Institutional Review Board Modification Form

This form is to provide an update to a previously approved Study.

The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4000

IRB Office Only

IRB Meeting Date dd/mmm/yyyy	**Attachment**	**Completed By** (initial / date)

TITLE of Clinical Research Study*

Principal Investigator's Name / Credentials*

Methodist IRB ID#*

Date of Original Methodist IRB Approval*

Study Enrollment Status* ☐ Open ☐ Closed ☐ Other

Total Participants locally enrolled to date*

Total Participants globally enrolled to date*

Method of Review Requested* ☐ **Expedited** (The modification poses no more than minimal risk to Participants.)

☐ **Full Board** (The modification poses more than minimal risk to Participants.)

Submission to IRB Date*

Modifications Requested

☐ Minor Administrative Change

☐ Protocol

- ☐ Study Treatment or Conduct
- ☐ Eligibility
- ☐ Accrual
- ☐ Risks
- ☐ Patient Facing Materials (recruitment, educational, etc.)
- ☐ Other,

If Modifications requires changes to the existing ICF, complete next 3 questions.

Will currently enrolled Trial Participants be required to reconsent if this modification is approved?
If no, provide details.

☐ No ☐ N/A ☐ Yes

Do the proposed changes materially effect the potential risks/benefits to Participants?
If yes, provide details.

☐ No ☐ N/A ☐ Yes

Will the proposed changes increase the Participant's cost to participate in the study?
If yes, provide details.

☐ No ☐ N/A ☐ Yes

METHODIST
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Documentation*

List any documents submitted with this request

Additional Information

Investigator's Certification*

I certify the provided information on this form is complete and accurate to the best of my knowledge. I will advise The Nebraska Methodist Institutional Review Board of any changes to the above completed fields when I become aware.

Signature of Principal Investigator or designee*/**

Printed Name of Principal Investigator or delegated staff*

Title of Principal Investigator or delegated staff*

Date (If not provided above)

* required field

** An electronic signature or typed name constitutes a binding electronic signature for this study.