SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1207
Date Last Revised: 05/10
Date Last Reviewed: 05/10

SUBJECT: **CLINICAL RESEARCH PROPOSAL SUBMISSIONS**

1. PURPOSE

   Outline the procedure for the submission of new clinical research proposals / protocols by an Investigator to the Institutional Review Board (IRB).

2. SCOPE

   All research protocols or Investigator-designed projects (e.g., case reviews whether or not intended for publication, chart reviews that are preparatory to research) 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).

3. POLICY

   Proposal submission dates are published annually by the IRB and made available through communication with the IRB Office or on the IRB web page.

4. PROCEDURE

   Protocol applications will be submitted to the IRB using the applicable Research Protocol Application, by the due date published by the IRB Administrator.

   The submission requirements and dates are available upon request to any physician and/or staff member.

   To be considered for review, each signed Protocol Application must be accompanied by the following required documents:

   - the current version of the study Protocol;

- the current version of the Investigator's Brochure (IB) or Package Insert (PI) for the drug or device under study;
- the proposed patient Informed Consent drafted using the SAMC IRB Informed Consent template;
- the 'California Experimental Patient's Bill of Rights';
- a valid HIPAA Authorization form;
- a signed 'Statement of the Investigator' (e.g., FDA Form 1572 or device equivalent);
- a signed 'Financial Disclosure By Clinical Investigator';
- Investigator(s) curriculum vitae and medical license.

REFERENCES

45 CFR 46	Protection of Human Subjects ("The Common Rule")
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure By Investigators
21 CFR 312.60 to 312.69	Responsibilities of Investigators
21 CFR 812.100 to 110, 812.140 to 812.150	Responsibilities of Investigators
ICH E6	Good Clinical Practice: Consolidated Guidance (April 1996)
CAMH RI.2.180	Protection of Research Subjects
CAMH MM 7.4	Investigational Medications