SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1208
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SUBJECT: PREPARATION AND REVIEW OF NEW RESEARCH PROPOSALS

1. PURPOSE

   Outline the administrative procedures for preparing and reviewing new research proposals to Institutional Review Board (IRB) for review.

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

   All proposals involving human subjects will be reviewed to determine whether the proposal is exempt from IRB review, or requires full board or expedited review.

4. PROCEDURE

   PREPARATION OF REVIEW MATERIALS

   4.1. Applications to the IRB will be received and reviewed for completeness by the IRB Coordinator and prepared for the Administrative Sub-Committee.

   4.2. The proposal is assigned a review number and entered into the records of the board and the IRB electronic database. The number is a five-digit number indicating the last two digits of the year followed by the sequential number assigned to new submissions received starting January 1 of each calendar year. [i.e., IRB # 07055 indicates that it was the 55th submission received beginning January 1, 2007].

4.3. The Investigator will be notified of the receipt of the application and informed of any outstanding documents that need to be submitted prior to the protocol being placed on the agenda.

4.4. All materials received will be prepared for Administrative Subcommittee review prior to preparing the final agenda and packet for distribution to the full board. The IRB Administrator is responsible for assisting the Administrative Sub-committee in prioritizing the issues of the submissions and providing adequate resources to assist them in the preliminary review process.

4.5. Submissions to the Board will be transmitted by the IRB Coordinator to the IRB members in sufficient time to allow thorough review of each Proposal before the scheduled meeting; Board members will receive all necessary supporting information for each proposal.

4.6 The Administrative Subcommittee may request a review/opinion from one or more qualified outside experts for presentation/discussion at the full board meeting.

IRB REVIEW

4.7 At the IRB meeting, the proposal will be presented by the Principal Investigator, Sub-Investigator, or other research personnel identified on Form 1572 in sufficient detail to permit adequate consideration. Following the presentation, the proposal will be discussed until adequate information is available for a decision. Discussion of the protocol will occur without the Investigator and/or sub-investigator present. The IRB will base its decision of whether or not to approve the research on the criteria outlined in IRB SOP R-1209.

4.8 Prior to any discussion of the research, an IRB member with a relevant conflict of interest must disclose the conflict of interest to the Board. This declaration will be noted in the meeting minutes. Although that member may be counted as present for the purpose of quorum, that member **may not participate in the voting process for the research proposal in which they have a conflict.**

4.9 By majority vote of the members present, the IRB may reach one of the following decisions regarding each proposal:

- **Approved** - Approved as presented no modifications required.
- **Approved With Conditions** - Approved subject to specific modifications requested by the IRB.
- **Disapproved** – the research will not be allowed to be conducted at Saint Agnes Medical Center.
- **Tabled** – Application remains on agenda as unfinished business pending receipt of additional information from the Investigator..

4.10 If the IRB approves a proposal subject to modifications, the IRB must specify, by majority vote of the members present, whether the modifications will require full Board review, be delegated to the Subcommittee, or reviewed and approved by the Chairperson only.

4.11 The IRB will also determine the interval for the continual review and approval of research at the time of approval using the Phase of Clinical Development as a general consideration; however more frequent intervals (e.g., monthly or quarterly) may also be imposed if the IRB feels closer oversight is needed to protect the rights and welfare of the research subjects participating in the study:

Phase	Purpose	Continuing Review & Approval Interval
I	"First in Humans" Initial Safety Evaluation (very few patients)	Every 3 months
II	Preliminary Efficacy Evaluation (small scale studies)	Every 6 months
III	Pivotal Efficacy Evaluation (large scale studies)	Every 12 months
IV	Post-Marketing (i.e., NDA)	Every 12 months

The expiration date of a study is the day before the next required IRB continuing review date. For example, a study approved for 12 months at a May 18, 2010 meeting would expire on May 17, 2011.

4.12 A draft letter summarizing the Board's decisions, including but not limited to the final disposition of each research Proposal, will be prepared by the IRB Coordinator for signature of the IRB Chairperson.

4.13 The salient points of the IRB's discussion concerning the research proposal and the members' votes on the proposal will be recorded in the meeting minutes.

4.14 If the proposal is not approved, the Principal Investigator has the option of accepting the disapproval, modifying and resubmitting, or appearing before the IRB again for reconsideration. If a proposal is disapproved, reasons for such disapproval will be documented. If a proposal requires modification, the items of concern will be detailed to assist the Investigator.

4.15 The Principal Investigator may appeal disapproval within 30 days of receipt of the notice of disapproval. If appeal is made, the item will be placed on a future meeting agenda and reviewed by the full Board. The Principal Investigator will be notified of a decision on the appeal within 60 days.

4.16 A copy of the stamped valid informed consent document that is to be used for all participants will be included in notifications of approval. Only IRB stamped informed consent documents that have a current date stamp are considered valid.

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 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)
OHRP	“Guidance on IRB Approval of Research with Conditions”, October 20, 2009 (DRAFT)
OHRP	“Guidance on IRB Continuing Review of Research”, October 29, 2009 (DRAFT)
OHRP	Guidance on Engagement of Institutions in Human Subjects Research
CAMH RI.2.180	Protection of Research Subjects