SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1218
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SUBJECT: **WAIVER OR ALERATION OF INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

1. PURPOSE

   Outline the process for altering or waiving informed consent to participate in research.

2. SCOPE

   This pertains to all research protocols or Investigator-designed projects (e.g., case reviews whether or not intended for publication, chart reviews that are preparatory to research, chart reviews designed to assess health outcomes) that may possibly qualify as "research" and involve "human subjects" as defined by the Health and Human Services' (HHS') Office of Human Research Subject Protection (OHRP).

   It **does not** apply to use of an investigational drug or device that is the subject of an Investigational New Drug application (IND) or an Investigational Device Exemption (IDE). Nor does it apply to the use of a test article in emergency situations **(for those applications refer to IRB SOPs 1219 and 1220)**.

3. POLICY

   - All requests for an alteration or waiver of "Informed Consent to Participate in Research' must be submitted to the IRB for review and approval.

   - All requests for an alteration or waiver of Informed Consent in these applicable situations must also be accompanied by a request to the Privacy Board for review of the HIPAA Authorization requirement (see IRB SOP 1230).

4. PROCEDURE

4.1 The IRB may alter some or all the elements of informed consent, or waive the requirement for the Investigator to obtain informed consent under the following conditions:

A. Public Benefit

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designated to study, evaluate or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alterations to those programs or procedures; or (iv) possible changes in methods or levels of payments for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

B. Minimal Risk

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration would not adversely affect the rights and welfare of the research subjects;

3. The research could not practicably be carried out without the waiver or alteration.

REGULATORY REFERENCES

45 CFR 46.116(c)(d)	Protection of Human Subjects (“The Common Rule”)
45 CFR 160,162,164	The Health Insurance Portability and Accountability Act (HIPAA)