Uses and Disclosures of PHI

Policy # 2.4.1

Disclosing PHI for Research

Original Effective Date: 10/24/2016

Revised Date: 3/22/2022

Purpose: To establish a formal process to ensure the privacy and confidentiality of PHI when participating in research activities that involve the disclosure of PHI.

Policy: Travis County Covered Components will use de-identified information whenever possible. If de-identified information cannot be used, Travis County Covered Components generally obtain either (1) patient or client authorization, (2) a complete or partial waiver, or (3) a data use agreement. All research projects are evaluated on a case-by-case basis, and participation in research activities is allowed only when approved in accordance with the process set forth in this policy. Failure to submit research proposals in accordance with this process may result in the denial of research requests.

Process:

1. Covered Components wishing to participate in research involving PHI will provide the research proposal to the HIPAA Compliance and Privacy Officer and/or Legal Counsel as soon as possible for evaluation, and no later than **3** weeks prior to the expected release of the data. Proposals submitted to the HIPAA Compliance and Privacy Officer and/or Legal Counsel must be approved through any internal department processes first. The research proposal must:
    - Include the name and contact information of the researcher
    - Identify the purpose of the research
    - Identify the subjects or class of subjects whose PHI will be required as part of the research
    - Identify the data fields to be provided and/or analyzed in the course of research
    - Describe how the research is likely to benefit Travis County or its clients
    - Demonstrate a plan for maintaining the confidentiality of any PHI requested
    - Provide a date by which the data will be required by the researcher

2. If the researcher represents that the data to be disclosed by the Covered Component is not PHI, Covered Components must verify the accuracy of the researcher's statement. Covered Components will consult the policy entitled, "De-identification of PHI" to confirm that the requested data does not constitute a "specific identifier" as set forth in 45 C.F.R. 164.514 (e)(2). In the event that the Covered Component is unable to confirm that the data is not PHI, the Covered Component will provide the research proposal to the HIPAA Compliance and Privacy Officer and/or Legal Counsel. The HIPAA Compliance and Privacy Officer and/or Legal Counsel will determine whether the research involves PHI; **when requested**, the HIPAA Compliance and Privacy Officer will make this determination.

3. The HIPAA Compliance and Privacy Officer or Privacy Liaison will review the research proposal and, where necessary, contact the researcher to obtain further documentation. The documentation required to be submitted is listed in procedure 4 below.

4. The HIPAA Compliance and Privacy Officer or Liaison may approve the disclosure of PHI when the researcher presents any one of the following:

Documentation	Requirements
Valid Authorization	Disclosure may be approved when: Covered Components are able to obtain valid Authorizations from Individuals for participation in the study. Valid Authorizations are obtained in accordance with policy 2.4, Authorization for the Release of PHI.
Written proposal to review PHI in preparation for research	Disclosure may be approved when the researcher certifies in writing that: • The disclosure of PHI is necessary to prepare a research protocol or other similar preparatory purpose. • The PHI will not be used in any research prior to IRB approval. • The PHI will not be removed from the Covered Component. • De-identified data cannot be used for this purpose. PHI released for this purpose allows researchers to do such things as identify prospective research participants, review charts or records, and review data base queries. Recruitment of Individuals for a study is <u>not allowed</u> as part of these activities.

Written representations 5. Prior to	Disclosure of *decedents' information* may be approved when the researcher: • Represents that the disclosure pertains solely to deceased individuals • Produces documentation of the death of such individuals; and • Represents that the PHI to be disclosed is necessary for the research.
Signed Data Use Agreement	Disclosure of a limited data set must be approved by the Travis County Commissioners Court. The Commissioner's Court is the signatory for any data use agreement executed with the researcher. The HIPAA Compliance and Privacy Officer works with legal counsel and the Covered Component to: • Ensure that the limited data set excludes the direct identifiers set forth in 45 C.F.R. 164.514 (e)(2). • Ensure that the data use agreement is appropriately executed prior to the data release.

5. Prior to making such disclosures:

   a. The HIPAA Compliance and Privacy Officer must have all documentation supporting the release of the data.
   b. The Security Officer must determine that the proposed method of transmitting the data is secure.

6. Unless the data is disclosed as part of a limited data set or pursuant to a valid Authorization, disclosures for most research purposes must be tracked in accordance with the policy entitled "Accounting of Disclosures."