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

Institutional Review Board
Report of Event

This form is to report an event related to a 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 other documentation (including the adverse event/safety report form) required by the Sponsor or the Protocol, **as well as a blank copy of the Study's informed consent form.**

Title of the Study/Research:

IRB Number, if applicable:

Date of Submission of this Report:

Principal Investigator's Name:

Date of Original Methodist Hospital IRB Approval:

Study Status:

- ☐ **Open**
- ☐ **Closed to Accrual**

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:

Category of Event (you may select more than one):

- ☐ Internal Adverse Event
  - An adverse event experienced by any subject enrolled at any affiliate of the Nebraska Methodist Health System.
- ☐ External Adverse Event
  - An adverse event is experiences by any subject enrolled at an institution or entity other than at any affiliate of the Nebraska Methodist Health System.
- ☐ Unanticipated Problem
  - Any incidents, experiences, or outcome that meet all of the following criteria:
    - Are unexpected (in terms of nature, severity, or frequency) given (i) the research procedures that are described in the Protocol-related documents, such as the IRB-approved research Protocol and ICF, and (ii) the characteristics of the subject population being studied;
    - Are related or possibly related to participation in the research; and
    - Suggest that the research places Subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Description of Event:

_____
_____
_____
_____

Location of Event:

Risks to Subjects:

In the opinion of the Principal Investigator, does this Event change the risk-versus-benefit consideration of participation in this Study?

- ☐ No
- ☐ Yes. Explain: _____

In the opinion of the Principal Investigator, should the informed consent form for this Study be modified following this Event?

- ☐ No
- ☐ Yes. Explain: _____

In the opinion of the Principal Investigator, should all patients presently or formerly enrolled in this Study at an affiliate of the Nebraska Methodist Health System be contacted with information regarding this Event?

- ☐ No. Explain: _____
- ☐ Yes. Explain: _____

Documentation
(List any documents that are being submitted with this Report of Event):

_____
_____
_____
_____
_____

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.