

APPLICATION FOR NEW STUDY REVIEW

I. PROJECT INFORMATION

Study Title:

Sponsor:

Principal Investigator:

Co-Investigators:

Contact Person:

Address:

Email:

Phone:

All personnel listed above have taken Human Subjects Protection Training.

Yes No

If no, training and documentation for all listed personnel must be completed before research is initiated.

II. CONFLICT OF INTEREST:

Do you, any member of your immediate family, any foundation or entity controlled or directed by you or any member of your immediate family, or any group practice of which you are a member:

1. Receive or are entitled to consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company) gifts or other emoluments, or "in kind" compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the prior calendar year exceeded the de minimis amount established in PHS regulation (at present \$10,000), or are expected to exceed that amount in the next twelve months?
 Yes No
2. Have or are entitled to equity interests, including stock options, of any amount in a non-publicly-traded financially interested company?
 Yes No
3. Receive or are entitled to equity interests in a publicly-traded financially interested company that exceed the defined de minimis amount?
 Yes No

5. Duration of the study:

6. Scientific Rationale:

a. Describe past experimental and/or clinical findings leading to the formulation of the study.

b. Describe any animal experimentation and findings leading to the formulation of the study.

IV. STUDY PARTICIPANTS

1. Estimate number of participants to be enrolled locally:

2. Total number of participants to be enrolled at all sites:

3. Participants age range:

4. Does the participant population include fetuses, pregnant women, children, mentally disabled, prisoners, non-English speaking participants, or any other participant that could be considered a vulnerable population: Yes No

If yes, describe:

5. If subjects are vulnerable, describe additional safeguards included in the protocol to protect the rights and welfare of the participants:

6. Explain recruitment procedures:

7. Describe the inclusion/exclusion criteria:

V. INVESTIGATIONAL DRUGS

1. Drug Name:

2. Manufacturer:

3. IND Number:

VI. INVESTIGATIONAL DEVICES

1. Device Name:

2. Manufacturer:

3. IDE Number:

4. Determination of Risk:

Significant

Non-significant

