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