I. 11.2.12 Uses and Disclosures of Protected Health Information for Research

Chapter 11 - Patient Privacy	Original Effective Date: April 2003
Section: 11.2 Uses and Disclosures of Protected Health Information	Date Last Reviewed: September 2026
Responsible Entity: Director, Institutional Review Board	Date Last Revised: September 2026

II. Purpose

UT Health San Antonio (UTHSA) protects the confidentiality and privacy of protected health information used in research by following federal regulations, professional ethics, and Institutional Review Board (IRB) policies and procedures.

III. Scope

This policy applies to all Workforce Members—including faculty, staff, students, healthcare providers, contractors, and researchers—who have direct or indirect access to Protected Health Information (PHI). This includes all PHI maintained by UTHSA and its controlled affiliates, such as clinics, hospitals, and research facilities.

IV. Policy

A. PHI for Research Activities

1. UTHSA may use or disclose PHI for research subject to the confidentiality provisions of state and federal law and following an approval by an Institutional Review Board (IRB) or Privacy Board in preparation for a research study, to recruit research subjects, or to aid in conducting a research study.
2. In some cases, the IRB or Privacy Board may determine that a patient's written authorization is not required if the research plan involves no more than a minimal risk to individual confidentiality in accordance with the law. If a patient's authorization is required, the patient will be asked to provide informed consent and written authorization before their information is included in a research study.

B. Privacy Regulations

1. The HIPAA Privacy Rule (45 CFR Parts 160 and 164) supplements existing federal regulations governing research, including the Common Rule and applicable Food and Drug Administration (FDA) regulations. The Privacy Rule provides individuals

with greater transparency regarding how their protected health information (PHI) may be used and disclosed for research purposes.

2. The Privacy Rule applies to all PHI used or disclosed for research, regardless of whether the research includes treatment or is limited to non-treatment activities.

C. Authorizations

1. The federal *Privacy Rules* (*45 CFR 160 and 164*) permits combining a HIPAA Authorization for research with other written permissions for the same research study, including the informed consent to participate in the study or another authorization. When an authorization includes both required (conditioned) and optional (unconditioned) research activities, it must clearly distinguish between them and allow individuals to choose whether to authorize the optional activities.

2. A research authorization is not required to be limited to a single study. An authorization may also permit the use or disclosure of PHI for future research, provided it clearly describes the types or purposes of the future research so that a reasonable individual would expect how their PHI may be used or disclosed.

D. IRB Policy

1. UTHSA may use or disclose PHI for research in accordance with the confidentiality provisions of state and federal law.

2. See the Institutional Review Board website for HIPAA research policies and guidance.

E. De-identified Information

1. De-identified information is health information that does not identify an individual because all applicable direct and indirect identifiers have been removed or the information has otherwise been determined to present a very small risk of identifying an individual.

2. UTHSA may determine that health information is de-identified by either: (1) obtaining a documented determination from a qualified individual with appropriate knowledge and experience who applies generally accepted statistical and scientific principles and concludes that the risk of re-identification is very small; or (2) removing all identifiers required by the HIPAA Privacy Rule so that, to the knowledge of UTHSA, the remaining information cannot reasonably be used to identify an individual. For detailed requirements and the complete list of identifiers, refer to IHOP 11.2.9 Deidentification of Protected Health Information.

F. Limited Data Set

1. A limited data set is patient health information that has had most direct identifiers removed. However, it may still include certain information, such as dates of service, dates of birth, or geographic information (for example, city, state, or ZIP code), when needed for research, public health, or health care operations. Because some identifying information remains, a limited data set is still protected under the

HIPAA Privacy Rule and may only be shared under a Data Use Agreement that limits how the information can be used and disclosed.

2. For detailed requirements, refer to IHOP policy 11.2.13 Limited Data Sets for more details.

G. Transition

1. Research studies started prior to the compliance date for the *Privacy Rules* (April 14, 2003) are able to continue after the compliance date without obtaining additional consent. Specifically, UTHSA may use or disclose PHI for research that is created or received either before or after the compliance date for the *Privacy Rules*, provided there is no agreed-to restriction, and UTHSA obtained, prior to the compliance date, either:

   a. An authorization or other express legal permission from an individual to use or disclose PHI for the research;

   b. The informed consent of the individual to participate in the research; or,

   c. An IRB waiver of informed consent for the research in accordance with the *Common Rule*.

V. Definitions

Terms used in this document have the meaning set forth in the Patient Privacy Policies Glossary *unless a different meaning is required by context.*

VI. Related References

For questions regarding this policy, contact the Privacy Program Director at 210-567-2014 or compliance@uthscsa.edu.

VII. Review and Approval History

The approving authority of this policy is the University Executive Committee.

Effective Date	Action Taken	Approved By	Approved Date
04/2003	Policy Origination		
03/2013	Policy Revision		
01/2023	Policy Review	ICPO	01/04/2023
09/2026	Policy Revision	Executive Committee	09/21/2026