

<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 Section 7: Standard Protocols for Uses, Disclosures and Requests of PHI Policy No: 7.27 Last Revised: March 10, 2003 Effective Date: April 14, 2003</p>
<p>Waiver or Alteration of Research Authorizations</p>	

POLICY:

UT Southwestern may use or disclose Protected Health Information (PHI) for purposes of research without the Individual’s written authorization where an IRB has granted a waiver of the requirement to obtain authorization or an alteration of authorization requirements.

DEFINITION:

A waiver of authorization is documentation, approved by the IRB, that states the use or disclosure of PHI for the proposed research meets the criteria to waive or alter the authorization requirements under the Privacy Rule.

PROCEDURE:

1. Submission of Waiver/Alteration Requests
 - a. This Policy permits UT Southwestern to consider requests (i) to waive the requirement to obtain a research authorization from an Individual to use or disclose PHI for research, or (ii) to alter a research authorization previously signed by an Individual to permit uses or disclosures of PHI that were not originally addressed in the research authorization.
 - b. Requests pursuant to this Policy may only be submitted by Principal Investigators.
 - c. The Principal Investigator who seeks the waiver/alteration may submit the request to the IRB office using the form available on the IRB website.

2. Review of Waiver/Alteration Requests
 - a. The IRB office will assign the request to an IRB chair for consideration.
 - b. The assigned IRB chair will review the request in accordance with the criteria in Section 3 of this Policy and in accordance with its full, expedited, or exempt review procedures.
 - c. The assigned IRB will render a determination in writing to the Principal Investigator.
 - d. If the waiver is approved, the IRB will issue an approval.

- e. If the research study requires access to the PHI of another covered entity, Principal Investigators will present the approved waiver document to the affiliated hospital or collaborating institution in order to gain access to PHI.
3. Waiver/Alteration Criteria. An IRB may grant a waiver or alteration request relating to PHI if it satisfies the following criteria:
- a. The use or disclosure of PHI involves no more than a minimal risk to the privacy of Individuals based on, at least, the presence of the following elements:
 - i. an adequate plan to protect the identifiers from improper use and disclosure;
 - ii. 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
 - iii. adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.
 - b. The research could not practicably be conducted without the waiver or alteration. This criterion is not satisfied in situations where the authorization requirement is merely inconvenient. For example:
 - i. Interventional research, such as most clinical trials, will not meet this criterion because a Principal Investigator who will have direct contact with research subjects should, in virtually all cases, be able to practicably seek and obtain an Individual's authorization for the use and disclosure of PHI for the research study.
 - ii. A records review study might meet this criterion if, for example, the study involved thousands of records, or if the contact information was unknown, making it *impracticable* to obtain authorization from each individual
 - c. The research could not practicably be conducted without access to and use of the PHI.
 - i. The purpose of this criterion is for Principal Investigators to demonstrate to the IRB why PHI is necessary for the research proposal. In considering this criterion, the IRBs should consider the amount of information that is needed for the study.
 - ii. For example, if a Principal Investigator could practicably use de-identified health information for the research study, PHI should not be used or disclosed for the study without authorization.
4. Minimum Necessary Rule
- a. UT Southwestern requires that the information to be used or disclosed pursuant to the waiver or alteration is the minimum reasonably necessary as required by the Privacy Laws.
 - b. UT Southwestern will meet this compliance obligation through reliance on the representations of the Principal Investigator regarding the minimum necessary

information for the research purpose, as such is described by the Principal Investigator on the request form required by Section 1c of this Policy.

5. Documentation Requirements. The IRB office will be responsible for maintaining the documentation required by Sections 1(c) and 2(c) of this Policy for a minimum of 6 years from the date of their creation.

LEGAL REFERENCES:

45 C.F.R. 164.512(i)(1)(i), 164.512(2), 164.514(d)(3)(iii)(D), 164.530(j)(1) (2001) (as amended by 67 Fed. Reg. 53182 (2002))