**SAINT AGNES MEDICAL CENTER**
**CLINICAL RESEARCH CENTER**
Fresno, California

**STANDARD OPERATING PROCEDURES**
**Institutional Review Board**

Date Effective: April 26, 2001 Index No. R – 1217
Date Last Revised: 04/12
Date Last Reviewed: 04/12

**SUBJECT: INFORMED CONSENT TO PARTICIPATE IN CLINICAL RESEARCH**

1. PURPOSE

Define the process of obtaining and documenting the informed consent to participate in clinical research of human subjects participating in research activities.

2. SCOPE

All research activities involving human subjects that are performed at Saint Agnes Medical Center (SAMC), or by Investigators using SAMC's Institutional Review Board (IRB) for oversight of studies at sites external to SAMC.

3. POLICY

- No Investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Exemption from this policy is permitted only under special circumstances (see IRB SOPs: R-1218, R-1219, R-1220, and R-1221).

- In California, the subject must be provided a copy of California's "Experimental Subject's Bill of Rights" prior to consenting to participate in the research.

- All research informed consent documents must be reviewed and approved by the SAMC IRB before any subject is enrolled in a research study.

- The investigator is responsible for ensuring that subject's informed consent to participate in clinical research is obtained before initiation of any research procedures. The consent interview may be formally delegated by the Investigator to a person knowledgeable about the study and appropriately trained to perform this activity.

- An Investigator shall seek consent only under circumstances that provide the prospective subject an opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information given to the subject or the representative shall be in a language understandable to the subject or representative.

- No informed consent may include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or release or appear to release the Investigator, the Sponsor, or the Institution, or its agents from liability for negligence.

## 4 PROCEDURE

### 4.1 Basic Elements of Informed Consent To Participate In Clinical Research

The following information shall be provided to each prospective subject after being presented with the 'California Experimental Subject's Bill of Rights':

- A statement that the study involves research, and explanation of the purpose of the research, the expected duration of the subject's participation, and the approximate number of subjects involved in the study;

- A statement regarding financial support of the study and identification of who is receiving funds;

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

- A description of the procedures to be followed and identification of any procedures which are experimental (i.e., would not be done if the participant was not on the study);

- A description of any reasonably foreseeable risks and discomforts to the subject;

- A description of any benefits to the subject or to others which may reasonably be expected from the research;

- Disclosure of appropriate alternative procedures;

- Any additional costs to the subject that may result from participation;

- A description of the extent to which confidentiality of records identifying the subject will be maintained [see HIPPA SOP HI-5-05];

- A statement that the FDA, the IRB, the sponsor, the Investigator, and his/her designated research staff may inspect the medical study records;

- Explanation of whom to contact if questions arise, if injury occurs, or if there is concern about their rights as a research subject;

- A statement that the Investigator will attempt to address any harmful consequences the subject may have experienced as a result of research procedures;

- A statement that the subject's participation may be terminated by the investigator, the sponsor, or the IRB without subject's consent;

- A statement that the subject will be provided with significant new findings developed during research which may relate to subject's willingness to continue;

- A statement that patient has had opportunity to ask questions and all questions have been answered to their satisfaction;

- A statement that patient has read the consent form or has had the consent form read to them;

- A statement acknowledging that the patient will get a copy of the consent form.

4.2 The Process of Obtaining and Documenting Written Informed Consent

In most circumstances, the IRB requires that informed consent to participate in clinical research is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. The investigator must allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed and dated.

- Investigators must use the IRB's Informed Consent template as a model for developing each study's research Informed Consent. An Informed Consent to Participate in Clinical Research document requires a stamp from the IRB indicating the IRB protocol number and date the document expires to be considered "valid" before use in enrolling any subject in a study.

- The Informed Consent must be signed and dated by the subject or his/her legally authorized representative [see IRB SOP R-1221] and the person conducting the consent process.

- The Investigator should be actively involved in the consent process and provide adequate time to review the consent with the patient, answer questions and sign and date the consent after the subject. The only time a

- A copy of the signed and dated 'Informed Consent to Participate in Clinical Research', including the 'California Experimental Subject's Bill of Rights and 'Authorization for Use and Disclosure of Health Information' must be given to the person signing the form.

- A copy of the signed and dated consent form must be placed in the SAMC medical record for patients who are participating in a study as an "in-patient" and in the Clinical Research subject file for a patient consented as an "out-patient".

- The investigator or designee is responsible for ensuring that adequate documentation of the consent process and discussion, including the outcome, is maintained in the subject's medical and/or research chart.

4.3 <u>The Process of Obtaining and Documenting Oral Presentation Using a Short Form Consent</u>

As an alternative to standard written informed consent, oral presentation of the elements of informed consent (21 CFR 50.25) may be used, however, **<u>it is not the preferred federally recommended method when a reasonable number of an investigator's potential subjects are expected to be non-English speaking</u>**. In such cases, a *short form* written informed consent to participate in clinical research, stating that the elements of consent have been presented orally to the subject or the subject's legally authorized representative.

- The IRB must approve the written summary of what is presented orally to the subject or the representative.

- A witness to the oral presentation is required. Only the subject or legally authorized representative must sign the *short form*. The witness must sign both the *short form* and a copy of the written summary. The person obtaining consent must sign a copy of the written summary of the information that is presented orally. The person obtaining consent may not be the witness to the consent.

- Copies of both the summary and the short form shall be given to the subject or the representative.

4.4 Use of Facsimile or Mail to Document Informed Consent

The IRB may approve a process that allows the informed consent to be delivered by mail or facsimile to the potential subject or the potential subject's legally authorized representative and to conduct the consent interview by telephone when the subject or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent to participate in clinical research must also be met when using this procedure.

4.5 The Process of Re-Consenting Subjects Previously Enrolled in an On-Going Clinical Research Study

When circumstances require additions to the procedures section of the protocol, or there is new information regarding foreseeable risks to those participating in the study, the Investigator must submit for IRB approval an updated Informed Consent. Any research subjects already enrolled in the study and who would be affected by the new procedures and/or additional investigational drug/device treatments, must sign the updated 'Informed Consent to Participate in Research' document. If the subject's participation is limited to only follow-up, then they must be sent a letter making them aware of any new information about the potential risks of having been treated with the investigational drug/device. They **do not** have to re-sign the updated 'Informed Consent to Participate in Research'.

REGULATORY REFERENCES:

| | |
|---|---|
| 45 CFR 46 | Protection of Human Subjects ("The Common Rule") |
| 21 CFR 50.25 | Elements of Informed Consent |
| 21 CFR 312.60 | Responsibilities of Investigators |
| 21 CFR 812.100 | Responsibilities of Investigators |
| FDA Information Sheet | A Guide to Informed Consent, The Consent Process |
| HHS, OHRP Staff Memo | Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English (November 1995) |
| ICH E6 | Good Clinical Practice: Consolidated Guidance (April 1996) |
| 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 RI.2.180 | Protection of Research Subjects |