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

Continuing Review Form

	To renew the study: • Complete and send this report at least 30 days prior to the approval expiration date • The PI or Designee must complete and sign this report • If the study was open to enrollment during the last approval period, a copy of the signed consent form for the last subject consented, not redacted. • Except where noted, please answer questions in relation to events that occurred in the last reporting period only (and not the entire course of the study).

1.	Date of Report:	Approval Expiration Date:	
2.	MetroWest Medical Center IRB Number:	Protocol Number:	
3.	Title:		
4.	Name of Principal Investigator:		
5.	Sponsor:		NA:

A. Study Status		
1.	Indicate Current status of study:	☐ Open to Accrual ☐ Closed to Accrual (***if closed to accrual check all that apply)*** ☐ The study is permanently closed to enrollment of subjects ☐ All research-related interventions (including questionnaires and surveys) involving enrolled subjects have been completed ☐ Study remains active for long-term follow-up of subjects

B. Study Summary				
1.	Have there been any significant new findings? *(Ex. results from an interim analysis, relevant recent literature, DSMB reports, updated product information, or Dear Doctor letters)*	☐ No	☐ Yes	☐ Yes **Previously submitted to MWMC IRB**

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2.	Have there been any changes to the approved protocol that have not been reviewed by MWMCIRB?	☐ No	☐ Yes *see attached
3.	FDA guidance requires that the IRB confirm that the latest version of the protocol is in use at each site. Please list the version date or number of the protocol that is currently in use	Version Date/Number: _____	

C. Risk Assessment			
1.	Provide a summary of any unanticipated problems that have occurred at your site: ***(An unanticipated problem is defined as an event(s) that is unforeseen; involves risks to subjects or others, and is related to the study.)***	☐ N/A	☐ *See Attached
2.	Have there been any unanticipated problems or serious adverse events associated with this study (at your site) that have not been previously reported to MWMCIRB? ***(if yes, attach an Unanticipated Problem Report or SAE Report)***	☐ No	☐ *Yes
3.	Taking into consideration any new and relevant information (published or unpublished), provide a current risk- benefit assessment of the study. ***If a change has occurred, describe the change and its affect on the research***	Assessment	
		☐ No Change	☐ *A change has occurred

**** Include previously unreported serious adverse events and an explanation of why the reports were not previously submitted.***

D. Subject Accrual				
1.	How many subjects is your site currently approved to enroll?	_____ # Subjects		☐ NA
2.	Has your site enrolled more subjects than originally anticipated?	☐ No	☐ Yes	☐ NA
3.	If additional subjects were enrolled; did MWMCIRB approve this increase prior to the enrollment of the additional subjects? ***If "no", submit an explanation, a revised accrual goal, and, if applicable, a revised statistical analysis plan.***	☐ *No	☐ Yes	☐ NA

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4.	To date, total number of subjects that signed the consent form, at your site.	_____ Subjects **** Lines 5 through 9 should add up to # of consented subjects***
5.	To date, total number of subjects that are currently active in the study, at your site	_____ Subjects
6.	Number of screen failures (signed consent and only completed some or all screening activities)	_____ Subjects
7.	Number of subjects who were discontinued due to an adverse event	_____ Subjects
8.	Number of subjects who withdrew, were lost-to-follow-up or discontinued (not due to adverse event) **PLEASE PROVIDE AN EXPLAINATION FOR THESE SUBJECTS**	_____ Subjects
9.	Number of subjects who have completed the study, at your site	_____ Subjects
10.	For this reporting period ONLY, how many new subjects have signed the consent form?	_____ Subjects

E. Informed Consent					
1.	If the study was open to enrollment during the last approval period and at least one subject was enrolled, please include a ***complete copy of the Informed Consent for the last subject enrolled at your site***. ***Please do not black out subject signature and dates. The language in the informed consent provides MWMCIRB with authority to review subject identifying information.***	☐ Attached ☐ N/A, a waiver of consent was approved ☐ N/A, no enrollment during this period			
2.	Have all subjects signed and received a copy of the approved informed consent document? ****if no, please explain***	☐ Yes	☐ *No	☐ No Patients consented	☐ N/A, a waiver of consent was Approved
3.	How many subjects consented at your site were non-English speaking?	_____ Subjects			
4.	What language(s) do these subjects speak?	Language:_____			

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5.	Have these subjects been consented using a MWMCIRB-approved translated consent form? ***if no, please explain***	☐ Yes	☐ *No	☐ N/A

F. Other Information			
1.	Has there been any change to study staff (investigators or those obtaining consent) that has not been submitted to MWMCIRB? ***If yes attach a summary of the changes and include a summary of the qualifications OR a CV for any new research staff.***	☐ *Yes	☐ No
2.	Have any new potential benefits been identified?	☐ *Yes	☐ No
3.	Have there been any complaints about the study?	☐ *Yes	☐ No
4.	In the last reporting period, has the PI or any sub-investigator developed any previously unreported conflicts of interest in this study or been offered any bonus payments by the study sponsor or CRO?	☐ *Yes	☐ No
5.	Since the last renewal period, has the PI or any sub-investigator been disciplined by a medical/licensing board, or been convicted of a crime or been disciplined/sanctioned by the FDA, OHRP or by an IRB?	☐ *Yes	☐ No
6.	Have there been any changes to the research staff or investigative site that affect the conduct of the research?	☐ *Yes	☐ No
7.	Have there been any changes to state or local law or professional standards that affect the conduct of the research?	☐ *Yes	☐ No
8.	Does the investigator have any concerns about the continuation of the study?	☐ *Yes	☐ No
If yes to any questions in this section, provide an explanation			

G. Accrual Categories (Mandatory for federally funded studies; suggested for other studies)		
1.	Provide the % of subjects accrued in each category	Ethnic Categories: ____ % Hispanic or Latino ____ % Not Hispanic or Latino Racial Categories: ____ % American Indian/Alaskan native ____ % Asian ____ % Native Hawaiian/Pacific Islander ____ % Black or African American ____ % White ____ % Other / Unknown

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2.	Provide the % of subjects accrued in each category	____ % Female ____ % Male	
3.	Is your accrual data similar to the demographics of your geographic location? You may obtain local demographic data at the website: http://www.census.gov/prod/cen2000.index.html ***Whether you use census data or another source for local demographics, please attach a copy.***	☐ Yes	☐ No

I certify that the information included in this report and its attachments is correct:

Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
	Signature of Principal Investigator or Designee
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.

	INCLUDE THE FOLLOWING WITH ALL SUBMISSIONS
	Complete copy of the Informed Consent for the last subject enrolled at your site.
	Explanation of subjects who withdrew or lost to follow up
	Please attach all documents requested from the sections on this form