METHODIST HOSPITAL

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

Institutional Review Board
Investigator's Status Report

Use of Form: This form is to be used by the principal investigator of a study previously approved by the IRB, to report on the status of the study. Periodic reports (at intervals established by the IRB, but no less than once per year) are required by law and as a condition to continuing approval of the study.

1. **Title of Study:** _____

   _____

   _____

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

3. **Date of this Report:** _____

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

5. **Number of Subjects in Study, to Date:** _____

   Locally (under NMH IRB Jurisdiction): _____

   Nationally (if known, or estimate): _____

6. **What is the current status of this study (check one):**

   a. ☐ Open to accrual of additional subjects (check this box even if accruals are temporarily suspended)

   b. ☐ Closed to accruals, some subjects still being treated under the study (requires annual reporting)

   c. ☐ Closed to accruals, no subjects still in treatment, data gathering still ongoing (requires annual reporting)

      Date of Closure _____

      Reason for closure _____

7. **If you checked 6a or 6b:**

   a. Is there any reason to believe the potential risks or benefits are materially different than believed at the time this study was last reviewed by this IRB?

      ☐ No

      ☐ Yes (explain): _____

      _____

   b. Has this IRB received all known safety/adverse event reports on this study?

      ☐ No (explain): _____

      _____

      ☐ Yes

c. **Have any significant new alternative treatments become available, which should be brought to the study subjects' attention?**

☐ No

☐ Yes (explain): _____

_____

d. **Have there been any modifications to this study, which have not been reviewed and approved by this IRB?**

☐ No

☐ Yes (explain): _____

_____

8. **Financial Interests.** (This paragraph does not need to be completed more than one time per year for any study group sponsoring multiple studies with the same financial considerations.)

a. Please detail below, all forms of payment which you or any member of your practice group receives from the Sponsor (or from any other source excluding normal reimbursement for professional medical services) in connection with this study, and how those funds are applied:

Funds received (including amounts): _____

_____

Application of funds: _____

_____

b. Please see Section VI.E of the IRB Handbook. Do you or any other investigators have any significant financial interests as defined in that Section? ☐ Yes ☐ No (explain):

_____

_____

9. **Other – Please Provide Any Other Information Which May Be Helpful to the IRB's Review of this Study:**

_____

_____

10. **PLEASE ATTACH A COPY OF THE CURRENT INFORMED CONSENT FORM.**

BY SIGNING THIS FORM, YOU CERTIFY THAT INFORMED CONSENT HAS BEEN OBTAINED AND WILL BE OBTAINED FROM EVERY STUDY SUBJECT, AND THAT THE INFORMED CONSENT PROCESS WILL BE FOLLOWED, IN COMPLIANCE WITH LEGAL AND REGULATORY STANDARDS AND THE STANDARDS SET FORTH IN THE METHODIST IRB HANDBOOK.

Signature of Principal Investigator: _____

Date Submitted: _____

A typed name in the above Signature of the Principal Investigator box constitutes a signature of the principal investigator for this study.

Submit