

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:	January 2004
Policy 11.2.12	Uses and Disclosures of Protected Health Information for Research	Responsibility:	Director, Institutional Review Board

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.

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).

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.

Permitted Uses and Disclosures

The Health Science Center may use or disclose protected health information for research, regardless of the source of funding of the research, provided that one of the following three conditions exist.

1. The IRB approves a waiver of authorization. The documentation of a waiver approval must include all the following:
 - a. A statement identifying the IRB and the date on which the waiver of authorization was approved.
 - b. Waiver criteria, to include:
 1. A plan to protect the identifiers from improper use and disclosure;
 2. A plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and,
 3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information is permitted.
 - c. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB.
 - d. The waiver must be signed by the chair or designee of the IRB.

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2. The use or disclosure of protected health information is only for the process preparatory to research. The Health Science Center obtains from the researcher representation that:
 - a. Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
 - b. No protected health information is to be removed from the Health Science Center or designated site by the researcher in the course of the review;
 - c. The protected health information is necessary for the research purposes.
 3. The use or disclosure is solely for research on the protected health information of decedents. The Health Science Center obtains from the researcher:
 - a. Representation that the use or disclosure sought is solely for research on the protected health information of decedents;
 - b. Documentation, if requested, of the death of such individuals; and,
 - c. Representation that the protected health information is necessary for the research purposes.
 4. A person who is the subject of protected health information collected or created in the course of a clinical research trial may access the information at the conclusion of the research trial.

Authorizations

Authorizations for use and disclosure of protected health information may be combined with any other legal permission related to the research study, including another authorization or consent to participate in the research. The authorization form must include an expiration date or event, or a statement that the authorization will have no expiration date. If the authorization informs the participant that there is no

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expiration date, appropriate disclosures after the termination of the research project are allowed. Specifically, protected health information stored in databases or repositories may be maintained indefinitely.

Participants are permitted to revoke their authorization at any time during the research project; however, an individual may not revoke an authorization to the extent that the Health Science Center has acted in reliance on the authorization. This permits the continued use and disclosure of protected health information already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of the research study. This does not permit use and disclosure of additional protected health information not already gathered at the time of the revocation.

See also [Section 11.2.3](#) of the *Handbook of Operating Procedures* (HOP), “Uses and Disclosures of Protected Health Information Based on Patient Authorization”.

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.

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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:

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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