SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1223
Date Last Revised: 05/03
Date Last Reviewed: 04/10

SUBJECT: **PAYMENTS / GIFTS / REIMBURSEMENT TO SUBJECTS**

1. PURPOSE

   Define the process for review and approval for payments, gifts, and reimbursement to subjects for participating in research.

2. SCOPE

   Any payment, gift, or reimbursement that is exchanged between the Investigator and / or the study sponsor to the participant requires full disclosure and approval by the Board prior to disbursement.

3. POLICY

   - Any payment to a participant must be identified as part of the submission application or requested as a revision to a previously approved study.
   - The Board must consider whether paid participants in research are recruited fairly, informed adequately, and paid appropriately whereby the payment is not perceived as an undue inducement and/or incentive to participate.

4. PROCEDURE

   4.1. The Investigator must disclose full payment to the participant at the time of application and/or as a revision to the Board at a later date.

   4.2. The Board may choose to not approve a study based on the payment and/or their concerns that the subject may not be able to freely determine participation due to the payment/inducement being offered.

   4.3. The Board may request that the Investigator substantiate the payment to the subject and/or revise the amount offered.

4.4. The Board may ask the Investigator to document that payment has been made to the subjects in the manner that is indicated in the application.

4.5. It is up to the discretion of the Board to determine whether the amount paid to a study subject is appropriate for reimbursement of specific inconveniences such as time away from work (lost wages), travel, etc.

4.6. Payment to subjects must be reasonable and approximate normal business reimbursement rates for time and travel.

4.7. Examples of appropriate reimbursement are $.36/mile; $10-15 per hour

REFERENCES

21 CFR 812	Investigational Device Exemptions
21 CFR 814	Premarket Approval of Medical Devices
OIP – 10	SAMC SOP: OIP Education
ICH E6	International Committee of Harmonization Guidelines
FDA / OPRR	Good Clinical Practice