



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? Yes No (explain):

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: