ROCHESTER REGIONAL HEALTH

Protocol Major Deviation /Violation Report

Clinical Investigation Committee

This form is to be used to report Major Deviations/ Violations only.

CIC Number and title of study_____
_____

Sponsor		Protocol No.	
Principal Investigator		Phone	
Participant Initials		Is Participant Still Enrolled?	

Date of Report		Date Deviation/Violation	

Major Protocol Deviations are to be submitted to the RRH CIC within 48 hours of investigator becoming aware of event.
Reason for Submission: (One of the following must be selected)

☐ Major Protocol Deviation/ Violation resulted in an increased risk to participant.

☐ Major Protocol Deviation/ Violation resulted in wrong dose

☐ Major Protocol Deviation/Violation resulted in wrong drug

☐ Major Protocol Deviation/ Violation affected the accuracy of study results

☐ Failure to obtain informed consent prior to initiating study procedures

Other Types of Deviation/Violation are to be submitted to the RRH CIC within 7 days of investigator becoming aware of event.
Other Types of Deviation/ Violation: (One of the following must be selected – please see examples of major protocol deviations in the Protocol Deviation Policy and Procedures form)

☐ Obtaining consent with a non-current consent form

☐ Enrollment of an ineligible patient

Other: _____

Description of the major protocol deviation / violation.

_____

_____

_____

Explain the reason for the major protocol deviation / violation.

_____

_____

_____

Describe any corrective action implemented to prevent recurrence

_____

_____

Recommendations – If this is a local investigator-initiated protocol

Do you recommend a change to the protocol based on this deviation? Yes ☐ No ☐
If yes please attach recommendation(s)

Do you recommend a change to the consent form based on this deviation?
Yes ☐ No ☐

If yes, please attach recommendation(s).

If no, explain why a consent form change is not required.

_____ _____
Print or type name of person completing this form Date

_____ _____
Signature of person completing this form Date