

Institutional Review Board Protocol Deviation Form

This form is to request acknowledgment of a protocol deviation.

IRB Meeting Date dd/mmm/yyyy

Attachment Completed By (initial / date)

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

IRB Office Only

TITLE of Clinical Research Study*

Principal Investigator's Name / Credentials*

Methodist IRB ID#*

Date of Original Methodist IRB Approval*

Method of Review Requested*

Expedited (The deviation poses no more than minimal risk to Subjects.)

Full Board (The deviation poses more than minimal risk to Subjects.)

Submitted to IRB Date*

Summary of Deviation*

Include likelihood of similar event to occur

Documentation*

List any documents submitted with this request

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.