SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1214
Date Last Revised: 04/11
Date Last Reviewed: 04/11

SUBJECT: **Study Status**

1. PURPOSE

   Define what is meant by study "status".

2. SCOPE

   All studies under the Institutional Review Board's (IRB's) jurisdiction.

3. POLICY

   - The Investigator must notify the IRB in a timely manner of any change in study status that originates from actions taken by either the Sponsor or Investigator.

   - The IRB must notify the Investigator in a timely manner of any change in study status that has originates from actions taken by the IRB to ensure the protection of human subjects.

4. PROCEDURE

   4.1 Definitions

   Study status is categorized as follows:

   OPEN – The IRB has approved the research and research activity consists of one or more of the following: subject screening, subject enrollment, subject treatment and or follow-up.

   CLOSED – The study has come to its intended conclusion without pre-emption by termination by the Sponsor or IRB.

HELD FOR INQUIRY - The IRB has requested the Investigator not to enroll new subjects pending resolution of IRB's questions regarding the Investigator's (or research staff's) performance or a complaint from any source. Subjects previously enrolled may be followed per IRB instruction as it relates to their safe continuation/discontinuation.

SUSPENDED – The IRB and or Sponsor suspends approval for whatever reason, and requests that the Investigator cease enrolling new subjects. The Investigator may be requested to stop all study procedures entirely, even for those subjects already on study. Subjects already enrolled may be allowed to continue treatment or follow-up until some point at which their participation may be discontinued safely. Pending positive resolution of the IRB's or Sponsor's concerns there is a possibility that the study may be reinitiated or terminated.

A Sponsor-imposed suspension may involve such factors as results from an interim data analysis or inadequate drug availability. The investigator will notify the IRB in writing of any sponsor-imposed suspensions.

IRB-imposed suspension may involve a preliminary inquiry into allegations of non-compliance or other study conduct issues and, depending on seriousness, may or may not lead to study termination (see IRB SOP 1235).

TERMINATED – The study is prematurely terminated by the IRB or the Sponsor or any applicable regulatory agency for a variety of reasons, including but not limited to Investigator noncompliance, research misconduct, or in-coming data indicating an unacceptable safety risk to subjects that was not previously know.

4.2 Notifications

- Investigator-initiated notifications regarding a change in study status must submitted to the IRB in a timely manner and should include any pertinent information that would aid the Board in reviewing the request.

- IRB-initiated notifications to the Investigator involving a "hold for inquiry", "suspension" or "termination" (see definitions above) will be in writing and may, depending on circumstances, contain specific requests for more information or recommendations for the safe follow-up and or withdrawal of subjects from the study.

- A 'Final Report' is required when a study is closed or terminated for whatever reason.

REGULATORY REFERENCES

45 CFR 46	Protection of Human Subjects (“The “Common Rule”)
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312.60 -312.70	General Responsibilities of Investigators
21 CRF 812.100 -812.150	General Responsibilities of Investigators
ICH E6	Good Clinical Practice: Consolidated Guidance
CA H&S Code 24170-24179.5	Protection of Human Subjects in Medical Experimentation
CA H&S Code 111515-111545	Experimental Use of a Drug
CAMH R1.2.180	Protection of Research Subjects