Institutional Review Board
Report of an Adverse Event

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

IRB Office Only	IRB Meeting Date dd/mmm/yyyy	Attachment	Completed By (initial / date)

This form is to report an event related to any already-approved Study. Events to be reported include: adverse events, serious adverse events, unanticipated problems, and suspected/unexpected serious adverse reactions. Along with this form, you must submit any form, report, or associated documentation required by the Sponsor or Protocol in addition to a blank copy of the Study's Informed Consent Form.

TITLE of Clinical Research Study*

Principal Investigator's Name / Credentials*

Methodist IRB ID#*

Date of Original Methodist IRB Approval*

Study Enrollment Status* ☐ Open ☐ Closed

Total Subjects enrolled to date*

Submitted to IRB Date*

Category of Event*

select all that apply

☐ **Internal Adverse Event -** An adverse event experienced by any subject enrolled at any affiliate of the Nebraska Methodist Health System, Inc. In the context of a single-center clinical trial, all adverse events are considered Internal Adverse Events.

☐ **External Adverse Event** - An adverse event is experienced by any Subject enrolled by an Investigator at another institution engaged in the Study, or when a Subject in a different study with the same study-related interventions, experiences an Adverse Event. Not all EAEs are required to be reported or reviewed unless requested by the Sponsor and/or elicits change in conduct, investigational treatment, and/or Informed Consent Form.

☐ **Unanticipated Problem** - Any incidents, experiences, or outcome that meets all of the following criteria:

- Are unexpected (in terms of nature, severity, or frequency) given:
  - the research procedures described in the Protocol-related documents such as the Protocol and ICF.
  - The characteristics of the subject population being studied.
- Are related or possibly related to participation in the research; and
- Suggest the research places Subjects, or others, at a greater risk of harm (including physical, psychological, economic, or social harm), than previously known or recognized.

Risk Evaluation

Does this Event materially effect the risk/benefit analysis for patient enrollment?

If yes, provide details.

☐ No ☐ N/A ☐ Yes

Should the Informed Consent Form for this Study be modified following this Event?

If yes, provide details.

☐ No ☐ N/A ☐ Yes

Should all active Subjects enrolled in this Study at an affiliated of the Nebraska Methodist Health System, Inc. be contacted with information regarding this event?

If yes, provide details.

☐ No ☐ N/A ☐ Yes

Should all completed Subjects enrolled in this Study at an affiliated of the Nebraska Methodist Health System, Inc. be contacted with information regarding this event?

If yes, provide details.

☐ No ☐ N/A ☐ Yes

METHODIST
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Documentation*

List any documents submitted with this report

Description of Event

Include where event occurred

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.