SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1212
Date Last Revised: 04/11
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SUBJECT: CONTINUING REVIEW OF RESEARCH

1. PURPOSE

   Define the continuing review requirements for clinical research.

2. SCOPE

   The Institutional Review Board (IRB) will conduct continuing review of previously approved research at intervals determined by the IRB upon initial study approval.

3. POLICY

   - Request for continuing review is the responsibility of the Principal Investigator and must be submitted for consideration prior to the date of expiration of the approval. Any research study not submitted to the IRB by its expiration date will be terminated.

   - At any time, the IRB will ensure prompt reporting to the Institution and the FDA of: 1) any unanticipated problems involving risks to human subjects or others; 2) any instance of serious and continuing noncompliance with federal regulations or the requirements or determinations of the IRB; and 3) any suspension or termination of IRB approval.

4. PROCEDURE

   4.1. Requests for renewal shall be made to the IRB using the 'Clinical Trial Status Report'. The 'Clinical Trial Status Report' provides information on the status of the study to date. It is the responsibility of The Principal Investigator to provide the Board sufficient information for thorough review and evaluation. A separate report is required for each protocol. The 'Clinical Trial Status Report' must be signed by the Principal Investigator for consideration by the Board.

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4.2. Full Board review is required for the renewal of all studies that were approved by the full Board, except as allowed by regulations. A study that was initially approved via expedited review is eligible for renewal by the expedited approval process. The categories of research that can be reviewed with an expedited process were published in the Federal Register: November 9, 1998 (Volume 63, Number 216), pages 60355-60357

4.3. In order to re-approve research at the time of continuing review, the IRB must determine that all of the following requirements are satisfied:

- Risks to subjects are minimized;
- Risks to subjects are reasonable;
- Selection of subjects is equitable;
- Informed consent will be sought from each prospective or the subject's legally authorized representative, and appropriately documented;
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence; and
- When the research involves pregnant women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval under HHS regulations at subpart B,C, D, respectively.

4.4. Additional criteria for consideration for renewal are:

- *Research Progress*: Information on the number of potential participants that were screened, consented, enrolled and withdrawn will be required for continuing review. The Board expects that the Principal Investigator is actively engaged in identifying participants, consenting and enrolling eligible participants. Therefore, studies that have been opened for enrollment for one year which have not consented or enrolled any subjects will not be renewed unless the Investigator can substantiate the basis for no enrollment, and present a plan that will affect enrollment in the future;

- *Investigator or Institutional Issues*: For example, changes in the Investigator's situation or qualifications, privileges, workload, medical license status, standards of professional conduct, reports from third-party observations, etc.

4.5. The actions the IRB may take upon continuing review are:

- **Approved** – Approved as presented no modifications required.
- **Approved With Conditions** - Approved subject to specific modifications requested by the IRB. Some modifications may only require a clarification or a correction to the 'Clinical Trial Status Report' itself and not to the actual conduct of the study.

- **Disapproved** – the research will not be allowed to continue at Saint Agnes Medical Center.

Additionally, the IRB will designate a specific status for the study (see IRB SOP 1214).

4.6. Upon decision by the IRB, the Principal Investigator will receive a letter from the Chairperson informing him/her of its decision regarding review of the study and a copy of the Informed Consent with a valid date stamp indicating the expiration date of the approval.

4.7. The Principal Investigator may appeal the decision by the board to suspend, close, or terminate a study. His/her appeal must be in writing and submitted to the Board within 30 days. The Board will address the Investigators request for reconsideration at the next convened meeting.

4.8. IRB Administration will assist the Principal Investigator in submitting their application for renewal by reminding them prior to the study termination date whenever possible. However, it is the Principal Investigator's responsibility to ensure that the Clinical Trial Status Report is filed and request for renewal is received prior to the expiration date of the study. The expiration date appears on each valid consent form to assist the Investigator in this process.

4.9. A study that is not renewed prior to the expiration date may be closed or terminated by the Board. The decision whether to close or terminate the original approval is dependent on the status of the patients enrolled and the risk to the patients by continued participation. The Board may request the Investigator to attend the meeting to address the reason for failure to apply for continuing review. The Principal Investigator will be immediately notified, in writing, of the change in status of the study due to non-compliance for continuing review, and be advised that no new subjects may be enrolled. For subjects already enrolled, their participation will be terminated safely. When all subjects have concluded follow-up activities, the Investigator must submit a 'Final Report' within seven days. Additionally, the study's Sponsor will be notified of the change in status. If a study is not renewed prior to the expiration date, a new application will be required to reinstate the study.

REGULATORY REFERENCES

45 CFR 46	Protection of Human Subjects ("The "Common Rule")
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure By Clinical Investigators

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
CA H&S Code 24170-24179.5	Protection of Human Subjects in Medical Experimentation
CAMH R 12.180	Protection of Research Subjects
OHRP	"Guidance on IRB Continuing Review of Research", October 29, 2009 (DRAFT)
OHRP	"Guidance on IRB Approval of Research with Conditions", October 20, 2009 (DRAFT)