



Procedure Name: General Requirements for HIPAA Compliance
Effective Date: February 26, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: CR-007, Rev 1
Application: Principal Investigators, Key Personnel
Page Page 1 of 1

PURPOSE:

The *Health Insurance Portability and Accountability Act of 1996 (HIPAA)* establishes a number of requirements and procedures. The portion of the act that is relevant to clinical research prohibits the release of *protected health information (PHI)* to anyone except the covered entity. This procedure refers to the safeguards required to protect PHI from unauthorized disclosure.

REFERENCES:

45 CFR 164	The Privacy Rule
UNTHSC Office of Research Policy	IRB Policies & Procedures, Section 18: Use of Protected Health Information.
OPHS-IRB Manual, Section 10	Privacy and Confidentiality

SCOPE:

US regulations (45CFR 164 and the HIPAA Act) protects the privacy of individually identifiable health information, while ensuring that researchers continue to have access to medical information necessary to conduct research. This procedure refers to methods researchers may use to prevent the unintended disclosure of PHI.

RESPONSIBILITY:

As the Principal Investigator (PI) and all Key Personnel are responsible for protecting PHI from disclosure to unauthorized parties, they will adhere to the above-referenced policies.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	08-015	Cross-referenced to applicable existing policies	Michael V.W. Bergamini