



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

Institutional Review Board Status Report of Study

This form is to report the status of a Study. Periodic reports, at intervals established by the Methodist Hospital IRB, are required by law as a condition of continued approval of a Study by the IRB.

Title of the Study/Research:

IRB Number, if applicable:

Date of Submission of this Status Report:

Principal Investigator's Name:

Date of Original Methodist Hospital IRB Approval:

Subjects Enrolled:

Number of Subjects Enrolled by the Principal Investigator to Date:

Number of Subjects Enrolled in the Study in total (Nationally, Internationally), if known:

Status of the Study:

- Open and accruing additional subjects, or accruing is temporarily suspended
- Closed to accruing additional subjects
 - Subject(s) are still involved in study-related activities
 - Subject(s) are no longer involved in study-related activities
- Other: _____

Date of Closure to Accruing Additional Subjects:

Reason for Closure to Accruing Additional Subjects:

Status Report Questions:

Is there any reason to believe the potential risks or benefits to Subjects are materially different than believed at the time this Study was last reviewed by this IRB:

- No
- Yes. Explain: _____

Has this IRB received all known Adverse Event Reports required to be reported for this Study?

- Yes
- No. Explain: _____

Are there any significant new alternative treatments available that should be brought to the attention of Subjects on this Study?

- No
- Yes. Explain: _____

Are there any modifications to this Study that have not yet been reviewed by the IRB?

- No
- Yes. Explain: _____

Financial Interests:

List all forms of Study-related payment received by any person or entity involved in this Study from the Study Sponsor or from any other source, and the application of such payments. Attaching the study budget may be sufficient if there are no other forms of Study-related payments received.

| Payments Received | Application of Payments Received |
|-------------------|----------------------------------|
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Have all Reportable Financial Interests (as defined in the Methodist Hospital IRB Handbook) been reported to the IRB?

- Yes
- No. Explain: _____

Documentation

(List any documents that are being submitted with this Status Report, including the informed consent form, if applicable):

Investigator’s Certification: I certify that the foregoing is complete and accurate to the best of my knowledge. I will advise the Chair of the IRB of any changes to any of the above questions of which I become aware.

Signature of Principal Investigator or designee:

Printed Name of Principal Investigator or designee:

Title of Designee, if applicable:

Date:

**** A typed name in the above signature of the delegated staff member box constitutes a binding electronic signature for this study.