HIPAA COMPLIANCE INFORMATION

The Health Insurance Portability and Accountability Act of 1986 (**HIPAA**) and associated privacy regulations were enacted, among other things, to establish federal standards regarding the use and disclosure of protected health information. On August 14, 2002, the Department of Health and Human Services issued a final rule (the **"Privacy Rule"**) establishing standards for privacy of individually identifiable health information with compliance required as of April 14, 2003.

The effect on research will be in the use of “Protected Health Information" (**PHI**) which is health information that includes identifiers.

Health information includes physical or mental health information whether it is past, present, or future as it is created, collected, or conceived in any medium: electronic, written, or verbal.

HIPAA regulated Patient identifiers include:

- Account Numbers
- Biometric identifiers
- Certificate/License numbers
- Dates
- Device identifiers
- Email addresses
- Fax numbers
- Health Plan Numbers
- IP address numbers
- Name(s) of relative(s)
- Names
- Medical Record Number
- Photographs and comparable images
- Postal Address
- Social Security Number
- Telephone numbers
- Vehicle identifiers including license plate numbers
- Any other unique identifying number, characteristic, or code

• Web URL's

CODED INFORMATION IS STILL PHI. Anything that could be used to identify an individual is an identifier, i.e. a linked code number.

PHI can only be used or disclosed in the following circumstances:

- For treatment, payment, or health care operations;
- If the individual authorizes the use or disclosure (clinical research);
- If the use or disclosure is permitted or required by law (public health reporting);
- If the **I**nstitutional **R**eview **B**oard grants a waiver of authorization.

HIPAA Authorization:

The UNTHSC HIPAA Policy mandates that permission is required to use patient information. To access UNTHSC HIPAA Policy, please visit the UNTHSC website.

If the study involves the collection and/or retention of *Protected Health Information*, individual **HIPAA Authorization** must accompany the informed consent process. For UNTHSC Investigator-Initiated Human Subject Research Protocols (i.e. not Sponsored Clinical Trials), please use the UNTHSC HIPAA Authorization template found on the North Texas Regional IRB website. NOTE: John Peter Smith protocols should use the HIPAA Authorization Form authorized and approved by their institution.

Alternatively, researchers may request a waiver of, or an alteration to, the Privacy Rule's requirement to obtain an individual's authorization to use or disclosure their **PHI** for research purposes. Note that a solid justification for the waiver request is needed. ***Usually, a waiver does not apply to prospective research studies.***

The Minimum Necessary Standard:

HIPAA regulations give subjects ***PRIVACY RIGHTS***, which means that they have the right to access their **PHI**, even in research. It is limited to the **PHI** in the designated record set. A "designated data set" is a group of records that a covered entity (**UNTHSC**) uses to make decisions about individuals, and includes a health care provider's medical record and billing records, and the health plan's enrollment, payment, claims adjudication, and case or medical management record systems.

Researchers need to limit the collection and/or use of **PHI** to the minimum amount necessary to accomplish the intended purpose. Only collect health information essential to the study and record as few identifiers as possible.

RESEARCHER RESPONSIBILITIES:

ACCESS TO PHI:

- Understand permissible route of access
- Use Authorization forms and Data Use Agreements

RESTRICTIONS ON USE/DISCLOSUREE OF PHI:

- Implement necessary safeguards - (*data protection and database registering*)

MINIMUM NECESSARY STANDARD:

- Limit the amount of **PHI**

PATIENT RIGHTS: ACCOUNTING AND ACCESS TO RECORDS:

- Log all uses and disclosures of **PHI** that are performed for preparatory research, decedent research, or under a waiver
- Subject may ask where their information has been sent, who has seen it, and for what purpose.

FOUR WAYS TO ACCESS PHI FOR RESEARCH PURPOSES:

1) Get authorization from subjects
2) Use de-identified data
3) Use a Limited Data Set with a Data Use Agreement
4) Obtain a waiver of authorization

Obtain Authorization:

- Authorization is combined with the consent document or attached to as a continuation of the document. See the IRB website for UNTHSC HIPAA Authorization Template. NOTE: JPS researchers should use the HIPAA Authorization Form authorized / approved by their institution.
- The guidelines that apply to whom may give and obtain Authorization are the same as those for consent.

Using De-identified Data:

Two Ways to De-Identify:

- Remove all HIPAA identifiers (see above for list)
- Statistical Certification: get a statistician to certify that de-identification methods have resulted in a "very small" risk that the information could be used to identify the individual

Using a Limited Data Set for Research:

Data may be used or disclosed as a "limited data set" with a data use agreement:

- A limited data set allows the inclusion of some identifiers
- A data use agreement specifies why the PHI will be used, who will use it, limits further disclosure or use, and requires recipient to enter into a similar agreement with agents or subcontractors
- There are no accounting requirements associated with using a Limited Data Set

LIMITED DATA SET ELEMENTS

Excluded:	**Included:**
Account number	Zip Codes
Addresses	Geocodes
Biometric identifiers	Date of birth
Certification/license number	Other date information
Device identification/serial number	Any other codes not specified at left

Email address

Fax numbers

Full face photograph; any comparable image

Health Plan Beneficiary number

IP address number

Names

Medical record number

Social Security number

Telephone numbers

Vehicle identification/serial number

Web URL's

Obtain a Waiver of Authorization:

Where appropriate, researchers may request a waiver of, or an alteration to, Individual Authorization under HIPAA. This means researchers are requesting to alter certain HIPAA elements, or completely waive the Privacy Rule's requirement to obtain an individual's authorization for the research use or disclosure of their identifiable health information (or **PHI).** See the IRB website for the HIPAA Waiver Request Form.

OTHER ITEMS TO CONSIDER:

Using PHI for Preparatory Research

An investigator may access health information to prepare a research protocol if the researcher certifies:

- Review is necessary to prepare a research protocol
- No health information will be removed by the researcher during the review
- Minimum Necessary Standard applies
- Accounting Procedure applies

Using PHI for Decedent Research

Researcher may review health information of deceased persons without authorization, if the researcher certifies that:

- Review is solely for research purposes
- Information that is sought is necessary to conduct the research
- Minimum Necessary Standard applies
- Accounting Procedure applies

Application Notes

A **HIPAA** authorization must be detailed and include a specific description of the use of **PHI** and specific identification of persons to whom PHI will be disclosed. When developing an Authorization, **THINK AHEAD**. If your intended use or disclosure is not in the Authorization, it can't be done without getting a second Authorization.