I. 11.2.16 Preparatory to Research Uses of Protected Health Information

Chapter 11 - Patient Privacy	Original Effective Date: June 2024
Section: 11.2 Uses and Disclosures of Protected Health Information	Date Last Reviewed: September 2026
Responsible Entity: Chief Compliance and Privacy Officer	Date Last Revised: September 2026

II. Purpose

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) contains a "preparatory to Research" exception to the general rule that patient Authorization must be obtained in order to use or disclose a patient's Protected Health Information (PHI). This policy explains when and how Workforce Members may use PHI for preparatory to Research purposes.

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 UT Health San Antonio (UTHSA) and its controlled affiliates, such as clinics, hospitals, and research facilities.

IV. Policy

A. Use of PHI for Preparatory to Research Purposes

1. PHI may be used without IRB permission and without obtaining the individual's written Authorization for the following preparatory to Research purposes:
   a. Developing a Research question and/or generation of Research hypotheses;
   b. Determining study feasibility;
   c. Preparing a Research protocol, including development of eligibility (inclusion and exclusion) criteria; and/or
   d. Identifying prospective Research participants who would meet the eligibility criteria for an IRB-approved protocol.
2. Except for the preparatory to Research purposes described above, all other Human Subjects Research-related activities require an IRB-approved protocol and either patient Authorization or an IRB Waiver of the Authorization requirement to continue using the PHI for Research purposes. See IHOP 11.2.12 Uses and

Disclosures of Protected Health Information for Research. Note: After an IRB has approved a Research protocol, authorized members of the research study are permitted under HIPAA to use potential participants' PHI from UTHSA-controlled facilities in order to obtain informed consent from those potential participants without obtaining a specific Waiver of the HIPAA Authorization requirement from the IRB.

B. Access to PHI for Preparatory to Research Purposes: To access and use PHI for preparatory to Research purposes, the Workforce Member

1. Must attest that:
    a. The use is sought solely to review PHI as necessary to prepare a Research protocol or for similar purposes preparatory to Research;
    b. The PHI will not be shared with anyone who is not a UTHSA Workforce Member;
    c. The PHI for which the use or access is sought is necessary for Research purposes
2. Must not remove PHI used for preparatory to Research purposes from UTHSA (physically or electronically) or share with individuals outside of UTHSA. Note: Non- UTHSA researchers and collaborators are not permitted to view UTHSA PHI for preparatory to Research purposes. Only aggregate and/or de-identified data may be shared with outside researchers engaged in preparatory to Research activities. Non-UTHSA individuals must either obtain a Waiver from an IRB to access, use, or Disclose UTHSA PHI, or enter into a Data Use Agreement to obtain access to a limited data set for Research purposes. See IHOP 11.2.13 Limited Data Sets policy.
3. Must access and store PHI securely in accordance with UTHSA's information security policies. PHI should never be stored on an unencrypted device or in a non-institutionally managed location. See IHOP 5.8.22 Data Protection policy.
4. Must limit access to or use of PHI to the minimum amount of PHI necessary to accomplish their intended purpose. For example, if a researcher needs to know patient demographics but not names, any queries or searches should be designed in a manner that excludes patient names, if technically feasible.

C. Sources of PHI

1. UTHSA clinical data (i.e., data obtained during the course of treating a patient) may be used for preparatory to Research purposes in accordance with this policy.
2. Identifiable information from patients' medical records may be accessed and used for preparatory to Research purposes.
3. Investigators may use identifiable data in Institutional Data Repositories (IDR) for preparatory to Research activities, subject to the IDR's own policies governing access and use. See the IHOP 5.8.4: Access Management.
4. In the event that UTHSA possesses another institution's identifiable clinical data, Workforce Members may not use PHI obtained from other institutions for uses preparatory to Research (however, de-identified information may be used, assuming any applicable contract between institutions allow for such use). Permission to use

another institution's clinical PHI (i.e. University Health PHI) must be obtained either from the other institution's patients through a HIPAA authorization or from an IRB in the form of a Waiver, and must be permissible under any applicable agreements between UTHSA and the other institution.

5. PHI originally obtained under a Research protocol may be subject to conditions that restrict its use for purposes other than those described in the associated protocol and informed consent/HIPAA Authorization document or IRB Waiver. Before using Research data for preparatory to Research purposes, Workforce Members should consult with the principal investigator for the original study source to confirm that the PHI and other data is not subject to any restrictions on its use.

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

11.2.12 Uses and Disclosures of Protected Health Information for Research

11.2.9 De-identification of Protected Health Information

11.2.13 Limited Data Sets

5.8.22 Data Protection

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
06/2024	Policy Origination	Executive Committee	06/10/2024
09/2026	Policy Review, Discretionary Edits	ICPO	09/21/2026