METHODIST HOSPITAL

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

Institutional Review Board
Request for Modification of Study

This form is to request approval of changes to an already-approved study, including, but not limited to, the purpose of study, targeted subject population, study methodology, informed consent form language, or other modification to a study.

Title of the Study/Research:

IRB Number, if applicable:

Date of Submission of this Modification:

Principal Investigator's Name:

Date of Original Methodist Hospital IRB Approval:

Study Status:

- ☐ **Open**
- ☐ **Closed to Accrual**

Number of Subjects Enrolled by the Principal Investigator to Date:

Modifications Requested:

- ☐ Minor administrative change
- ☐ Protocol
  - ☐ Study treatment or procedure
  - ☐ Accrual
  - ☐ Eligibility criteria
  - ☐ Risks
  - ☐ Status Change
  - ☐ Recruitment/educational materials
  - ☐ Informational Report
  - ☐ Other: _____

Requested Method of Review of Modification:

- ☐ Expedited (the modification poses no more than minimal risk to subjects)
- ☐ Full board (the modification poses more than minimal risk to subjects)

If the Proposed Modifications include Modification to the Informed Consent Form

Will currently enrolled subjects be require re-consenting to the modified form?

- ☐ No (the modifications would not effect a subject's willingness to continue participation)
- ☐ Yes (the modifications could effect a subject's willingness to continue participation)

Will the proposed changes materially effect the risk/benefit analysis?

- ☐ No
- ☐ Yes. Explain: _____

Will the proposed changes increase the patient's cost to participate in the study?

- ☐ No
- ☐ Yes. Explain: _____

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

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.

Signature of Principal Investigator or designee:

Printed Name of Principal Investigator or designee:

Title of Designee, if applicable:

Date:

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