

<p style="text-align: center;">The University of Texas SOUTHWESTERN MEDICAL CENTER At Dallas</p>	<p style="text-align: center;">Privacy Compliance Program Privacy Manual</p> <p style="text-align: center;">Section 7: Standard Protocols for Uses, Disclosures and Requests of PHI</p> <p>Policy No: 7.30 Last Revised: March 10, 2003 Effective Date: April 14, 2003</p>
<p>Research Recruitment</p>	

POLICY:

UT Southwestern may not use Protected Health Information (PHI) to recruit research participants without written authorization from the Individual or an IRB waiver of authorization, unless a prior treatment relationship with the Individual exists. UT Southwestern will not disclose PHI for a research purpose, including recruitment, without written authorization from the Individual or an IRB waiver of authorization.

DEFINITION;

Research recruitment means reviewing PHI in medical records of Individuals for the purpose of identifying potential candidates for participation in a IRB approved research protocol and contacting Individuals who have been identified as potential research participants to inquire if they are interested in participating in an IRB approved research protocol.

PROCEDURE:

1. Access For Research Recruitment Activities by UT Southwestern Workforce
 - a. Treating health care providers, researchers, or their staffs may review PHI in medical records of Individuals for the purpose of identifying potential candidates for participation in an IRB approved research protocol as described in this section.
 - i. Treating health care providers, or their staff, may review PHI of Individuals from within their own medical practice for the purpose of identifying potential study candidates.
 - ii. Prior to receiving access to PHI, researchers without a prior treatment relationship with the Individuals who are the subject of the PHI, will either obtain the Individual’s written authorization or obtain a waiver of authorization as described in Section 7.27 of this Manual, which sets forth the policy and procedure on Waiver or Alteration of Research Authorizations.
 - b. Only treating health care provider(s) may contact the Individual directly to request participation in the study, without prior written authorization from the Individual or an IRB waiver of authorization. Treating health care providers may

designate an individual to contact potential research subjects on their behalf. The designated individual(s) must:

- i. Act under the direct supervision, and on behalf of the treating physician;
 - ii. Be qualified to explain the research project to the potential subject; and
 - iii. Have access to the PHI by virtue of a treatment-based relationship.
-

LEGAL REFERENCES:

45 C.F.R. 164.502(a)(1)(i), 164.512(i)(1)(ii)

65 Fed. Reg. 82462, 82537, 82701

67 Fed. Reg. 53182, 53230-31