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 Participants enrolled to date*

Submitted to IRB Date*

Category of Event*

select all that apply

☐ **Internal Adverse Event -** An adverse event experienced by any Participant 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 Participant enrolled by an Investigator at another institution engaged in the Study, or when a Participant 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 participant population being studied.
- Are related or possibly related to participation in the research; and
- Suggest the research places Participants, 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 Participant 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 Trial Participants 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 Trial Participants 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
The Nebraska Methodist Hospital
8303 Dodge Street
Omaha, Nebraska 68114
(402) 354-4000

Institutional Review Board
Report of an Adverse Event

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.