research purposes. The hospital based training program pertains to health care, while the Office of Research Compliance and Assurance requires that all researchers and key personnel complete HIPAA training as it pertains to research reviewed by the IRB.

This tutorial satisfies the training requirement set fo

researchers

- Establishes criminal and civil penalties for improper use and disclosure
- Gives the patient the right to: receive a Notice of Privacy Practice, list of possible disclosures, inspect / copy / amend their medical record, request alternate communications, and file a complaint about violations

2) One of the following criteria must be met:

- IRB Waiver of Subject Authorization
- Review Preparatory to Research
- Use of Limited Data Set with Data Use Agreement
- Research using Decedents' Information (note: decedent research not covered by Common Rule)
- Use of De-identified Data and no longer governed by HIPAA

All research projects that use PHI will fall into one of the categories listed above. The remainder of this tutorial describes the various conditions for using PHI in research and information about how the rules are being applied at the University of South Alabama.

Research Use of PHI with Authorization

Written authorization from the subject is the default requirement for use of protected health information in research. Prospective research, such as a clinical trial, generally requires prior authorization. The authorization differs from informed consent in that the authorization obtains specific permission to use and disclose protected health informm

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process. A full committee review will be required in those circumstances where a waiver has been requested by risk to the subject's privacy is considered to be greater than minimal. The IRB follows the Common Rule when reviewing the waiver request. Once the IRB has approved the waiver of authorization, the investigator must provide the covered entity maintaining the PHI with documentation from the IRB of approval. A waiver of authorization may be sought for three specific research uses of PHI to identify potential research subjects through:

review of their PHI
to contact potential subjects in order to determine their interest in research participation
to receive or collect PHI during the conduct of research studies

Reviews Preparatory to Research

The Privacy Rule recognizes the necessity of accessing PHI, without patient authorization, in order to prepare a research protocol. This "preparatory to research" provision may be useful for examining medical records in order to formulate hypotheses, assess feasibility of a project, or determine the availability of data or a patient base. Researchers may **review** identifiable data in order to make these determinations; however, HIPAA requires that any information recorded during the review must meet de-identification standards. Thus, the preparatory review may not be used for study recruitment because researchers may not record names and contact information from the charts.

In order to release records for a preparatory review, the holder of the medical record must receive certain documentation from the researcher. Under this provision of the regulations, the investigator must provide the following assurances to the covered entity:

The information is being sought solely to prepare a research protocol or for similar purposes
Only de-identified data will be recorded during the review
No protected health information will be removed from USA campuses.
The information being sought is necessary for research purposes.

The Privacy Rule does not require IRB approval of activities preparatory to research. As a general rule, this pre-research activity will not require an IRB application because no formal protocol exists. Questions about the necessity of IRB review should be directed to the IRB office. Investigators may use PHI as preparatory to research if the investigator certifies the above provisions by completing Appendix D, Reviews Preparatory to Research form available in IRBNet in Forms and Template.

Research Involving Decedents and Limited Data Sets

Research on decedents is not subject to human subject regulations; however, the Privacy Rule now requires that we oversee the use of decedent information for research purposes. In order to access medical records on decedents, the researcher must provide the holder of the medical record with assurances that:

The information being sought is solely for research on decedents
The information being sought is necessary for research purposes

The holder of the medical record has a right to require documentation of the death of the individuals.

Investigators may use PHI in research on decedent's information if the investigator certifies the above provisions by completing the Appendix E, Research Involving Decedent's form available in IRBNet in

Forms and Templates. This certification should be given to the holder of medical records for access to the information.

Research Involving the Use of Limited Data Sets

Regulations permit covered entities to use or disclosure PHI for research purposes without subject authorization if the use or disclosure only involves a "limited data set" and the covered entity enters into a data use agreement with the investigator. A "limited data set" is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual subjects:

- Names
- postal address information, other than town or city, state and zip code
- telephone numbers
- fax numbers
- email addresses
- social security numbers
- health plan beneficiary numbers
- account numbers
- certificate/license numbers
- vehicle identifiers and serial numbers
- device identifiers and serial numbers
- web universal resources locators (URLs)
- Internet protocol (IP) address numbers
- biometric identifiers, including finger and voice prints
-

De-identified data, Subject's Rights, and Recruitment

De-Identified Information

The de-identified health information under HIPAA is much more specific than the general de-identification standard applied under the federal laws relating to human research subjects. PHI can be released freely if it does not contain "individually identifiable information." PHI is not individually identified if the subject is not identified, directly or indirectly, and has no reasonable basis to believe that the information can be used to identify the subject. For example, a de-identified data set might include age, gender, marital status, ethnicity, diagnosis codes, and other medical data or an unidentified tissue sample. It may be used in research without subject authorization or a waiver of authorization. The Privacy Rule refers to such health information as "de- identified data." Research which involves the use of "de-identified data" is exempt from the HIPAA requirements. To be exempt from HIPAA, none of the 18 subject identifiers can be reviewed or recorded by the research team. In

Pre-screening Logs

Pre-screening logs which are used to document recruitment efforts in clinical trails often include PHI, such as initials, or dates of procedures. These logs should NOT be shared with a pharmaceutical sponsor without some form of privacy protection. In order to comply with the Privacy Rule, the data may be de-identified prior to sharing with the study sponsor. Alternately, if de-identified data is not feasible, the study sponsor can sign a Data Use Agreement and obtain the information in the form of a Limited Data Set.

Repositories and Databases

Research Repositories:

It may be necessary to create a repository that will support future research activities. The Privacy Rule specifies three ways in which PHI can be compiled for a research repository:

- individual, written authorization obtained from the subject
- waiver of the individual authorization requirement obtained from an IRB
- the PHI is obtained from a covered entity in a limited data set and accompanied by a data use agreement

If the repository is being created as new patients come to USA hospitals, the collection of data or tissue samples generally requires informed consent and authorization for the use and disclosure of PHI. Researchers should note that if approval is granted for the general purpose of constructing and maintaining the repository, then subsequent studies of the material also require IRB oversight. Depending on the nature of the subsequent study, the IRB will determine whether informed consent/HIPAA authorization is required or if the informed consent/HIPAA authorization requirement is waived.

Research Databases:

If a researcher maintains a database containing PHI, then the investigator has an obligation to insure that the use and disclosure of PHI is in compliance with HIPAA policies.

A. Maintaining applicable security for the database, including physical security and access control;

B. Control and manage the access, use and disclosure of PHI, including verifying appropriate IRB approvals and patient authorizations; and

C. Any PHI in the database used for treatment or payment purposes must be a duplicate and the original must be included in the patient's medical record.

Remember, HIPAA applies to uses of PHI. In order to use a research database containing PHI, one must have authorization or a waiver from the IRB. Another pathway to using PHI in a research database is by utilizing a limited data set and completion of a Limited Data Use Agreement, enabling certain identifiers to be used during the research study. The users of a tissue bank database would need to obtain individual authorization or a IRB waiver if he/she wanted to use and disclose the information in a research study.

Security

Computer Security for Research Records

HIPAA requires that privacy of PHI be maintained by limiting its use and maintaining appropriate computer

Additional Resources

Additional information and resources regarding the HIPAA Privacy Rule are available at:

DHHS Office of Civil Rights HIPAA Website: https://www.hhs.gov/hipaa/

National Institutes of Health: HIPAA Privacy Rule- Information for Researchers
https://privacyruleandresearch.nih.gov/pr_02.asp

Resources referenced to create this training module include:

USA HIPAA Research Website (HIPAA Research Compliance Plan):
http://www.southalabama.edu/departments/research/compliance/humansubjects/hipaa.html

Office for Civil Rights HIPAA Guidance, December 2002

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