer: Yes.

Your document or device contains patient identifiers – patient initials and medical record number – that can be used to identify the patient(s). It does not matter that the full patient name is not included. PHI is anything that is received, sent or stored in any form by a health care provider or health plan:

- That identifies the patient or can be used to identify the patient;
- That is about a patient’s past, present and/or future treatment and payment of services.

In other words: PHI is any health information that can lead to the identity of the individual or the contents of the information can be used to make a reasonable assumption as to the individual’s identity.
Test Yourself

Take Away:

Do not use patient identifiers if you do not need to do so.

If the use of patient identifiers cannot be avoided, then only use those identifiers that you minimally need and nothing more.
Treatment, Payment and Operations (TPO)

- **Treatment [T]:** Various activities related to patient care.
- **Payment [P]:** Various activities related to paying for or getting paid for health care services.
- **Health Care Operations [O]:** Generally refers to day-to-day activities of a covered entity, such as planning, management, training, improving quality, providing services, and education.
- **NOTE:** Research is not considered TPO. Written patient authorization is required to access PHI for research unless authorization waiver is approved by the IRB. See the education program on research for more information.
Minimum Necessary Rule

Generally, the amount of PHI used, shared, accessed or requested must be limited to only what is needed. Workers should access or use only the PHI necessary to carry out their job responsibilities.

For Example:

When we bill for a blood test, the billing company is not provided with the entire medical record. Rather, we only provide the applicable diagnosis and procedure codes, etc. for the bill to be processed and paid.
Workers should have only such PHI as their job responsibilities require.

For example, someone who delivers food trays to patients may need PHI about the patient’s diet, but does not need to know why the patient is in the hospital.
What is “Use” of PHI?

- Use of PHI refers to how PHI is internally accessed, shared and utilized by the covered entity. For UMHS, “use” refers to accessing, sharing, and utilizing PHI within the health system. For other university providers such as University Health Service (UHS), “use” refers to accessing, sharing, and utilizing PHI within UHS.

What is “Disclosure” of PHI:

- Disclosure of PHI refers to how PHI is shared with individuals or entities externally. For UMHS, “disclosure” refers to sharing PHI with others outside of (external to) the health system.

Different rules apply to Use vs Disclosure of PHI
What is an Authorization?

- A written permission signed by the patient or the patient’s personal representative (e.g., a parent) to allow a Covered Entity to Use or Disclose a patient’s PHI for reasons generally not related to Treatment, Payment or Healthcare Operations (TPO purposes).

- The Authorization must include: A detailed description of the PHI to be disclosed, who will make the disclosure, to whom the disclosure will be made, expiration date, and the purpose of the disclosure.
There are 3 Types of Disclosures:

1. No Authorization Required
2. Authorization Required, but Must Give Opportunity to Object
3. Authorization Required

Each one of these is covered separately in the next three slides
1. **No Authorization is required to make the following disclosures:**

   - To disclose PHI to the patient

   - To use or disclose PHI for treatment, payment or healthcare operations (Examples: A physician discusses the patient’s condition with another consulting physician; a health provider submit a bill to a health insurance plan; and patient records are reviewed for quality improvement purposes)

   - Certain disclosures required by law (for example, public health reporting of diseases, child abuse/neglect cases, etc.)
2. **No Authorization is Required, but Must Offer Opportunity to Object:**

- The Patient must be offered an opportunity to object before discussing PHI with a patient’s family or friends.

Before discussing patient information in an exam room, ask the patient if it is okay to discuss information in front of the patient’s family member or friend. Alternatively, you can ask the family member or friend to leave, especially if the information is highly confidential.

- Limited PHI (e.g., patient’s hospital room/location number) is included in the “Hospital Directory” but patients are offered an “Opt Out” opportunity and certain disclosures to clergy members.
3. **Authorization Is Required:**

Written authorization is required from the patient for the following:

– To access, use or disclose PHI for research (unless an Institutional Review Board such as the U-M IRBMED approves a waiver of authorization)

– To conduct certain fundraising activities

– For marketing activities and sale of PHI

**NOTE:** There are additional HIPAA Training Modules for individuals involved in Research, Fundraising and/or Marketing Activities. Contact the Compliance Office at 734-615-4400
Incidental Disclosures

Some disclosures are not completely avoidable. These are permitted under HIPAA and are called “Incidental Disclosures”

- Examples of “Incidental Disclosures”: Visitors hear a patient’s name called out in a waiting room; a hospital patient in a 2-bed room hears a physician speaking to the other patient.

- HIPAA requires reasonable steps to be taken to minimize incidental disclosures such as:
  - Speaking in soft tones when discussing PHI in open areas such as the recovery room, emergency department, etc.;
  - Do not discuss PHI in public hallways, elevators or other public locations such as the cafeteria;

Only use the minimum necessary to minimize incidental disclosures
Highly Confidential Information

- Michigan and other Federal law provide even more protection than HIPAA in some cases. These “Highly Confidential” areas include:
  - Mental Health and Substance Abuse
  - HIV/AIDS Testing or Treatment
  - Genetic Tests/Information
  - Certain communicable diseases (e.g., sexually transmitted disease, hepatitis, etc.)
  - Certain diagnostic and treatment services rendered to minors like pregnancy and prenatal care
  - If you have questions about handling highly confidential information, ask your supervisor or contact hipaaquestions@umich.edu.

- Discuss with your supervisor about special precautions to protect highly confidential information.
Question:
You are a nurse asking a newly admitted patient a number of questions as part of the admission process. You see that the patient is HIV positive. Would it be appropriate for you to discuss the patient’s HIV status in front of the patient’s accompanying family member?
Because HIV status is highly confidential information, it is subject to greater protections beyond HIPAA. If you need to discuss the patient’s HIV status, you must take extra precautions to prevent others (including other patients) from overhearing the information. In this scenario, you should not discuss any highly confidential information in front of the patient’s family member without patient’s permission. Instead, require that the family member to leave the room before proceeding with gathering your information to complete your admission paperwork.
• Use your electronic access to information systems only to perform your job-related duties and only access PHI on a need-to-know basis

• All electronic systems are audited – a log of all accesses is maintained and designed to protect patient privacy

• Inappropriate access to a patient’s electronic medical record can lead to disciplinary action, up to and including termination from employment
Test Yourself

Question:
Would it be permissible for you to look up a coworker’s address in the electronic medical record so you can send the coworker a get well card?
Test Yourself

Answer: No.

You cannot access a coworker’s electronic medical record. If you need information about a coworker, check with your supervisor. Accessing the electronic medical record system for purposes other than to complete your job responsibilities is not permitted. Inappropriate access to a patient’s electronic medical record can lead to disciplinary action, up to and including discharge.
Right of Access to Medical Record Information

- Patients have the right to obtain a copy of their medical record – generally within 30 days of their request. Some exceptions exist.
- Patients have a right to request an electronic copy of their health information held in an electronic medical record system.
- If a patient request copies – paper or electronic – direct them to the Medical Records/Health Information Management Department which will manage the request within the appropriate time frames.
HIPAA Learning Module: Basic

Sharing Immunization Records

- HIPAA allows Health Care Providers to share immunization records directly with schools with either written or verbal consent from the parent or guardian (for minor child) or from the individual (for adults)
- If verbal consent is obtained, document the consent in the patient’s medical record
- Best Practice at UMHS: Immunization records can be obtained directly by the patient or, the parent in the case of a minor, through the patient portal (MyChart). Encourage the person to sign up for the patient portal and they can then access immunization records directly and provide the record to the school themselves
Information Security

- Use difficult to break passwords
- Never share your password with another person
- Log off from all electronic record applications (e.g., the electronic medical record system) before walking away from the computer
- Secure all electronic records using encryption – Call IT support to set up secure electronic systems
- Do not save any PHI on unencrypted portable electronic devices such as laptop computers, flash/thumb drives, electronic tablets, etc., whether you personally own the device or if it was purchased by UMHS
- Immediately report to your Supervisor or the UMHS Compliance Office if any of these devices are lost or stolen
Protecting Electronic Data

Sensitive information stored on computers and other electronic devices must be appropriately secured. To do this, you should:

- Avoid internet threats
- Encrypt the data
- Create and use strong passwords
- Secure computers and other mobile devices
- Report immediately if the device is lost or stolen

Refer to:

http://www.safecomputing.umich.edu/main/phishing_alerts/
http://www.itcs.umich.edu/help/faq/viruses.php
In addition to encryption, a “strong” password is an important way to protect confidential information stored electronically.

- Use at least 8 characters (9 or more is ideal), unless limited by system capabilities.
- Use at least 3 of the following character types:
  - lowercase letters
  - uppercase letters
  - numbers
  - symbols (@, %, $, & etc.)
  - punctuation marks (?!, etc.)
- Do not use names, identifiers, simple phrases or words in any language ("password", "michigan", your user ID, "hello2u", etc.)
- Do not use sequences of characters or keys ("123456", "abcdef", "qwerty", etc.)
- Use different passwords on different systems so if one password is lost or stolen, there is no risk to the other systems.
- To help you remember your password, create an acronym from a phrase and substitute letters with numbers and symbols. For example, pick a phrase that is meaningful to you, such as "Moose Tracks ice cream is better with sprinkles". Using that phrase as your guide, you might use "MT1c1bw$" (where the "i"s have been replaced with "1"s and the "s" with "$")) for your password.
- For more information, see http://www.itcs.umich.edu/itcsdocs/r1162/
HIPAA Learning Module: Basic

Internet Threats

- Phishing
- Malware
- Personal E-mail
- Cloud Computing
Phishing is unwanted e-mail ("spam") that tries to trick you into revealing confidential information, like your user name and passwords, credit card information, etc.

Do NOT reply to any e-mail message that might be a phishing attempt. Do NOT click on links or download files if you are not sure they are safe.

See [http://www.med.umich.edu/u/compliance/area/phishing.htm](http://www.med.umich.edu/u/compliance/area/phishing.htm) for more information.
Malware is software designed to harm your computer. Malware gets into your computer through e-mail attachments, compromised websites, etc.

Malware is blocked through an up-to-date antivirus software program and antispyware scanning program. Contact your IT Support for help.

Examples: Computer virus, worms and spyware. It can destroy your data and cause inappropriate access to or disclosure of sensitive information such as PHI.
Cloud computing gives access to computer files and programs over the internet, and may include backing up or synchronizing those files with a cloud service provider.

Gmail, Google Calendar, Google Docs, etc. are examples of “Cloud Services”.

NEVER store PHI or other sensitive information on public cloud services*

*A Business Associate Agreement is required before doing so. As of 09/2013, no cloud service Provider has entered into a BAA with either U of M or with the UMHS.
UMHS Users: Email within the UMHS E-mail System is secure (using your “@med.umich.edu” e-mail to others within the same system.)

UMHS Users: E-mail sent outside of the UMHS E-mail System is NOT secure. Examples: “@umich.edu” or “@gmail.com” email account.

Personal E-mail

Do NOT transmit PHI or other sensitive information to or from your personal email.

Internet Threats
HIPAA Learning Module: Basic

**E-mailing PHI**

- **For UMHS E-mail Users:** E-mail to e-mail transmission within the UMHS E-mail System ("med.umich.edu") is considered secure, but use/send only the minimum necessary PHI.
  - E-mail from the UMHS e-mail system to any other system is **not** secure (This includes email to a “umich.edu” address or to a hotmail®, yahoo®, comcast®, or other type of personal e-mail address)

- **For non-UMHS users:** Check with your supervisor for department-specific procedures for emailing PHI

- Do not send documents or files that contain PHI from the UMHS E-mail System to an external system or vice versa. Use a secure file transfer system such as MiShare or check with your supervisor. Click [here](#) for more information.
Proper Encryption makes data on computers and other electronic devices unreadable. Users must have an “encryption key” to “unlock” the encryption to access the data.

All sensitive information, including PHI, must be encrypted prior to being sent electronically outside of the University of Michigan Health System. These outside/external communications include electronic communications sent from persons within UMHS to persons within U of M.
Encryption Resources

At UMHS, Contact Medical Center Information Technology (MCIT) for assistance with encryption.

For Non-UMHS: Check with your supervisor and work with your IT Support for determining appropriate encryption methods available to you. See http://safecomputing.umich.edu/protect-personal/what-is-encryption.php for more information.
Test Yourself

Question:

Which of the following is a strong password?

A. Michigan1
B. 1234abcd
C. MT1c1bw$
**Test Yourself**

**Answer: C.**

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<td>A. <strong>Michigan1</strong></td>
<td><strong>This is a weak password.</strong> Do not use names, identifiers, simple phrases or words in any language (&quot;password&quot;, &quot;michigan&quot;, your user ID, &quot;hello2u&quot;, etc.)</td>
<td></td>
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<tr>
<td>B. <strong>1234abcd</strong></td>
<td><strong>This is a weak password.</strong> Do not use sequences of characters or keys (&quot;123456&quot;, &quot;abcdef&quot;, &quot;qwerty&quot;, etc.)</td>
<td></td>
</tr>
<tr>
<td>C. <strong>MT1c1bw$</strong></td>
<td><strong>This is a strong password.</strong> Mix numbers, letters and special characters to create a strong password</td>
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Computers, Etc.

- Log out or Lock your computer when you leave
- Position your screen away from public areas
- Place Printers and fax machines where PHI can be printed should not be positioned in public areas (like waiting rooms)

Mobile Devices

- Mobile devices with PHI or other sensitive information should be encrypted and password protected. If not able to encrypt, they should physically secured in a locked drawer or safe
Report Lost or Stolen Devices

Report immediately if the device is lost or stolen

Even if you just suspect a security incident (e.g., your laptop might have been stolen, but you don’t know for sure), immediately notify your IT Service Provider.

Within UMHS - Contact the **MCIT Help Desk** at (734) 936-8000.
HIPAA was modified between 2009 and 2013.
Under these modifications…
All violations are **PRESUMED** a “BREACH”

As a result: All HIPAA incidents must be analyzed under a 4-prong test to overcome this Breach presumption. *This analysis is conducted by the UMHS Compliance Office. This analysis must be documented and retained for 6 years. (Thus, do NOT do this analysis yourself!)*

You don’t need to know the 4-prong test, **BUT YOU MUST REPORT ALL PRIVACY CONCERNS!**

4-prong test:

1. **Nature and extent of information involved,** including the types of identifiers and risk of re-identification
2. Unauthorized person who used the PHI or to whom it was disclosed
3. Whether the PHI was actually acquired or viewed
4. Extent to which risk to the PHI has been mitigated
When there is a Breach, the Covered Entity must provide written “Breach” notice:

- To Every Individual Affected
- To Federal Government - Department of Health & Human Services/Office for Civil Rights (“OCR”)
- To Media – If >500 individuals residing in single state or “jurisdiction” (e.g., SE Michigan)

The Covered Entity is subject to tight time frames for sending these breach notices

So it is important that you **Immediately** report all HIPAA concerns!
When is a “Breach” discovered?

Breach is “discovered” as soon as an employee or another agent knows or should reasonably have known of the incident causing the breach

The “clock” will start ticking the moment you become aware of a privacy or information security violation

Your duty: Report the violation immediately – even just a suspected violation
Under the 2013 modifications:

- **Civil Fines Increased Up to $1.5 million** per HIPAA violation per year (prior max was $25,000/violation/year)

- **Criminal fines**: $250,000/up to 10 years imprisonment, **criminal penalties expanded to individuals**. NOTE: Individuals (This means You!) can be subject to criminal prosecution, fines and imprisonment
The Covered Entity’s policies require disciplinary action be taken against individuals for violating HIPAA, up to and including discharge.
PRACTICAL APPLICATION

FOR HEALTH CARE PROFESSIONALS ...
GENERAL RULES

How Do I Apply These Rules?

- Accessing a patient’s electronic medical record is allowed if access is necessary for you to do your job, including taking care of the patient (for treatment) or quality improvement (for health care operations.)

- Accessing a patient’s electronic medical record is not appropriate if access is not necessary (do not access for curiosity purposes)
GENERAL RULES

If Protections Are in Place:

- Except in public locations like the cafeteria or elevator, you can talk with other providers or patients, even if you may be overheard.
- You can verbally arrange for services at nursing stations.
- You can discuss a patient’s condition with the patient, other providers.
- You can discuss information with the patient, even in a patient’s semi-private room.
GENERAL RULES

If Protections Are in Place:

- You can talk about patient conditions in our education programs.
- Prescriptions can be discussed between you and a pharmacy or with the patient by phone.
- Messages can be left on answering machines or with those who answer the phone, but the message should be limited to minimum necessary and sensitive information like HIV status should not be disclosed.
GENERAL RULES

If Protections Are in Place:

- You must try to honor patient requests about how and where to reach them, such as at work instead of at home.
- Sign-in sheets can be used but should not ask the reason for the visit.
- Patients’ names can be called in waiting rooms or over speakers.
GENERAL RULES

If Protections Are in Place:

- Charts at bedsides or outside exam rooms are allowed, but consider having them face backwards (a reasonable safeguard to minimize incidental disclosure.)

- Patient care signs can be posted, such as for special diet needs.

- X-ray boards and whiteboards are allowed.

- PHI can be shared in group therapy settings for treatment.
HIPAA Learning Module: Basic

ADDITIONAL INFORMATION FOR THOSE INVOLVED IN RESEARCH...
The definition of “research” is the same under the Common Rule and HIPAA *BUT* the application is different . . .

**Common Rule**
- a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge
- applies *only* to human subjects (i.e. live people)

**HIPAA**
- a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge
- applies to records and data, for living *and generally* for deceased patients
HIPAA Authorization IS Needed

- Written Patient permission or "authorization" is needed to use or share PHI for research.
Authorization must address specific issues and include all of the following elements:

- What information will be used or disclosed
- Who can use or disclose
- Who can receive the information
- Purpose of disclosures
- Right to revoke authorization
- Notification of any consequences of refusing to sign the authorization (e.g., no participation in the research project)
- Warning: once authorized information is disclosed, it may no longer be protected under HIPAA
- Expiration date or event (may be “at the end of the project” or “none”)
- Signature, date, and (if applicable), authority of representative to sign
Authorization Exceptions

Authorization requirement is subject to some exceptions:

1. Waiver of authorization (approved by IRB or Privacy Board)
2. Use of PHI “preparatory to research”
3. Use of decedents’ information for research purposes
4. Disclosure of limited amounts of PHI under a “data use agreement”
1. Waiver of Consent and Authorization

- Most studies regulated under the Common Rule are conducted under active written informed consent
- Some studies qualify for a “waiver” of written informed consent or a waiver of documentation of consent under the Common Rule
- HIPAA permits a waiver of “authorization” – but Common Rule waiver of informed consent versus a HIPAA waiver of authorization are NOT the same thing
A waiver may be granted by an IRB or a Privacy Board only if certain conditions are met:

**IRB-Common Rule:**
- Minimal risk to subjects
- No adverse effect on subject’s rights
- Impracticable to do research without waiver
- Information to subjects when appropriate

**IRB or Privacy Board-HIPAA:**
- Minimal risk to subjects’ privacy
  - Adequate plan to protect identifiers
  - Adequate plans to destroy identifiers (break links) when and if possible
  - Written assurance no inappropriate re-use or re-disclosure
- Impracticable to do research without waiver and without access to PHI

Even if your project is “exempt” from IRB oversight under the Common Rule, you still may need a waiver from the IRB or Privacy Board under HIPAA!
2. PHI may be used without authorization for “reviews preparatory to research”
   - Researcher must demonstrate to UM (through the IRB or Privacy Board) that:
     • the PHI will be used only to prepare a protocol
     • no PHI will be removed from UM or disclosed outside UM
     • the PHI to be used is necessary for the research purpose
   - Purpose of exception is to prepare a protocol, e.g., facilitate study design work or feasibility analysis – can also facilitate subject recruitment in some cases
   - Exception is available only to UM workforce members (no sharing outside UM, e.g. with collaborators at other sites)
   - The information reviewed under this exception may not be used for the research project itself or for any future project; only name/contact information should be extracted for recruitment
RESEARCH Authorization Exceptions

3. PHI may be used or shared for research on decedents’ information...

- Researcher must demonstrate to UM (through the IRB or Privacy Board) that:
  - use or disclosure is only for research on decedents’ information
  - deaths are documented
  - PHI to be used or disclosed is necessary for the research purpose
- Note: deceased individuals are not considered human subjects under the Common Rule, but in most circumstances their records and data are still subject to HIPAA
RESEARCH
Authorization Exceptions

4. PHI in a “limited data set” may be used or shared without authorization for research purposes
   – The researcher must sign a “Data Use Agreement” (a simple one-page contract)
   – At UM, the Data Use Agreement must be filed with and approved by the Privacy Board or its designee (Contact the UMHS Compliance Office for further guidance.)
RESEARCH

Limited Data Sets - Definition

- **A limited data set may include:**
  - geographic information like city and zip code (but not street address)
  - dates (including dates of birth, death, admission and discharge), and age in hours, days, months or years

- **A limited data set may not include any of the following information with respect to the patient, patient’s household members, or patient’s employer:**
  - Name; street address; telephone and fax numbers; e-mail, URL, and IP addresses
  - Social security, medical record, health plan beneficiary or account numbers, certificate/license numbers, vehicle identifiers and serial numbers, including license plate numbers
  - Device identifiers and serial numbers; biometric identifiers, including finger and voice prints; and full face photographic or comparable images
Privacy Board (PB)

- HIPAA permits a privacy board to grant a waiver to the “authorization” requirement that applies to most research activities
- Includes people with relevant experience and expertise, including at least one non-affiliated (community) member
- At UMHS, the PB makes determinations regarding HIPAA compliance for exempt human subjects’ research and for activities not regarded as human subjects research

Institutional Review Board (IRB)

- Functions under the Common Rule to review, approve, and maintain oversight over human subjects research; HIPAA permits the IRB to approve authorization waivers as well
- Includes people with relevant and diverse experience and expertise, including at least one non-scientist and at least one non-affiliated (community) member
- At UMHS, the IRBMED incorporates HIPAA requirements into its regular review process, except for projects that do not require use or sharing of PHI
**RESEARCH**

**Implementation at UMHS**

- HIPAA allows either an IRB or a “Privacy Board” to grant a “waiver of authorization” for use or disclosure of PHI for research purposes (including creation/maintenance of research databases).
- At UMHS, the Privacy Board also assists in other ways, including:
  - Certifications for reviews preparatory to research
  - Certifications for research on decedents’ information
  - Approval of data use agreements
  - Clearinghouse/expertise on privacy issues relevant to human subjects research projects
- A privacy board is not authorized to review and approve research under the Common Rule.
HIPAA requires covered entities to “account” for many research-related disclosures made without patient authorization

Exceptions:
- internal uses do not need to be tracked
- disclosures made through a limited data set with a data use agreement do not need to be tracked
- disclosures of “deidentified data” do not need to be tracked (no information listed included in the data set)
- disclosures made in studies involving more than 50 subjects do not need to be tracked if we keep a list available of all such studies, including title, PI, and contact information

See UMHS policies/procedures for accounting of disclosures or contact the IRBMED
No PHI in Research

– If you are conducting a project without use of PHI, HIPAA does not apply but IRBMED’s informed consent template must be used for all new projects and scheduled continuation reviews

– **Caution!**
  
  • If you do a blood test or radiological scan or other procedure only for research purposes, and not related to treatment, the information may not be PHI and your project is not regulated by HIPAA; *but*
  
  • If the test or results information passes through the subject’s UM electronic medical record (“EMR”) (because the medical record number is used and/or information is derived from and/or posted to the EMR or other clinical information systems), then HIPAA may apply
Multicenter Trials

- **Four ways to share PHI with other centers:**
  - Written permission from the subject/patient (authorization)
  - Waiver from IRB or Privacy Board
  - Limited Data Set with Data Use Agreement
  - Deidentified data (nothing on “PHI” list)

- **When we need information from other centers for our own research projects:**
  - The IRBMED informed consent template is intended to comply with the privacy rule and to allow any health care provider or health plan to disclose PHI to us (or UMHS to disclose PHI to our co-investigators) for research purposes.
  - However, every site may have its own rules and policies.
  - If another site or a sponsor requires an additional form to be signed by your subject, IRBMED must review and approve that form in advance.
## RESEARCH
Application: Subject Recruitment
Alternatives Under HIPAA

<table>
<thead>
<tr>
<th></th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review Preparatory to Research</td>
<td>Simple Application to Privacy Board</td>
<td>For internal use only; should only get name/number; can’t use information collected for the project</td>
</tr>
<tr>
<td>Waiver of Authorization from Privacy Board</td>
<td>Simple Application to Privacy Board</td>
<td>Possible accounting requirement; IRB MED approval needed re: recruiting procedures</td>
</tr>
<tr>
<td>(Partial) Waiver of Authorization from IRB MED</td>
<td>Can disclose information outside UM (e.g., use survey vendors); can use information for the project</td>
<td>Time required for IRB MED application; possible accounting requirement</td>
</tr>
<tr>
<td>Tell Patients About Study Opportunities But Let Them Contact Study Staff</td>
<td>No disclosure of PHI (docs with existing treatment relationship can always tell their patients about possible studies) so no HIPAA issues</td>
<td>Makes recruitment process passive and therefore likely less effective</td>
</tr>
<tr>
<td>Written Permission</td>
<td>Can use information collected for the project; no accounting</td>
<td>Generally must discuss with/obtain from patient at point of care; may need IRB review/approval</td>
</tr>
</tbody>
</table>
We can create and maintain databases or registries for treatment, payment, and health care operations (“TPO”) purposes without patient authorization - TPO activities include:

– Clinical care, billing, utilization review
– Quality assurance/assessment, accreditation activities
– Education, planning

IRB or Privacy Board approval is required to access a TPO database for research purposes (even reviews preparatory to research)

Written patient permission or IRBMED or Privacy Board approved waiver is needed to create and maintain a database or registry solely for research purposes . . . patient permission, if sought, must be specific as to research purpose (HIPAA prohibits “blanket” authorizations)
“Screening logs”

- If no use or disclosure of PHI, no HIPAA issue (information received directly from a subject through a survey is not PHI; but if the survey information is verified or supplemented by medical record information, then PHI is used.)

- If the log includes PHI but was created or used for TPO purposes, then ok to continue maintaining without patient permission.

- If the log includes PHI and is used only for research purposes, need patient authorization or IRB or Privacy Board waiver of authorization.

- Alternatives for sending data from screening log to sponsors (without patient or IRB/Privacy Board authorization):
  - “De-identify” the data (no elements listed on the “PHI” list may be present in the data set sent)
  - Provide a “limited data set” with a data use agreement
Existing Datasets

- HIPAA does not require that existing datasets be destroyed.
- New data cannot be added into an existing research dataset without written authorization or waiver, unless the data is first deidentified (all identifiers listed on the “PHI list” are eliminated) or made part of a limited data set.
- Data cannot be removed from an existing dataset for research purposes without IRB or Privacy Board approval.
RESEARCH

Application: IRBMED or Privacy Board?

- **IRBMED**
  - Any research project subject to federal regulations for the protection of human subjects.
  - Reviews preparatory to research may be submitted to IRBMED

- **Privacy Board**
  - Waiver of authorization for a project that does not require IRBMED review (e.g., exempt from Common Rule oversight)
  - Review preparatory to research
  - Research on decedents’ information
  - Limited data sets disclosures
HIPAA Learning Module: Basic

ADDITIONAL INFORMATION FOR YOUR AWARENESS...
Business Associate:

- Vendors who have access to or use PHI on our behalf must have a Business Associate Agreement - a signed agreement promising to keep PHI confidential in accordance with HIPAA.

- Example: A company developing order entry software must see actual PHI so they would need a written agreement.

NOTE: Contact the UM Procurement Office for help to determine if a Business Associate Agreement is needed with a vendor.

You may need to take the additional HIPAA training module on business associates, depending on your job responsibilities. Talk to your Supervisor or call the UMHS Compliance Office (615-4400)
**MARKETING AND FUNDRAISING**

Written Permission IS Needed

- Patient permission or “authorization” is needed to use or share PHI for certain marketing and fund-raising activities.

For example, a doctor cannot give a diaper company the names of pregnant patients without an authorization that includes what the PHI will be used for, who can use it and for how long.

**NOTE:** Contact the UMHS Compliance Office for more information about fundraising and marketing of 3rd party products or services.
Questions?

For questions about HIPAA:  
http://www.med.umich.edu/u/compliance/area/privacy/index.htm

For more information:  
http://www.hhs.gov/ocr/privacy/  
http://www.cms.hhs.gov/HIPAAAGenInfo/
FAQs

- You must complete the next section on Frequently Asked Questions (FAQs).
- Click HERE to Continue to the FAQ Section.
- External Individuals who are taking this module prior to interacting with UMHS: After reviewing the FAQ section, be sure to click on and complete the form on the last slide of the FAQ section. This is the only way for you to get a certificate and credit for this education module.