APPLICATION FOR NEW STUDY REVIEW

I. PROJECT INFORMATION

Study Title:

Sponsor:

Principal Investigator:

Co-Investigators:

Contact Person:

Address:

Email:

Phone:

Fax:

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

4. Receive royalty income or have the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work?
   ☐ Yes ☐ No

5. Receive non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution). This includes any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested company or from the institution on milestone payments tied to the achievement of particular research results?
   ☐ Yes ☐ No

6. Serve as an officer, director, or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service?
   ☐ Yes ☐ No

7. No list of examples of conflict of interest can be complete. Do you have reason to believe that you may have a financial conflict of interest in research that is not covered by items 1-6?
   ☐ Yes ☐ No

III. STUDY SUMMARY

1. Phase of Study
   ☐ N/A (not a clinical trial) ☐ Pilot ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4

2. Site of Study
   ☐ Mercy Medical Center ☐ St. Luke's Hospital ☐ Other:

3. State the purpose of this trial:

4. Summarize study methods and procedures:

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 disable, 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

VII. FINANCIAL CONSIDERATIONS: RESEARCH PARTICIPANTS

1. In the event of a research related injury, will the sponsor pay for medical care and/or hospitalization beyond what insurance does not cover?
   ☐ Yes ☐ No

2. Proposed compensation/reimbursement to participants:

VIII. RISK/BENEFIT CONSIDERATIONS

1. State potential or real risks to participants:

2. State potential benefits to participants or the general public:

3. Please give an assessment of the risk/benefit ratio:

IX. PRIVACY AND CONFIDENTIALITY

a. Describe provisions to protect the privacy of participants:

b. Describe provisions to maintain the confidentiality of data:

X. ACCOMPANYING DOCUMENTS (<u>check all documents submitted</u>)

☐ Complete Protocol and Supporting Documents
☐ Informed Consent Documents
☐ All recruitment materials, including advertisements intended to be seen or heard by potential participants
☐ Documentation of Human Subject's Protection Training, if not already on file in the IRC office
☐ All Personnel listed above are credentialed and privileged to complete the necessary privileges requested in the study being performed with a list of the approved delineation of privileges

Submit New Study Application and all Documents to:

Mercy Medical Center & St. Luke's Hospital IRC
Attn: Shannon Rieniets
701 10th Street SE
Cedar Rapids, IA 52403
(319) 369-4466 [Office Phone]
srieniets@mercycare.org

XI. AFFIRMATION OF PRINCIPAL INVESTIGATOR

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Signature of Principal Investigator Date