USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH

Policy

The Health Science Center 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.

Definitions

INSTITUTIONAL REVIEW BOARD (IRB): An oversight Board appointed by the President of the Health Science Center and approved by the Office for Human Research Protections of the Department of Health and Human Services to protect the rights and welfare of human subjects who take part in research and to ensure that all research activities are conducted in compliance with federal regulations and organizational policy.

GENETIC INFORMATION: Genetic tests of the individual or of the individual’s family members and about diseases or disorders manifested in an individual’s family members.

PROTECTED HEALTH INFORMATION: Individually identifiable health information, including demographic data, that is maintained in any medium that related to:

- The individual’s past, present or future physical or mental health or condition,
- The genetic information of the individual,
- The provision of health care to the individual, and/or
- The past, present, or future payment for the provision of health care to the individual and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.
Protected health information does not include individually identifiable health information of persons who have been deceased for more than 50 years.


Privacy Regulations

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 protected health information may be used for research than currently allowed by existing laws.

The rules apply to any protected health information obtained for research purposes and does not make a distinction between research that involves treatment and research that does not involve treatment.

Authorizations

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 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 in to the unconditioned research activities.

An authorization for the use or disclosure of protected health information for research purposes need not be study specific. An authorization for uses and disclosures of protected health information for future research purposes must adequately describe such purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research.
IRB Policy

The Health Science Center may use or disclose protected health information for research. See the Institutional Review Board Web site at http://research.uthscsa.edu/irb/policy_procedure.shtml for HIPAA research policies and guidance.

De-identified Information

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.

See Section 11.2.9 of the HOP, “De-identification of Protected Health Information” for specific requirements and a complete list of identifiers.

Limited Data Set

The Health Science Center may maintain some patient information in limited data sets, which do not contain direct identifiers, such as name, address, social security number, but may contain date of birth and dates of treatment.

See Section 11.2.13 of the HOP, “Limited Data Sets” for details.

Transition

Research studies started prior to the compliance date are able to continue after the compliance date without obtaining additional consent. Specifically, the Health Science Center may use or disclose protected health information for research that is created or received either before or after the compliance date for the Privacy Rules (April 14, 2003), provided that there is no agreed-to restriction, and the Health Science Center obtained, prior to the compliance date, either:

1. An authorization or other express legal permission from an individual to use or disclose protected health information for the research;
2. The informed consent of the individual to participate in the research; or,

3. An IRB waiver of informed consent for the research in accordance with the Common Rule.