TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO
Office of Institutional Compliance

Texas Tech University Health Sciences Center El Paso
HIPAA Privacy Policy

Policy: ~~HPP 4.9~~ Using and Disclosing PHI- Research- Using PHI	~~**Effective Date:** July 5, 2016~~ Policy # HPP 4.9
~~Research- Using PHI~~ Effective Date: July 5, 2016	**Last Revision Date:** ~~May 17, 2022~~ July 16, 2024
References: ~~http://www.hhs.gov/ocr/hipaa~~ https://www.hhs.gov/hipaa/index.html 45 CFR Part 164.512	

Policy Statement

Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) recognizes that an individual's rights to privacy and confidentiality are a critical aspect of maintaining quality care and service and is committed to allowing individuals to exercise their right to privacy and confidentiality under the HIPAA Privacy Rule, and other applicable federal state and/or local laws and regulations. To support this commitment, TTUHSC El Paso will maintain and update, as appropriate, written policies and procedures to ~~provide guidance on~~guide employee and organizational responsibilities regarding using, disclosing, or requesting protected health information (PHI) to be used in research.

Scope

This policy applies to all PHI maintained by TTUHSC El Paso.

Policy

De-Identified Health Information is health information that is not "individually identifiable health information" and, as such, is not protected by the Privacy Rule because it does not meet the definition of PHI. Two methods of determining this are acceptable:

1. The first method is the "Expert Determination" method. If a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable determines:
    a. that the risk is ~~very small~~minimal that information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is the subject of the information; **and**
    b. documents the methods and results of the analysis that justify such determination.
2. The second method is the "Safe Harbor method. This requires:
    a. the following eighteen (18) identifiers related to the patient, ~~his/her~~their relatives, employers, or household members are removed:
        1) Names;
        2) All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for ~~3~~ three digits of a zip code if according to the current publicly available data from the Bureau of the Census:
            i. the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people~~,~~ and

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ii. the initial ~~3~~ three digits of a zip code for all such geographic units containing 20,000 people or fewer is changed to "000".

3) All elements of dates (except year) for dates that are directly related to an individual, including birth date, discharge date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category age 90 and older;
4) Telephone numbers;
5) Fax numbers;
6) E-mail addresses;
7) Social Security numbers;
8) Medical record numbers;
9) Health plan beneficiary numbers;
10) Account numbers;
11) Certificate/license numbers;
12) Vehicle identifiers and serial numbers;
13) Device identifiers and serial numbers, including license plate numbers;
14) Web Universal Resource Locators (URLs);
15) Internet Protocol (IP) address numbers;
16) Biometric identifiers, including finger and voice prints;
17) ~~Full face~~Full-face photographic images and any comparable images;
18) Any other unique identifying number, characteristic, or code, except as permitted under HIPAA (45 CFR 164.514(c)) to re-identify data

AND

b. The covered entity does not ~~have actual knowledge~~know that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

Human Subjects are defined by the Department of Health and Human Services as living individuals about whom a researcher conducting research obtains data or biospecimens through intervention or interaction with the individual~~,~~ or obtains identifiable private information or biospecimens (45 CFR 46.102~~[f]~~(e)(1)(i)(ii). The FDA defines a human subject as an individual who is or becomes a research participant, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Commented [AM1]: Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
Not sure if you wanted to leave it summarized or include the full information. The regulation number changed with the revised common rule.

Limited Data Set is a subset of de-identified information that includes dates and any specific identifiers (1, 2, and 4-18 listed above) that ~~are required to~~must be removed to create de-identified information.

Protected Health Information (PHI) means individually identifiable health information maintained or transmitted by TTUHSC El Paso or any other Covered Entity in any form or medium, including information transmitted orally~~,~~ or in written or electronic form. PHI does NOT include employment records held by TTUHSC El Paso ~~in its role~~ as employer or education records covered by the Family Educational

Rights and Privacy Act (FERPA) 45 CFR 160.103. See also HPP 1.1 Glossary of HIPAA Terms.

Research means a systemic investigation, including research, development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

TTUHSC El Paso Privacy Board ~~means~~ is the TTUHSC El Paso Institutional Review Board (IRB) designated pursuant to the TTUHSC El Paso IRB Policies and Procedures.

Procedure

1. **Authorization**

The HIPAA Authorization form or a request for a Waiver of Authorization shall be included in initial applications for any human research project ~~which~~ that utilizes protected health information. Generally, TTUHSC El Paso investigators should obtain an "Authorization to Use and/or Disclose Your Protected Health Information for Research Study" before using or disclosing PHI.

Such authorization shall satisfy the requirements of 45 CFR § 164.508, except that the authorization may state that it does not expire, that there is no expiration date or event, or that it continues until the end of the research study. ~~The authorization form may not be altered by an investigator~~An investigator may not alter the authorization form. Any request to ~~alter~~ modify the HIPAA document should be submitted to the TTUHSC El Paso HIPAA Privacy Officer using the "Addendum to Authorization to Use and/or Disclose PHI for Research Study" form found at https://elpaso.ttuhsc.edu/hipaa/

The authorization form must be reviewed and signed ~~at the same time~~simultaneously as the consent to participate in the research form and/or any other legal permission form related to the research study is completed. Research involving Psychotherapy Notes cannot be combined with any other Authorizations.

The ~~original completed authorization form is retained by the investigator~~investigator retains the original completed authorization form in the research regulatory binder. A copy of the authorization form shall be filed in the subject's medical record.

2. **Waiver of Authorization**

TTUHSC El Paso may also use and disclose specified PHI for research purposes without an individual's authorization and/or without the necessity for an opportunity to agree or object under limited circumstances with documented Privacy Board approval. For purposes of HIPAA, the TTUHSC El Paso

Institutional Review Board will act as Privacy Board as defined by 45 CFR Part 164.512(i). IRB administrators shall verify Privacy Board Agreements with affiliated Entities are in place before a Privacy Board Review. The IRB Director is a member of the Privacy Board and may acknowledge HIPAA waiver requests. All IRB decisions are documented in the IRB meeting minutes and communicated to the principal investigator and designated research team members via the iRIS system.

3. Waiver of Authorization for Human Research

Principal Investigators may request to use and disclose specified PHI without an individual's specific authorization and/or without the necessity for an opportunity for the individual to agree or object for research purposes provided that the criteria required by 45 CFR 164.512(i) are satisfied. These criteria include:

a. The intended use and/or disclosure of the Protected Health Information (PHI) ~~involve~~involves no more than a minimal risk to the privacy of the individuals.
b. The research could not practicably be conducted without the waiver.
c. The research could not practicably be conducted without access to and use of the protected health information.

HIPAA Waiver questions are included in the IRB Application Form in iRIS and ~~are to~~will be completed by investigators who wish to request a waiver of HIPAA Authorization. Responses to the questions are reviewed by a member of the Institutional Privacy Board and will be acknowledged as part of the IRB review process.

4. Waiver of Authorization – Preparatory to Research

PHI may be used or disclosed to a researcher in preparation for research without authorization consistent with 45 CFR Part 164.512(i)(1)(ii). To obtain a Waiver of HIPAA Authorization in preparation for research, the Principal Investigator should complete the relevant section of the Principal Investigator's Request to Use and Disclose PHI Without an Authorization form found at https://elpaso.ttuhsc.edu/hipaa/ completed forms should be submitted to the HIPAA Privacy Officer, to a local IRB Administrator (acting in the role of Privacy Board member) for review.

The review by a Privacy Board member is to assure each of the following:

a. Use or disclosure is solely to review PHI as necessary to prepare a research protocol;
b. PHI will not be removed from TTUHSC El Paso; and
c. PHI is necessary for research purposes.

5. Waiver of Authorization for Decedent Information

Principal Investigators may request to use and disclose specified PHI without an individual's specific authorization and/or without the necessity for an opportunity for the individual's family member(s) or representative(s) to agree or object for research purposes provided that the criteria required by 45 CFR 164.512(i)(1)(iii) are satisfied.

To obtain a Waiver of HIPAA Authorization to obtain information about a decedent's PHI, the Principal Investigator should complete the relevant section of the Principal Investigator's Request to Use and Disclose PHI Without an Authorization form found at https://elpaso.ttuhsc.edu/hipaa/.Completed forms should be submitted to the HIPAA Privacy Officer, to a local IRB Administrator (acting in the role of a Privacy Board member) for review.

The review by a Privacy Board member is to assure each of the following:

a. The use or disclosure is sought solely for research on the protected health information of decedents;
b. ability to provide documentation of the death of such individuals; and
c. ~~That the protected health information for which use or disclosure is sought is necessary for the~~ The protected health information for which use or disclosure is sought is necessary for research purposes.

6. De-identified Data

A researcher may utilize a de-identified data set (as defined above) without a subject's Authorization.

7. Limited Data Set

A researcher may use a Limited Data Set (as defined above) for research purposes if the researcher enters into a Data Use Agreement. Refer to HPP 6.2 Data Use Agreements

Knowledge of a violation or potential violation of this policy must be reported directly to the Institutional Privacy Officer or the Fraud and Misconduct Hotline at (866) 294-9352 or www.ethicspoint.com under Texas Tech University System.

Frequency of Review

This policy will be reviewed on each even-numbered year (ENY) by the Institutional Privacy Officer, Office of Research, and the HIPAA Privacy and Security Committee, but may be amended or terminated at any time.

Questions regarding this policy may be addressed to the Institutional Privacy Officer or the Institutional Compliance Officer.

Review Date: ~~May 9, 2022~~July 8, 2024

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Revision Date: August 9, 2016, July 18, 2017, May 17, 2022, July 16, 2024