



## Uses and Disclosures

### Policy # 2.4.1

## Disclosing PHI for Research

Original Effective  
Date:

10/24/2016

Revised Date:

**Purpose:** 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 Privacy Officer or the department Privacy Liaison as soon as possible for evaluation, and no later than three weeks prior to the expected release of the data. Proposals submitted to the Privacy Officer or Privacy Liaisons 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.

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 Privacy Officer or Privacy Liaison. The Privacy Officer or Liaison will determine whether the research involves PHI; when requested, the Privacy Officer may assist the Privacy Liaison in making this determination.

2. The 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 3 below.

3. The Privacy Officer or Liaison may approve the disclosure of PHI when the researcher presents any one of the following:

Documentation	Requirements
<b>Valid Authorization</b>	<p>Disclosure may be approved when:</p> <p>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.</p>
<b>Written proposal to review PHI in preparation for research</b>	<p>Disclosure may be approved when the researcher certifies in writing that:</p> <ul style="list-style-type: none"> <li>• The disclosure of PHI is necessary to prepare a research protocol or other similar preparatory purpose</li> <li>• The PHI will not be used in any research prior to IRB approval.</li> <li>• The PHI will not be removed from the Covered Component</li> <li>• De-identified data cannot be used for this purpose.</li> </ul> <p>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.</p>
<b>IRB/Privacy Board Waiver of Authorization</b>	<p>Disclosure may be approved when a legally established Institutional Review Board (IRB) or privacy board has followed proper review procedures in approving a waiver to HIPAA's Authorization requirement. The following documentation must be obtained and approved by the Privacy Officer and legal counsel:</p> <ul style="list-style-type: none"> <li>• A statement identifying the board, and the date that the alteration or waiver of Authorization was approved.</li> <li>• A statement that the board approved the alteration or waiver of Authorization because the following criteria were met: <ul style="list-style-type: none"> <li>○ Use or disclosure of the PHI involves no more than a minimal risk to the privacy of Individuals based on, at least, the following elements: <ul style="list-style-type: none"> <li>▪ An adequate plan to protect the identifiers from improper use and disclosure;</li> </ul> </li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>▪ An adequate plan to destroy the identifiers at the earliest opportunity unless a health or research justification for retention of the identifiers exists, or retention is required by law; and</li> <li>▪ Adequate written assurances that the PHI will not be reused or disclosed to any one, except: as required by law, for authorized oversight of the study, or for other research that a use or disclosure of the PHI would be permitted by HIPAA <ul style="list-style-type: none"> <li>○ The research could not practicably be conducted without the waiver or alteration; and</li> <li>○ The research could not practicably be conducted without the PHI.</li> </ul> </li> <li>• A brief description of the PHI that the board has determined to be necessary to use or access for the study.</li> <li>• A statement that the waiver was reviewed and approved under either normal or expedited review procedures and in accordance with the applicable requirements of 45 C.F.R. 164.512(i)(2)(v)(A)-(C)</li> <li>• Signature of the board chair or other member, designated by the board chair</li> </ul>
<p><b>Written representations</b></p>	<p>Disclosure of <i>decedents' information</i> may be approved when the researcher:</p> <ul style="list-style-type: none"> <li>• Represents that the disclosure pertains solely to deceased individuals</li> <li>• Produces documentation of the death of such individuals; and</li> <li>• Represents that the PHI to be disclosed is necessary for the research.</li> </ul>
<p><b>Signed Data Use Agreement</b></p>	<p>Disclosure of a limited data set must be approved by the Travis County Commissioners Court. The Commissioners Court is the signatory for any data use agreement executed with the researcher. The Privacy Officer works with legal counsel and the Covered Component to:</p> <ul style="list-style-type: none"> <li>• Ensure that the limited data set excludes the direct identifiers set forth in 45 C.F.R. 164.514 (e)(2).</li> <li>• Ensure that the data use agreement is appropriately executed prior to the data release.</li> </ul>

- 4. Prior to making such disclosures:
  - a. The 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.
- 5. 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."