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

Completion Report

To report to MWMCIRB **that this study has been completed at your site:**
FDA- regulated studies:

- **All subjects have completed the study treatment and all study related procedures, including observation periods; AND .**
- **All serious adverse experiences have been submitted to MWMCIRB; AND**
- **All study information has been submitted to MWMCIRB**

HHS-supported studies:

- **Individually identifiable follow-up data are no longer being collected on subjects enrolled in an HHS-supported protocol; AND**
- **Analysis that could indicate new information is complete,**

This report should also be submitted if a study is canceled or the study is closed to enrollment and no subjects were enrolled at this site.

Complete and send this report within 30 days of end of study or expiration date. The Principal Investigator or designee may complete and sign this report.

A. **Study Information**		
1.	Date of Report:	Approval Expiration Date:
2.	MWMC IRB Number:	Protocol Number:
3.	Title:	
4.	Name of Principal Investigator:	Sponsor:

B. **Study Completion Information**			
1.	☐ Completed	Date:	
	☐ Terminated	Date:	Reason for termination: _____
	☐ Not Begun		Reason not Begun: _____

C. **Study Summary**			
1.	Results obtained to date, if any:	☐ No	☐ *Yes **See attached**
2.	Have there been any significant new findings?	☐ No	☐ *Yes **See attached**

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3.	Has there been an interim analysis?	☐ No	☐ *Yes **See attached**
4.	Interim reports, findings, or abstracts	☐ No	☐ *Yes **See attached**
5.	Have there been any changes to the approved protocol that have not been reviewed by MWMCIRB?	☐ No	☐ *Yes **See attached**
6.	Please provide a summary for final report as soon as available.		

D. Serious Adverse Events			
1.	Number of Serious Adverse Events (SAE), which occurred at your site:	_____ # Initial SAE Reports _____ # F/U SAE Reports	
2.	Have all serious adverse events, whether related to the study article or not, been reported to MWMCIRB?	☐ No	☐ *Yes **See attached**

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

E. Subject Accrual and Follow-up		
1.	Accrual Goal (total number of subjects anticipated at onset of study)	_____ # Subjects
2.	Total number of subjects that signed the consent form, at your site.	_____ #Subjects ***The total from lines 3-6 should equal the # of subjects consented***
3.	Number of screen failures (signed consent and only completed some or all screening activities)	_____ # Subjects
4.	Number of subjects who were discontinued due to an adverse event	_____ # Subjects
5.	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
6.	Number of subjects who have completed the study, at your site	_____ # Subjects

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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 the approved informed consent document?	☐ Yes	☐ No	
		☐ N/A *a waiver of consent was approved*	☐ No Patients consented	
3.	How many subjects consented at your site were non-English speaking?	_____ Subjects		
4.	What language(s) do these subjects speak?	Language: _____		
5.	Have these subjects been consented using a MWMCIRB-approved translated consent form?	☐ Yes	☐ No	☐ N/A

** If any items in this section are answered "no", provide an explanation*

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

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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:	
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