

Section: Compliance Policies

Subject: Privacy Related

Policy Number: 6.2.30

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## **I. Title**

*Use and Disclosure of PHI for Research*

## **II. Policy**

A. UTMB, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), requires that patient information be kept private and confidential.

B. UTMB protects the confidentiality and integrity of PHI as required by law, professional ethics, and accreditation requirements. The use and disclosure of PHI in research must have the appropriate authorizations and safeguards in place. The UTMB IRB review process shall make all determinations regarding the applicable federal and state privacy standards as applied to the use and disclosure of PHI for research. As a result, all personnel must strictly observe the following standards relating to the use and disclosure of PHI for research and abide by the Institutional Review Board Policies and Procedures Manual.

C. Violation of this policy may result in disciplinary action up to and including termination for employees; a termination of employment relationship in the case of contractors or consultants; or suspension or expulsion in the case of a student. Additionally, individuals may be subject to loss of access privileges and civil and/or criminal prosecution.

## **III. IRB Approval of Research and Use of De-Identified Information and Limited Data Sets**

A. In order to provide for the adequate discharge of institutional responsibility, no research activity involving human subjects may be undertaken by any faculty, staff, employee or student at UTMB or affiliated entities (e.g. Shriners Burns Hospital), unless a UTMB IRB has reviewed and approved the research prior to commencing the research activity. See the Institutional Review Board Policies and Procedures Manual for a more detailed explanation of the process and requirements related to the IRB.

B. Whenever possible, de-identified PHI should be used. De-identified PHI is rendered anonymous when identifying characteristics are completely removed. De-identified PHI may only be used and disclosed in accordance with IHOP Policy 6.2.29 De-Identification of PHI.

C. If PHI cannot be de-identified the next step should be to use a limited data set in accordance with IHOP Policy 6.2.13, Use and Disclosure of PHI for Limited Data Sets. Only when both de-identified PHI and a limited data set are inadequate can PHI be used for research.

## **IV. Research Subjects Rights to PHI**

A. A patient has a right to inspect and obtain a copy of his/her protected health information (PHI) in UTMB's designated record set; however, access to PHI created or obtained in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress if the patient has agreed to the denial of access

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when consenting to participate in the research study and has been informed that the right of access will be reinstated upon completion of the research.

B. All personnel involved with research or the release of information are to ensure that the Research Informed Consent form signed by and provided to the participant prior to enrollment in the study outlines how and if the participant may obtain a copy of documentation regarding their participation in the research study.

C. Depending on the terms of agreement for the study and the terms in the informed consent, the participant may or may not have access to the study information.

D. Documentation of human research subjects enrolled in clinical trials is not always included in the UTMB medical record because many of these research protocols do not involve traditional medical treatment and care.

E. Violation of this policy may result in disciplinary action up to and including termination for employees; a termination of employment relationship in the case of contractors or consultants; or suspension or expulsion in the case of a student. Additionally, individuals may be subject to loss of access privileges and civil and/or criminal prosecution.

## V. Documentation & Medical Record Number Assignment

A. The Principal Investigator (PI) will be responsible for working with the Health Information Management Department (HIM) and, if necessary, the Office of Research Services to determine the extent to which PHI can be disclosed according to the contract terms.

B. The PI will complete the UTMB medical record or complete the [Notice of Research Participation form](#) for inclusion in the UTMB medical record. This documentation is important for other health care providers to know, especially, if the participant has an adverse event or is seeking emergency medical treatment at UTMB. The [Notice of Research Participation](#) form will include contact information for the research study so that other UTMB treatment providers can contact the PI or other study staff to understand the drug or class of drugs the patient may be taking as part of the study.

C. If the participant will receive any clinical care as part of the participation in the research study, the participant will be registered in the UTMB system and must have a Medical Record Number assigned.

## VI. Disclosure

A. Research Study Sponsors may not obtain any PHI from UTMB unless the UTMB participant has provided authorization. This requirement is included in the IRB protocol review process. PIs are responsible for disclosing PHI to research sponsors in accordance with the informed consent process and related hospital PHI disclosure policies. ([IHOP Policy 6.2.1](#), Use and Disclosure of PHI Based on Patient Authorization).

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## VII. Management of Release

A. UTMB participants should be directed to Health Information Management (HIM) when requesting research documentation. HIM will provide any results from lab work, radiology studies or other diagnostic work ups without contacting the department PI. However, if the participant is requesting more detailed research documentation or documentation that does not exist in the UTMB medical record, HIM will work with the Office of Research Services and the PI to approve the disclosure and gather the information. The PI will be responsible for informing HIM of what information can and cannot be disclosed pursuant to the requirements of participation in the research study. The requirements of participation in the research study will be documented and addressed in the research study's informed consent documentation. Even though subjects are given a copy of their informed consent with contact information, they may not understand or know who to contact to obtain copies of their participation in the research study.

## VIII. Definitions

De-identification: Health information that does not identify an individual in any manner with no reasonable basis to believe that the information can be used to identify the individual. See IHOP Policy 6.2.29, De-identification of PHI.

Designated Record Set: The Designated Record Set includes the Unit Medical Record (UMR) and billing records of patients. The Designated Record Set also includes medical records from non-UTMB sources used to make health care decisions.

Disclosure: The release or transfer, providing access, or divulging in any other manner of protected information (PHI) **outside** of UTMB.

Institutional Review Board (IRB): A committee group comprised of UTMB personnel and community representatives with varying backgrounds and professional experience that review and approve the research protocol involving human subjects.

Limited Data Set: A limited amount of Protected Health Information (PHI) that may be used and disclosed for research, public health or health care operations. This limited amount of PHI may be shared with another entity only after both parties have executed a data use agreement. See IHOP Policy 6.2.13, Use and Disclosure of PHI for Limited Data Set.

Protected Health Information (PHI): Individually identifiable health information transmitted or maintained in any form or medium, including oral, written, and electronic. Individually identifiable health information relates to 1) the past, present, or future physical or mental health, or condition of an individual; 2) provision of health care to an individual; or 3) past, present, or future payment for the provision of health care to an individual. Information is considered PHI where there is a reasonable basis to believe the information can be used to identify an individual. Demographic information on patients is also considered PHI.

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Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Unit Medical Record (UMR): The UTMB medical record maintained by the HIM Department that is designed to contain a composite of all significant hospital and clinical information gathered on a given patient, whether as an inpatient, outpatient, or emergency care patient. Portions of the UMR may be housed at various locations throughout the UTMB system. The UMR has a permanent retention schedule.

Use: With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information that identifies, or reasonably can be used to identify, a patient within UTMB.

## **IX. Relevant Federal and State Statutes**

45 C.F.R. § 164, Subpart E – Privacy of Individually Identifiable Health Information

45 C.F.R. §164.501 – Definitions

45 C.F.R. §164.524 – Access of Individuals to Protected Health Information

Texas Health & Safety Code §181.102 – Consumer Access to Electronic Health Records

## **X. Related UTMB Policies and Procedures**

[IHOP Policy 6.2.1](#), Use and Disclosure of PHI Based on Patient Authorization

[IHOP Policy 6.2.29](#), De-Identification of PHI

## **XI. UTMB Responsible Vice President**

Vice President and Chief Compliance Officer

## **XII. UTMB Responsible Entity**

Office of Institutional Compliance

## **XIII. Dates Approved or Amended**

Originated - 4/11/2003

Reviewed with Changes

-10/08/2007

-08/26/2014

## **XIV. Contact Information**

Questions or comments about this policy should be directed to:

- 409.747.8700 (ext. 78700)