

Please complete and return with any protocol submitted for initial and continuing review.

Name of PI:

IRB #:

Study Sponsor Name:

Sponsor Protocol Number:

Study Title:

Person Signing Form:

Role in Study:

Study Responsibilities (check all that apply):

- | | | |
|---|---|--|
| <input type="checkbox"/> Screen Participants | <input type="checkbox"/> Randomize Participants | <input type="checkbox"/> Discharge Instructions |
| <input type="checkbox"/> Perform Physical Exam | <input type="checkbox"/> Dispense Study Drug | <input type="checkbox"/> Follow-up Phone Calls |
| <input type="checkbox"/> Record Medical History | <input type="checkbox"/> Drug Accountability | <input type="checkbox"/> Complete Source Documents |
| <input type="checkbox"/> Determine Eligibility | <input type="checkbox"/> Assess AEs | <input type="checkbox"/> Sign Data Query Forms |
| <input type="checkbox"/> Administer Consent | <input type="checkbox"/> Complete CRFs | <input type="checkbox"/> Other |

In order to protect participants from financial conflicts of interest the IRB requires that such potential conflicts during the past 12 months be disclosed. If the IRB determines that a conflict exists that could influence the research or jeopardize the well-being of participants, the IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the participant in the Informed Consent Statement.

Please indicate the following:

- Yes No I or a member of my immediate family own(s) equity (stock ownership, stock options, convertible note(s), or other ownership interest in any amount) in the company or other legal entity whose drug, procedure, technique, device, or software I am testing (the "Company").
- Yes No The Company holds patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings).
- Yes No I or a member of my immediate family hold(s) a position of senior management officer, or director of the Company.
- Yes No I or a member of my immediate family am/is a scientific advisor, consultant, or speaker for the Company and receive payments from the Company (including direct or indirect payments, honoraria, and all other forms of compensation).
- Yes No If a device, technique, software, or procedure involved in the research is marketed, I or a member of my immediate family may be entitled to royalty income or income from the sale of the product.
- Yes No I or a member of my immediate family have any other financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent.

IF ANY BOX ABOVE IS CHECKED YES, INCLUDE ON A SEPARATE SHEET AN EXPLANATION OF THE CONFLICT (INCLUDING THE AMOUNT OF MONEY) FOR THE IRB'S CONSIDERATION. INFORMATION PROVIDED IS CONSIDERED CONFIDENTIAL.

My signature below is my representation that I have accurately completed this form to the best of my knowledge.

Signature of Investigator/Sub-investigator

Date