SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1213
Date Last Revised: 05/10
Date Last Reviewed: 05/10

SUBJECT: CHANGES TO PREVIOUSLY APPROVED RESEARCH

1. PURPOSE

Outline the procedures for reviewing amendments and modifications to research.

2. SCOPE

Any modification, amendment, or change in research activity must be reported to the IRB.

3. POLICY

- It is the responsibility of the Investigator to notify promptly the IRB of any changes in research activity and not implement any changes without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

- Minor changes to previously approved research may be eligible for expedited review (see IRB SOP R-1211).

4. PROCEDURE

4.1 Any changes in previously approved research are reported to the IRB using the 'Request for Modification' form obtained from the IRB office. All requests for modifications must identify the specific changes and be accompanied by the appropriate supporting documentation (e.g., revised protocol, informed consent, investigator brochure).

4.2 Any revisions to the research Informed Consent document should be provided to the IRB electronically with all changes highlighted ("tracked").

REGULATORY REFERENCES

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)