MetroWest Medical Center IRB
85 Lincoln Street, Framingham, MA 01702

Serious Adverse Event Reporting Form

Reporting Policy: ***Events which are serious and/or unexpected must be reported to the IRB, Hospital Risk Manager or Patient Safety Officer within 48 hours of knowledge of the event. For studies involving an investigational device, the report must be submitted within 10 days of the onset of the event. Please refer to Tenet policy CQ-2.03*** ***MWMCIRB Review Policy:*** *All reported events will be reviewed in a timely manner by MWMCIRB. MWMCIRB's review of serious and/or unexpected events will be documented to the investigator.*

Date:	
Sponsor Protocol Number:	MWMCIRB Number:
Title of Study:	
Study Article:	
Principal Investigator Name:	

Patient Information			
Subject ID:		Age:	☐ Male ☐ Female
1.	Type of Event (check all that apply)	☐ Serious	☐ Unexpected
2.	Relationship: ☐ Related ☐ Probably/ Possibly Related ☐ Unrelated		
3.	Type of Report ☐ Initial Report ☐ Follow-Up Report ☐ Follow-up # _____		
4.	Date of Event Onset:	Date Investigator became aware of Event:	
5.	Dates of study treatment: From: To:		

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6.	Event Resulted in: ☐ Death – Date: _____ Cause of Death: _____ ☐ Threat to Life ☐ Hospitalization: Date of Admission: _____ ☐ Severe or Permanent Disability ☐ None of the Above

Description of the Event			
1.	Key words to describe event (will be used on MWMCIRB's acknowledgement):		
2.	More **detailed** description, including treatment and status: Describe the actions taken in response to this event. If these included changes the research without IRB approval, describe the changes:		
3.	Did these actions alleviate the problem?	☐ YES	☐ NO
4.	If the problem is still unresolved what further action will be taken?		
5.	Did Subject continue participation in the study?	☐ YES	☐ NO
6.	Has the sponsor been notified of these events, including whether or not subject continued in the study? ***If no, indicate why.***	☐ YES	☐ * NO
7.	If not reported to MWMCIRB within 48 hours, please explain lapse.		

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Name of Person Completing Form (contact person for questions)	
Name:	
Title:	
Phone Number:	
Email Address:	
Signature of Principle Investigator or Designee ***Signature required as attestation that PI is aware of SAE**	
Date:	Signature:

PLEASE EMAIL COMPLETED FORMS AND REQUIRED DOCUMENTS TO MWMCIRB@mwmc.com you will receive an acknowledgement once all required information has been submitted.

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Reporting Form Requirements

Investigators will be required to promptly report, within 5 business days of becoming aware, to the IRB any changes in the research activity and the problems listed below:

- **Internal adverse events which are unexpected and related to the research;**
- **External adverse events which are unanticipated problems involving risks to participants and others, as determined by the study investigator;**
- **Changes made to the research without prior IRB approval in order to eliminate apparent immediate harm;**
- **Other unanticipated information that indicates participants or others might be at increased risk of harm such as a new risk, identified in an interim safety analysis, revised package insert, revised investigator brochure, publication in the literature or a DSMB report.**
- **Unanticipated problems involving risks to participants or others will be defined as any report of information that is (1) unanticipated and (2) indicates that participants or others are at increased risk of harm.**
- **Allegation or finding of non-compliance;**
- **Major protocol deviations or violations that might affect the rights safety and welfare of subjects;**
- **Unanticipated adverse device effects (Any serious adverse effect on health safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application) or any other unanticipated serious problem associated with a device that relates to the rights safety, or welfare of subjects.)**