HIPAA COMPLIANCE INFORMATION

HIPAA Policy

Use of Protected Health Information for Research Policy

University of North Texas Health Science Center at Fort Worth

Applicability: All University of North Texas Health Science Center (UNTHSC) faculty, staff, and students involved in research activities.

UNTHSC Privacy Policy

This policy supplements the requirements of the UNTHSC "Protected Health Information Privacy Policy." The purpose of this policy is to describe the procedure for conducting research involving Protected Health Information (PHI). The federal "Health Insurance Portability and Accountability Act" ("HIPAA") Privacy Rule directly applies to "covered entities": health plans, health care clearinghouses, and health care providers who transmit health information electronically. Under HIPAA, UNTHSC is a "covered entity". Researchers who obtain Protected Health Information from covered entities (whether inside or outside of UNTHSC) to conduct research must comply with the HIPAA rules pertaining to use and disclosure of PHI for research.

Definitions:

Disclosure: the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information. .

Protected Health Information ("PHI"): individually identifiable health information transmitted or maintained in any form or medium, including oral, written, and electronic communications. Individually identifiable health information relates to an individual's past, present or future health status or condition, furnishing health services to an individual or paying or administering past, present or future health care benefits to an individual. Information is considered PHI where the individual is identified or there is a reasonable basis to believe the information can be used to identify an individual.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

Use and Disclosure of PHI for Research

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information if done in accordance with this policy and the HIPAA Privacy Rule. As a general rule, a researcher must obtain a patient authorization from all participants in research prior to the internal use or external disclosure of PHI for any research related purpose that is not otherwise permitted or required under this Policy. However, patient authorization is not needed under limited circumstances set forth in the HIPAA Privacy Rule.

(A) Research Use/Disclosure With Individual Authorization.

(1) The Privacy Rule permits covered entities to use or disclose Protected Health Information for research purposes when a research participant authorizes the use or disclosure of information about his or her health information.

(2) The IRB will provide an Authorization template that complies with HIPAA requirements. The researcher must complete the Authorization template and submit it to the IRB for prior review and approval.

(3) To use or disclose Protected Health Information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the Privacy Rule. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes. The authorization must contain each of the following items:

(a) A description of the extent to which PHI will be used or disclosed.

(b) A specific description of the PHI to be disclosed; the person(s) that will be using or disclosing the PHI; the person(s) authorized to receive the PHI; the purpose(s) for which the PHI will be used/disclosed.

(c) A statement as to whether the PHI will be subject to use by or re-disclosure to entities not covered by the HIPAA Privacy Rule.

(d) The expiration date or expiration event for use or disclosure of the PHI.

(e) A statement of the patient's right to revoke the authorization.

(f) A statement that treatment, payment, enrollment or eligibility for benefits cannot be conditioned upon the patient's signing the authorization. However, participation in research may be conditioned on a signed authorization, including treatment protocols.

(g) A statement that the PHI that is disclosed may potentially be re-disclosed and may no longer be protected under HIPAA.

(h) The individual's signature (or that of his/her authorized representative) and date. The individual must be provided with a copy of the signed authorization.

(4) Special provisions apply to research authorizations:

(a) Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the "end of the research study;" and

(b) An authorization for the use or disclosure of Protected Health Information for research may be combined with consent to participate in the research, or with any other legal permission related to the research study.

(5) Individual's Access to Research Information

(a) As a general rule, individuals who participate in research have a right to access their own PHI that is

maintained in a Designated Record Set of a Covered Entity. Designated Record Sets are those that are used to make treatment, payment and healthcare operations decisions about individuals. In general, research data sets are not among the "Designated Record Sets" of a Covered Entity. However, the Covered Entity's Designated Record Sets include the individual's medical records, payment records, etc. All data about an individual that is generated in clinical research and entered into the individual's medical or financial records at the Covered Entity are that individual's PHI.

(b) Individuals participating in research protocols that include treatment (for example, a placebo controlled clinical trial) may be temporarily denied access to their PHI obtained in connection with that research protocol, provided that:

(i) The PHI was obtained in the course of the research;
(ii) The individual agreed to the denial of access in the Research Authorization;
(iii) The research remains in process; and
(iv) The individual's rights to access such PHI are re-instated once the research study has concluded.

(6) Individual's Revocation of Authorization.

(a) As a general rule, an individual may revoke his/her authorization, in writing to the Principal Investigator, at any time.

(b) The revocation will be applicable to the protocol or protocols specified by the individual. However, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the individual pursuant to a valid authorization before it was revoked.

(c) The Principal Investigator shall maintain a copy of each written revocation and shall report them to the IRB at the time of continuing review.

(B) Research Use/Disclosure Without Authorization. To use or disclose Protected Health Information without authorization by the research participant, a covered entity must obtain one of the following:

(1) Documented IRB or Privacy Board Approval. Documentation that an alteration or waiver of research participants' authorization for use/disclosure of information for research purposes has been approved by an Institutional Review Board (IRB) or a Privacy Board. At UNTHSC, any such waiver of authorization must be approved by the UNTHSC IRB. A covered entity may use or disclose protected health information for research purposes pursuant to a waiver of authorization by an IRB, provided it has obtained documentation of all of the following:

- Identification of the IRB and the date on which the alteration or waiver of authorization was approved;
- A statement that the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria in the Privacy Rule;
- A brief description of the Protected Health Information for which use or access has been determined to be necessary by the IRB;
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the chair or other member, as designated by the chair of the IRB.

The following three criteria must be satisfied for an IRB to approve a waiver of authorization under the Privacy Rule:

(a) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

- An adequate plan to protect the identifiers from improper use and disclosure;
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
- Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(b) The research could not practicably be conducted without the waiver or alteration; and

(c) The research could not practicably be conducted without access to and use of the Protected Health Information.

(2) Preparatory to Research:

To allow use of this method, the covered entity must require representations from the researcher, either in writing or orally, that the use or disclosure of the Protected Health Information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any Protected Health Information from the covered entity, and representation that Protected Health Information for which access is sought is necessary for the research purpose.

(3) Research on Protected Health Information of Decedents:

This alternative requires representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on the Protected Health Information of decedents, that the Protected Health Information being sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is being sought.

(4) De-Identified Health Information:

Individual health information that conforms to the HIPAA definition of “de-identified” is exempt from HIPAA and may be used or disclosed for research purposes without an authorization or waiver of authorization or data use agreement. Researchers must provide documentation to the IRB that the health information has

been de-identified by one of the following two methods:

(a) Method 1: Health information is de-identified if a set of specific identifiers is deleted before the information is released by the covered entity to the researcher. These identifiers are the following:

- Names
- Address (including all geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geo-codes, except for the initial three digits of most zip codes)
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death
- All ages over 89 and all elements of dates (including year) indicative of age over 89, except that ages over 89 may be aggregated into a single category of “age 90 or older”
- Telephone number
- Fax number
- E-mail address
- Social security number
- Medical record number
- Health plan beneficiary number or account number
- Certificate/license number
- Vehicle identifiers and serial numbers including license plate numbers
- Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric indicators such as fingerprints or voiceprints
- Full-face photographic images and any comparable images
- Any other uniquely identifying number, characteristic, or code that could be used to identify the individual

Also, neither the covered entity nor the researcher has a reasonable basis to believe that the information can be used alone or in combination with other information to identify an individual.

(b) Method 2: The second method of de-identifying under HIPAA allows a person with appropriate knowledge and experience to apply generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable to make a determination that there is a very small risk that the information could be used by others to identify a subject of the information, and documents the methods and results of the analysis that justify such determination.

(5) Limited Data Sets with a Data Use Agreement:

This alternative involves a data use agreement entered into by both the covered entity and the researcher, pursuant to which the covered entity may disclose a limited data set to the researcher. A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. *The data use agreement must:*

- Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;
- Limit who can use or receive the data; and
- Require the recipient to agree to the following:

    * Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
    * Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
    * Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
    * Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
    * Not to identify the information or contact the individual.

Under the limited data set approach, the following identifiers of the individual, relatives, employers, and household members of the individual must be removed before the data is released by the covered entity to the researcher:

- Names
- Postal address information other than city, State, and zip code
- Telephone and fax numbers
- E-mail address, URLs and IP addresses
- Social security number
- Medical record numbers, health plan beneficiary numbers and other account numbers
- Device identifiers and serial numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plates
- Full face photos and other comparable images
- Biometric identifiers including fingerprints and voiceprints

The IRB has templates for Internal and External Data Use Agreements. See “HIPAA Compliance” for these

templates.

(C) Publications or Public Presentations:

PHI from research may not be included in presentations or publications of any type unless explicitly permitted by either the individual's authorization or the IRB's waiver of authorization and in accord with the terms and conditions of all existing agreements governing how that individual's information may be used including: the terms and conditions of IRB approval of the research protocol, the authorization or waiver of authorization, the informed consent or waiver of informed consent, any data use agreement that has been executed, etc.

(D) Transition Provisions.

For Research involving PHI and carried out according to a protocol reviewed and approved by the IRB prior to April 14, 2003:

a. A research study may continue to use or disclose the PHI created or received prior to April 14, 2003 without HIPAA documentation.

b. A research study operating under a waiver of informed consent approved by the IRB prior to April 14, 203, may continue to create, receive, use, and disclose PHI for the study after April 14, 2003, without an IRB Waiver of Authorization unless the research study subsequently seeks informed consent, in which case an authorization would be required together with the informed consent.

c. If the protocol approved by the IRB before April 14, 2003, required the obtaining of an informed consent, then with respect to any individual who has executed informed consent before April 14, 2003, no additional authorization is required to create, receive, use and disclose that individual's PHI for the approved study.

d. For any research participant for which informed consent is required, any informed consent or reconsent on or after April 14, 2003, must include an authorization for use or disclosure of the subject's PHI. If the research has been previously approved but will be enrolling participants on or after April 14, 2003, the researcher must submit a protocol revision to the IRB in order to include an individual authorization with any informed consent obtained on or after April 14, 2003.

(E) Texas Medical Privacy Act.

Enactment of the Texas Medical Privacy Act (added by Acts 2001, 77th Leg.) added Chapter 181 ("Medical Records Privacy") to the Texas Health and Safety Code. Chapter 181 greatly expands the list of entities that will be affected by the HIPAA privacy regulations. Although the HIPAA Privacy Rule narrowly defines "covered

entity," Chapter 181 defines "covered entity" to include "any person who…comes into possession of protected health information." The compliance date for Chapter 181 is September 1, 2003.