THE NEBRASKA METHODIST HOSPITAL 8303 DODGE STREET OMAHA, NEBRASKA 68114 402-354-4000

Institutional Review Board
New Study Application

This Application is to request initial review of a proposed clinical research involving human subjects. This form is not for status reports of previously approved clinical research. This Application may be submitted by an investigator/researcher or their designee.

Title of the Proposed Study/Research:

Date of Submission of this Application:

Principal Investigator:

Name, Credentials:

Department, School:

Office Address:

Office Phone:

Email Address:

Sub-Investigator(s) (list name and credentials):

Principal Investigator is:

- ☐ Employee or Contractor of Nebraska Methodist Health System or any affiliate.
- ☐ Student of Nebraska Methodist College
- ☐ Student of _____
- ☐ Non-Employee/Non-Student

Sponsor/Manufacturer Name, if Applicable:

Contact Person Office Address:

Contact Person Office Phone:

Contact Person Email Address:

Study Will Be Conducted:

- ☐ Wholly at Methodist Hospital or Methodist Women's Hospital
- ☐ Wholly at Methodist Jennie Edmundson
- ☐ Wholly at Methodist Fremont Health
- ☐ Wholly at a Methodist Physicians Clinic, clinic location: _____
- ☐ At the following locations:

  _____
  _____
  _____

Vulnerable Subject Population: The proposed research involves the following vulnerable subject populations:

☐ Not Applicable
☐ Pregnant Women
☐ Infants/Children
☐ Disabled, explanation of disabled population: _____
☐ Other: _____

Please provide summary statements addressing the following. You may reference a protocol or other summary document, but must attach such protocol or summary document as part of the Application.

Nature and Purpose of the Study:
(Describe the overall purpose of the study):

Characteristics of Subject Population
(Describe the characteristics of the subject population, including, but not limited to, the number of subjects to be enrolled, age ranges, gender, ethnic background, health status, criteria for inclusion and exclusion, and justification for the utilization of any vulnerable populations):

Generalizability (only required if a non-industry sponsored study)**:**
(Describe whether one intent of the study is to contribute to or develop generalizable knowledge, that is, to generate conclusions or research findings that can be applied to other groups or settings and yield same or similar results)?

Method of Subject Selection
(Describe the methods to be employed in the identification and recruitment of potential subjects):

Risks to the Subjects
(Describe the potential risks of taking part in the study, including probability, severity, potential duration and reversibility of risks):

Protection Against Risks
(Describe the procedures to be utilized to prevent or minimize any potential risks):

Benefits
(Describe any potential benefits to be gained by the subject as well as benefits to medical science or society in general):

Risk-Benefit Analysis
(Describe why the risks to subjects are reasonable in relation to the anticipated benefits to the subject and/or in relation to the importance of the knowledge that may reasonably be expected to result):

Alternatives
(Describe any available alternatives for subjects if subjects choose not to participate):

Informed Consent:
(Describe the process by which you will obtain the informed consent from each subject, addressing (i) who conducts the main consent discussion with the subject, (ii) when this discussion takes place, (iii) who is present at this discussion and what materials are presented to the subject, (iv) when the subject is asked to sign the consent document, (v) whether the subject is provided a copy of the consent document, (vi) whether you anticipate ever enrolling a subject with surrogate consent because the subject is not competent to consent for himself or herself, and (vii) any circumstances under which you might enroll a subject without informed consent):

Privacy
(Describe how privacy and confidentiality of subjects will be maintained, including how study data will be protected):

Documentation
(List any documents that are being submitted with this Application):
_____
_____
_____
_____
_____

National Clinical Trial (NCT) Number or Clinical Trial Identifier (IDE):

Webpage/Link, if applicable:

Financial Considerations:

Do any study investigators or staff involved in the conduct of the study have any financial or other interest in the sponsor, manufacturer, or outcome of the study?

- ☐ No
- ☐ Yes. Explanation: _____

Will there be any payments from the study sponsor, study group or other interested party to any study investigators or staff involved in the conduct of the study, whether designated for the study budget, fees, expenses, or otherwise?

- ☐ No
- ☐ Yes (check all that apply)
  - ☐ Payments to an affiliate of Nebraska Methodist Health System
    Explain: _____
  - ☐ Payments directly to any study investigators or staff involved in the conduct of the study
    Explain: _____
  - ☐ Payments or Compensation to subjects.
    Explain: _____
  - ☐ Payments for standard of Care procedures
  - ☐ Payments for non-standard of care procedures
  - ☐ Other:_____

Will there be any costs or charges to the subjects for participating in this study, beyond what they would incur from standard of care treatment or procedures?

- ☐ No
- ☐ Yes. Explanation: _____

Has a Financial Disclosure Form (FDF) been submitted on behalf of each applicable delegated staff member involved in the study?

- ☐ Yes
- ☐ No. Explain: _____
- ☐ N/A

Research/Investigator Status:

Has the proposed study, or any substantially similar study, previously been denied approval or had its approval suspended or revoked by this IRB or any other IRB?

- ☐ No
- ☐ Yes. Explanation: _____

Has any study investigator or staff involved in the conduct of this study ever been subject to any of the following (or is any formal investigation or other formal action pending which could lead to such a result):

- ☐ Revocation of approval to serve as an investigator or staff in a research study or, imposed by any IRB, sponsor or other entity?
  - ☐ No
  - ☐ Yes. Explanation: _____
- ☐ Debarment or disqualification any government program, private grant, or research program?
  - ☐ No
  - ☐ Yes. Explanation: _____
- ☐ Criminal prosecution or civil lawsuit seeking criminal penalties, injunction or damages arising out of clinical research?

☐ No
☐ Yes. Explanation: _____

Investigator's Certification: I certify that the foregoing is complete and accurate to the best of my knowledge. I will advise the Chair of the IRB of any changes to any of the above questions of which I become aware. I have received, read and understand the Handbook for IRB Members and Investigators, including the Statement of Ethical Principles and Policy, and agree to comply with all of the terms, conditions and standards contained within the Handbook, with all periodic reporting requirements, and with all applicable laws and regulations.

Signature of Principal Investigator or designee:

Printed Name of Principal Investigator or designee:

Title of Designee, if applicable:

Date:

****Please note: The Methodist Hospital IRB Guidelines require a one-time fee of $3,500.00 for submission of new protocols. This fee applies to industry-sponsored studies, not nonprofit cooperative research group trials or local physician-investigators. The fee is due within sixty (60) days of the Methodist Hospital IRB's review.

**** A typed name in the above signature of the delegated staff member box constitutes a binding electronic signature for this study.