SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 14, 2003 Index No. R-1230
Date Revised: 05/09
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SUBJECT: Uses and Disclosures of Protected Health Information for Research

1. PURPOSE

To outline the conditions by which Saint Agnes Medical Center (SAMC) will use and disclose, for research purposes, individually identifiable health information known as *protected health information* (PHI).

2. POLICY

- SAMC will ensure that its use and disclosure of PHI for research purposes is in accordance with the Health Insurance Portability and Accountability Act's (HIPAA's) *Standards for Privacy of Individually Identifiable Health Information* (i.e., the Privacy Rule), and other federal and state regulations governing the confidentiality a research subject's health information. Such use or disclosure will be limited to the minimum necessary to achieve the purpose of the use or disclosure.

- This policy applies to all types of research whether it involves prospective data collection or retrospective chart review, interventional and non-interventional patient methodologies, health services research, quality or outcomes research, data compiled in repositories or limited data sets for research analysis purposes.

3. PROCEDURE

3.1 Purview

All formal and informal requests for use or disclosure of PHI that are made to any SAMC department (e.g., Health Information Management, Quality Resources, Decision Support, Clinical Research, etc) that *appear to be research* in nature will be referred to the Clinical Research Department for evaluation. Clinical Research will determine whether the project/request satisfies the definition of research and should either be reviewed by Institutional Review Board (IRB) or the Privacy Board. The IRB typically reviews uses and disclosures as it pertains to FDA or HHS regulated research in which the subject of the research must also provide consent to

participate along with their Authorization to allow use and disclosure of PHI. The Privacy Board is a subcommittee of the IRB which reviews requests for waiver or alteration of the subject's Authorization to disclose PHI independent of the need for consent.

3.2 Permitted Uses and Disclosures

SAMC will permit uses[a] and disclosures[b] of PHI under the following circumstances as they relate to research:

A) If the individual that is the subject of the PHI provides a written Authorization

A valid Authorization must contain the following core elements and statements:

- A description of the PHI to be used or disclosed, identifying the information in a specific meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom t he covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of research study" or "none" are permissible including the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.
- A statement of the individual's right to revoke their Authorization and how to do so, and if applicable, the exception to the right to revoke Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.
- A statement of the potential risk that PHI will be re-disclosed by the recipient and no longer protected.

B) <u>Without the individual's Authorization when the following has been determined by the Privacy Board, that the request</u>

- Does not involve the collection of PHI and is therefore not protected by the Privacy Rule and does **not require** an Authorization or documentation of a waiver or alteration of Authorization.
- Involves the collection and use of *de-identified*[c] *health information* [45 CFR 164.514 (a), as described in the Privacy Rule, and is therefore not protected by the Privacy Rule and **does not require** an Authorization or documentation of a waiver or alteration of Authorization.
- Involves the use and disclosure of PHI in a *limited data set*[d] (under a data use agreement with an external entity) [45 CFR 164.514 (e) (1) and (3)] and **does not require** an Authorization or documentation of a waiver or alteration of Authorization.
- involves *activity preparatory to research*[e] [45 CFR 164.512 (i) (1) (ii)] and **does not require** an individual's Authorization, a waiver or alteration of Authorization, or a data use agreement, provided the researcher represents (in oral or written form) (1) the use or disclosure is used solely for the preparation of a protocol or similar purpose preparatory to research, (2) the PHI <u>will not be removed</u> from Saint Agnes Medical Center, and (3) the PHI is necessary for research purposes. **[In this situation, actual "disclosures" (as opposed to "uses") must be accounted for by Saint Agnes Medical Center.]**
- involves research on *decedent's information* [45 CFR 164.512 (i) (1) (iii)] and **does not require** an individual's Authorization or documentation of a waiver or alteration of Authorization, or a data use agreement provided the researcher represents (in oral or written form) (1) that the use or disclosure is sought solely for research on the PHI, (2) the PHI is necessary for research purposes, and (3) documentation of the death of the individuals whose PHI is sought. **[In this situation, actual "disclosures" (as opposed to "uses") must be accounted for by Saint Agnes Medical Center.]**
- Involves uses and disclosures for *research* purposes [45 CFR 164.512 (i) (1) (i)] and **does require** documentation of a waiver or alteration of an individual's Authorization provided that:

  1) The disclosure involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

  - an adequate plan to protect PHI identifiers from improper use;
  - an adequate plan to destroy the identifiers at the earliest opportunity;

- Written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law.

2) The research could not practicably be conducted without the waiver or alteration.

3) The research could not practicably be conducted without access to and use of the PHI.

[In this situation, actual "disclosures" (as opposed to "uses") must be accounted for by Saint Agnes Medical Center.]

3.3 Accounting for Disclosures

The Privacy Rule allows for three methods of accounting for research-related disclosures that are made without an individual's authorization: (1) a standard approach, (2) a multiple-disclosures approach, and (3) an alternative for disclosures involving 50 or more individuals.

The Clinical Research Department will be responsible for accounting of research-related disclosures using the Standard Method which includes for each disclosure the following information:

- The date the disclosure was made
- The name and, if known, the address of the person or entity receiving the PHI
- A brief description of the PHI disclosed
- A brief statement of the reason for the disclosure

DEFINITIONS

a *"Use"* - The sharing, employment, application, utilization, examination or analysis within the entity that maintains the PHI

b "*Disclosure***"** - The release, transfer, access to, or divulging of information in any other manner outside the entity holding the PHI.

c *"De-identified*" - Removal of all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members. **[See the Appendix for a list of these 18 elements.]**

d *"Limited Data Set"* – PHI that excludes 16 elements of direct identifiers. **[See Appendix)**

e *"Activity Preparatory to Research"* - Activity that involves screening potential research participants in order to contact them for possible inclusion (recruitment) in a research

study, or for purposes of seeking their Authorization to use or disclose PHI for a research study.

REGULATORY REFERENCES:

45 CFR 46.102 (f)(2)	Protection of Human Subjects (“The “Common Rule”)
45 CFR 46.116 (a)(5)	Protection of Human Subjects (“Informed Consent”)
45 CFR 164.502	Uses and disclosures of protected health information: general rules
45 CFR 164.512	Security and Privacy (“Uses and disclosures for which an authorization or opportunity to agree or object is not required”)
45 CFR 164.528	Security and Privacy (“Accounting of disclosures of protected health information”)
21 CFR 50.25 (a)(5)	Protection of Human Subjects
21 CFR 56.111(a)(7)	Institutional Review Boards
R-1234	SAMC IRB SOP: Privacy Board

APPENDIX

The Privacy Rule does not cover de-identified information. De-identified is generally defined under the Privacy Rule as information (1) that does not identify the individual and (2) for which there is no reasonable basis to believe the individual can be identified from it.

The Privacy Rule specifies two ways in which information can be de-identified:

1. Statistical methods can be used to establish de-identification instead of removing all 18 identifiers. A person with appropriate expertise can render information "not identifiable" if s/he can determine that the risk is very small that the recipient could identify the individual who is the subject of the PHI, alone or in combination with other reasonably available information. The person certifying statistical de-identification must document the methods and results of the analysis that justify the determination.

2. The following identifiers of the individual and his/her relatives, employers or household members must be removed:

(1) Names

(2) All geographic subdivisions smaller than a State, including: street, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of the ZIP Code if:

a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.

b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 people or less are changed to 000.

(3) All elements of dates (except year) related to an individual, including birth date, admission date, discharge date, date of death. For individuals > 89 years of age, year of birth cannot be used - all elements must be aggregated into a category of 90 and older.

(4) Telephone numbers
(5) FAX numbers
(6) Electronic mail addresses
(7) Social Security numbers
(8) Medical record numbers
(9) Health plan beneficiary numbers
(10) Account numbers
(11) Certificate/license numbers
(12) Vehicle identifiers and serial numbers, including license plates
(13) Device identifiers and serial numbers
(14) Web universal resource locators (URLs)
(15) Internet protocol (IP) address
(16) Biometric identifiers, including finger and voice prints
(17) Full face photos, and comparable images
(18) Any other unique identifying number, characteristic or code