

DEPARTMENT: Research Compliance		Reference# IRB.007
Effective Date: 1/23/2006	Page: Page 1 of 4	Replaces Policy Dated: 4/28/2003
Description:	Conflict of Interest	

All Sunrise Health-affiliated facilities engaged in human subject research must ensure that IRB members who review, and clinical investigators who submit, Clinical Research Protocols for consideration to the IRB have no conflicts of interest or financial interest in research that may affect the rights of research subjects.

The IRB, the institution and investigators engaged in human subject research must each work to ensure that financial interests do not compromise the protection of research subjects.

DHHS regulations (45 CFR 46.107(e)) and FDA regulations (21 CFR 56.107(e)) address conflicts of interest by requiring that no IRB have a member participate in the IRB's initial or continuing review in which the member has a conflicting interest, except to provide information requested by the IRB. These regulations prohibit an IRB member with a conflicting interest in a project from participating in IRB deliberations on that project. Each IRB must also:

- determine that financial disclosure statements are included in the Informed Consent document presented by the Investigator to the IRB such that any potential conflicts of interest are disclosed to the patient;
- recognize that some conflicting financial interests may occur, but that no financial arrangements with an investigator may have been made where study outcome could affect compensation;
- determine that the investigator:
 - a. has no proprietary interest in the tested product;
 - b. does not have a significant equity interest in the sponsor of the covered study; and
 - c. has not received significant payments of other sorts; and
- ensure disclosure of specified financial arrangements and any steps taken to minimize the potential for bias.

Sunrise Health IRB requires clinical investigators to disclose the following financial arrangements:

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- a. Compensation made to the investigator in which the value of compensation could be affected by the study's outcome.
- b. A proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement
- c. Any equity interest in the sponsor of a covered study, *i.e.*, any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. Any equity interest in a publicly held company that exceeds \$50,000 in value. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one (1) year following completion of the study.
- d. Significant payments of other sorts, which are payments that have a cumulative monetary value of \$25,000 or more made by the sponsor of a covered study to the investigator or the investigator's institution to support activities of the investigator exclusive of the costs of conducting the clinical study or other clinical studies, (*e.g.*, a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for one (1) year following completion of the study.

Definitions

Clinical Investigator - Any listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

Conflict of Interest - An actual, potential or perceived conflict of interest occurs in those circumstances where an individual's judgment could be affected because the individual has a personal interest in the outcome of a decision over which the individual has control or influence. A personal interest exists when an individual colleague or a member of his or her family stands to directly or indirectly gain as a result of a decision.

Covered clinical study - Any study of a drug, biological product or device in humans submitted in a marketing application or reclassification petition that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a

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significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols and parallel track protocols. The Sponsor of the Clinical Study or the IRB may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements.

Financial Interest - A financial interest includes income or other remuneration, as well as investments and ownership interests in excess of 5% of the total interest. It does not include stocks, bonds, and other securities sold on a national exchange; mutual funds; or certificates of deposits and other depository accounts at financial institutions.

Sponsor of the covered clinical study - The party providing support for a particular study at the time it was carried out.

The IRB will consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects and should ask the following questions in their deliberations:

- a. What financial relationships and resulting financial interests could cause potential or actual conflicts of interest?
- b. At what levels should those potential or actual financial conflicts of interest be managed or eliminated?
- c. Who should be educated regarding financial conflict of interest and policies?
- d. What entity or entities should examine individual and/or institutional financial relationships and interests?
- e. Determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as an institutional financial interest.

The IRB will identify the following in its deliberations:

- a. how the research is supported or financed;

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- b. where and by whom the study was designed;
- c. where and by whom the resulting data will be analyzed;
- d. whether individuals or institutions receive any compensation that may be affected by the study outcome; and
- e. do individuals or institutions have any proprietary interest in the product including patents, whether trademarks or licensing agreements; have an equity interest in the research sponsor; receive significant payments such as grants; receive payment (to the physician or institution such as for data management or research support) per participant or incentive payments and are the payments reasonable.

All IRB members must receive education regarding this policy and any facility conflict of interest policies. Any actions taken regarding IRB member conflicts of interest related to particular protocols (such as the Principal Investigator leaving the meeting room during deliberations of the IRB) must be documented in the meeting minutes.

Investigators must document whether they or any other person responsible for the design, conduct, or reporting of this research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by, the research.