



## 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: January 2023
Responsible Entity: Director, Institutional Review Board	Date Last Revised: January 2023

### I. Purpose

UT Health San Antonio 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.

### II. Scope

This policy applies to all faculty, staff, students, residents, healthcare providers, researchers, contractors, or any other individual (collectively, Workforce Member, including employees and non-employees) who has direct or indirect access to patient protected health information (PHI) created, held or maintained by any UT Health San Antonio controlled affiliate, including, but not limited to its clinics, hospitals, and research operations.

### III. Policy

#### A. Privacy Regulations

1. The federal *Privacy Rules (45 CFR 160 and 164)* are intended to build on existing federal regulations that address research, such as the *Common Rule* and Food and Drug Administration (FDA). The *Privacy Rules* allow research participants to have more information about how their PHI may be used for research than currently allowed by existing laws.
2. The Rules apply to any PHI obtained for research purposes and does not make a distinction between research that involves treatment and research that does not involve treatment.

#### B. Authorizations

1. The federal *Privacy Rules (45 CFR 160 and 164)* permits the combining of an authorization for a research study with any other written permission for the same

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study, including another authorization or informed consent to participate in the research. Specifically, a covered entity is allowed to combine conditioned and unconditioned authorizations for research, provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt into the unconditioned research activities.

2. An authorization for the use or disclosure of PHI for research purposes need not be study specific. An authorization for uses and disclosures of PHI for future research purposes must adequately describe such purposes such that it would be reasonable for the individual to expect that their PHI could be used or disclosed for such future research.

### C. IRB Policy

UT Health San Antonio may use or disclose PHI for research. See the [Institutional Review Board website](#) for HIPAA research policies and guidance.

### D. De-identified Information

1. De-identified information is information that does not identify individuals. Primary and secondary identifiers, such as patient name, address, date of birth, social security number, e-mail address, etc., have been removed from the data. Patient information that is de-identified is not subject to *Privacy Rules*; however, any codes used to render the information re-identifiable must be kept confidential and held to the same level of privacy as protected health information.
2. See the Institutional Handbook of Operating Policies policy [11.2.9 Deidentification of Protected Health Information](#) for specific requirements and a complete list of identifiers.

### E. Limited Data Set

1. UT Health San Antonio may maintain some patient information in limited data sets, which do not contain identifiers, such as name, address, social security number, but may contain date of birth and dates of treatment.
2. See IHOP policy [11.2.13 Limited Data Sets](#) for details.

### F. 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, UT Health San Antonio 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 UT Health San Antonio 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,

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

### IV. 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.

### V. Related References

For questions regarding this policy, contact the Privacy Program Director at 210-567-2014 or [compliance@uthscsa.edu](mailto:compliance@uthscsa.edu).

### VI. Review and Approval History

- A. The approving authority of this policy is the University Executive Committee.
- B. The review frequency cycle is set for three years following the last review date, a time period that is not mandated by regulatory, accreditation, or other authority.

Effective Date	Action Taken	Approved By	Date Approved
04/2003	Policy Origination		
03/2013	Policy Revision		
01/2023	Policy Review	ICPO	01/04/23