

GA 104-A

01/01/07

*Print on SHS/Research Letterhead*To: (IRB Member)
(Address)

Date: (Today's Date)

IRB MEMBER RECUSAL AGREEMENT

I _____ certify that I shall recuse myself from deliberation and voting on any study submitted to the IRB in which I have a potential or perceived conflict of interest concerning protocols reviewed by the IRB. This would include:

A. Service in any of the following categories with respect to the study in question:

- Principal Investigator (PI),
- Co-principal Investigator,
- Investigator receiving funding from the study, as listed in the study budget,
- In a supervisory or subordinate role with the PI of the study, or in a mentor/trainee relationship,
- Family member of PI.

B. I, my spouse and/or dependent children have a financial interest as follows:

1. Any financial arrangement with the Sponsor, Sponsor representative, or any other entity whereby the value of my compensation could be affected by the outcome of the study as defined in Sparrow Health System Policies on financial relationships at 21 CFR 54.2(a); DHHS COI guidelines;
2. A proprietary interest in any products, intellectual property or any outcome of the study;
3. A significant equity in the Sponsor as defined in Sparrow Health System Policies on financial relationships and 21 CFR 54.2(b);
4. I am the recipient of significant payments of other sorts (such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria), as defined in 21 CFR 54.2(f).

I will make known any conflict of interest prior to the beginning of the IRB's discussion of the protocol under review.

Acknowledged and Agreed:

Signature: _____

Date: _____

Printed Name: _____

21 CFR 54.2 Definitions.

For the purposes of this part:

(a) **Compensation** affected by the outcome of clinical studies means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the Investigator in the form of an equity interest in the Sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

(b) **Significant equity interest** in the Sponsor of a covered study means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds \$50,000 during the time the Clinical Investigator is carrying out the study and for 1 year following completion of the study.

(c) **Proprietary interest** in the tested product means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.

(d) **Clinical Investigator** means only a 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.

(e) **Covered clinical study** means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part 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 significant contribution to the demonstration of safety. This would, in general, not include phase I 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. An applicant may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements.

(f) **Significant payments** of other sorts means payments made by the Sponsor of a covered study to the Investigator or the institution to support activities of the Investigator that have a monetary value of more than \$25,000, 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 1 year following the completion of the study.

(g) **Applicant** means the party who submits a marketing application to FDA for approval of a drug, device, or biologic product. The applicant is responsible for submitting the appropriate certification and disclosure statements required in this part.

(h) **Sponsor** of the covered clinical study means the party supporting a particular study at the time it was carried out.