

Section 6	Compliance Policies	00/00/03	- Effective
Subject 6.2	Privacy and Disclosure		- Revised
			- Reviewed
Policy 6.2.30	Use & Disclosure of PHI for Research	Compliance Office	- Author

Use & Disclosure of PHI for Research

Audience

The information in this document applies to all UTMB faculty, staff, students, volunteers, and any other contractors or agents involved in research activities.

Definitions

Protected Health Information (PHI): Individually identifiable health information transmitted or maintained in any form or medium, including oral, written, and electronic communications. Individually identifiable health information relates to an individual's health status or condition, furnishing health services to an individual or paying or administering health care benefits to an individual. Information is considered PHI where there is a reasonable basis to believe the information can be used to identify an individual.

Use with respect to individually identifiable health information:

The sharing, employment, application, utilization, examination, or analysis of such information within the UTMB system.

Disclosure: The release, transfer, provision of access to, or divulging in any other manner of information outside of the UTMB system.

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: Protected health information (PHI) that excludes the direct identifiers listed below for the individual or of relatives, employers, or household members of the individual.

1. Names;
2. Postal address information, other than town or city, State, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;

Section 6	Compliance Policies	00/00/03	- Effective
Subject 6.2	Privacy and Disclosure		- Revised
			- Reviewed
Policy 6.2.30	Use & Disclosure of PHI for Research	Compliance Office	- Author

Use & Disclosure of PHI for Research

Definitions (cont'd)

11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Policy

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 it applies 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.

IRB Approval of Research

In order to provide for the adequate discharge of the 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. Please see the [Institutional Review Board Policies and Procedures Manual](#) for a more detailed explanation of the process and requirements related to the IRB.

Use of De-Identified Information and Limited Data Sets

Use of De-identified Information and Limited Data Sets:

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 policy 6.2.30, *Identification of PHI*.

Section 6	Compliance Policies	00/00/03	- Effective
Subject 6.2	Privacy and Disclosure		- Revised
			- Reviewed
Policy 6.2.30	Use & Disclosure of PHI for Research	Compliance Office	- Author

Use & Disclosure of PHI for Research

Use of De-Identified Information and Limited Data Sets

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

Enforcement

All supervisors are responsible for enforcing this policy. Individuals who violate this policy will be subject to the appropriate and applicable disciplinary process, up to and including termination or dismissal.

References

45 C.F.R. §164.512(e)
45 C.F.R. §164.512(i)
Texas Health & Safety Code §181.102
