SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 14, 2003 Index No. R-1234
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SUBJECT: Privacy Board

1. PURPOSE

This policy defines the role and function of the Privacy Board

2. POLICY

The Privacy Board shall function as a subcommittee of the Institutional Review Board of Saint Agnes Medical Center. The purpose of the Privacy Board is to review requests for waiver or alteration of Authorization to disclose protected health information (PHI) as it pertains to research-related activities that would not otherwise be reviewed by the Institutional Review Board.

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 be reviewed by the Institutional Review Board and/or the Privacy Board.

3. PROCEDURE

- MEMBERSHIP

  The Chair of the Institutional Review Board (IRB) shall appoint the Chair of the Privacy Board after soliciting recommendations from the convened IRB members. Membership shall be composed from a selection of current IRB members who have varying backgrounds, appropriate professional competency and who express an interest. The Privacy Board will consist of a

minimum of five members, one of whom must not be affiliated with Saint Agnes Medical Center or the entity conducting or sponsoring the research, or related to any person who is affiliated with any such entities. The Director of Clinical Research will serve as the Privacy Board Administrator as well as an active voting member.

- TRAINING

  Each new member of the Privacy Board must complete an orientation. The Director of Research will be responsible for coordinating the training which will focus on applicable HIPAA standards and SAMC policies and procedures for complying with them.

- MEETINGS

  - Review Proceedings

    The Privacy Board will convene when necessary to review a request for waiver or alteration of Authorization in the use and disclosure of PHI. The request and all associated study /project materials will be available to Board members at the meeting.

    The basis for determining whether a request qualifies for waiver or alteration in Authorization is clearly delineated in SAMC's IRB SOP R-1230 and will not be repeated here.

    A quorum will consist of three members. The Privacy Board will not have a member participating in the review of any project in which the member has a conflict of interest. The Director of Clinical Research will serve as the Privacy Board Administrator and may also participate as a voting member when the Director does not have a conflict of interest in the project being reviewed.

  - Voting

    The Privacy Board's action on requests for approval of a waiver or an alteration of Authorization must be approved by a majority (i.e., 50% plus 1) of the members present at the meeting, unless the Privacy Board elects to use an *expedited* process.

    An **expedited review** procedure can be used if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is being sought. An expedited process may also be used if an external IRB, acting on behalf of a federal or state agency, has approved a waiver or alteration of Authorization for a multicenter study. If the expedited process is elected, the review and approval of the SAMC waiver of Authorization may be carried out by the Chair, or by one or more members of the Privacy Board as designated by the Chair, including the Director of Clinical Research.

- ACCOUNTING FOR DISCLSOURES

  For those categories of research where an accounting for disclosures must be maintained (i.e., activity preparatory to research, research on a decedent's information, and research requiring documentation of a waiver or alteration of Authorization), the Privacy Rule allows for three methods of accounting for 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 cooperate with Health Information Management in 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

  An individual's right to receive an accounting of disclosures (unless an exception applies) goes back 6 years from the date of the request, not including periods prior to the HIPAA compliance date.

- DOCUMENTATION

  The documentation of the waiver or alteration of Authorization is achieved by the signature of the Chair (or the Chair's designee) on the **"Request for Waiver or Alteration of Authorization to Disclose PHI"** form. This form, along with information about individual disclosures will be maintained for 6 years.

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 164.512	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-1230	SAMC IRB SOP: Uses & Disclosures of Protected Health Information