METHODIST HOSPITAL

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

Institutional Review Board
Request for Modification
of Investigational Study

Use of Form: This form is to be used by the principal investigator of a study previously approved by the IRB, to request IRB approval of a change in protocol, change in consent form, or other study modification.

1. **Title of Study:**

2. **Principal Investigator's Name:**

3. **Date of this Request:**

4. **Date of Original Methodist IRB Approval:**

☐ **Open** ☐ **Closed to Accrual**

5. **Number of Subjects Enrolled Locally:**

6. **Summary of Modifications Requested:**

(a) Study modification:

☐ Administrative change
☐ Accrual
☐ Eligibility criteria
☐ Status Change: ☐ Suspension ☐ Reactivation
☐ Recruitment/educational materials
☐ Informational Report
☐ Study treatment or procedure
☐ Confidentiality
☐ Risks

(b) Method of review allowed:

Expedited ☐ Full board ☐

(c) Summary of consent form changes, and reasons for changes:

Reconsent Required ☐ YES ☐ NO

7. Will the proposed changes materially affect the risk/benefit analysis?

☐ No ☐ Yes-Please explain:

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

☐ No ☐ Yes- Please explain:

9. Are the following documents attached to this request?

☐	Yes	☐	No	**Protocol modification / revised protocol**
☐	Yes	☐	No	**Revised consent form**
☐	Yes	☐	No	**Other supporting documents (list)**

Signature of Principal Investigator:

Date Submitted:

A typed name in the above signature field confirms you are the Principal Investigator submitting this Request for Modification of Investigational Study form.

Submit