



METHODIST

The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4000

Institutional Review Board Annual Continuing Review Form

This form is to provide at minimum an annual status of a previously approved Study.

IRB Meeting Date dd/mmm/yyyy

Attachment

Completed By (initial / date)

IRB Office Only

TITLE of Clinical Research Study*

Principal Investigator's Name / Credentials*

Methodist IRB ID#*

Date of Original Methodist IRB Approval*

Study Enrollment Status*

Open

Closed

Other

Total Subjects locally enrolled to date*

Total Subjects globally enrolled to date*

Submission to IRB Date*

Status Clarifications

Is there reason to believe the potential risks/benefits to Subjects are materially different than at the time of the most recent review?

If yes, provide details.

No

N/A

Yes

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

If yes, provide details.

No

N/A

Yes

Are there any significant, new alternative treatments available that should be brought to the attention of the consented Subjects?

If yes, provide details.

No

N/A

Yes

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

If yes, provide details.

No

N/A

Yes

Have there been any changes to the Financial Disclosure Forms (FDFs) not yet been reviewed by the IRB?

If yes, provide details.

No

N/A

Yes



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Documentation*

List any documents submitted with this request

Additional Information

Investigator's Certification*

I certify the provided information on this form is complete and accurate to the best of my knowledge. I will advise The Nebraska Methodist Institutional Review Board of any changes to the above completed fields when I become aware.

Signature of Principal Investigator or designee*/**

Printed Name of Principal Investigator or delegated staff*

Title of Principal Investigator or delegated staff*

Date (If not provided above)

* required field

** An electronic signature or typed name constitutes a binding electronic signature for this study.