

**HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES**

Chapter 11	Patient Privacy Policies	Effective:	April 2003
Section 11.2	Uses and Disclosures of Protected Health Information	Revised:	April 2010
<b>Policy 11.2.12</b>	<b>Uses and Disclosures of Protected Health Information for Research</b>	Responsibility:	Director, Institutional Review Board

**USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH**

**Policy**

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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.

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**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.

PROTECTED HEALTH INFORMATION: Individually identifiable health information transmitted or maintained in any form or medium, including oral, written, and electronic. 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 protected health information where there is a reasonable basis to believe the information can be used to identify an individual.

THE COMMON RULE: Code of Federal Regulations for Protection of Human Subjects (45 CFR Part 46 Subpart A).

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**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.

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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.

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**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](http://research.uthscsa.edu/irb/policy_procedure.shtml) for HIPAA research policies and guidance.

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**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.

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**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.

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**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:

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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.
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