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

Study Transition Form:

Additional Information for a Currently Active Study

Complete this form for studies being transitioned to MWMCIRB from the jurisdiction of another IRB. This form must accompany a completed Site Submission From along with required documents. (see Site Submission Form for a list of required documents)	
Protocol Title:	Date:
Protocol Number:	
Principle Investigator:	
Name and Address of Primary Research Site:	
Address of PI if different from Research Site:	

A GENERAL STUDY INFOMRATION		
A-1	Reason for requesting IRB transfer:	
A-2	Name of previous IRB:	
A-3	Date of IRB expiration:	
A-4	List any restrictions placed on the study by the previous IRB:	
A-5	Indicate the current status of the study:	☐ Open to accrual ☐ Closed to accrual: ***Please check all that apply*** ☐ The study is permanently closed to enrollment of subjects ☐ All research-related interventions (including questionnaires and surveys) involving enrolled subjects has been completed.

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		☐ Study remains active for long-term follow-up of patients

B SUBJECT ACCRUAL INFORMATION	
B-1	To date, total number of subjects that signed the consent form, at your site: _____
B-2	To date, total number of subjects that are currently active in the study, at your site: _____
B-3	For each active subject, list which visit the subject has last completed: _____

C ACCOUNTABILITY OF NON-ACTIVE SUBJECTS:	
C-1	Number of screen failures (signed consent and only completed some or all screening activities): _____
C-2	Number of subjects who were discontinued due to an adverse event: _____
C-3	Number of subjects who withdrew, were lost-to-follow-up or discontinued (not due to adverse event) ____

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C-4	Provide an explanation for each subject in #C3: _____
C-5	Number of subjects who have completed the study, at your site: _____

D	Provide a summary of any unanticipated problems or noncompliance issues that have occurred. Attach additional pages as necessary: _____

Note: MWMCIRB does not asume any responsibility for the study until MWMCIRB issues a final approval for the study.

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

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By signing this form, I acknowledge and agree that:

- All information submitted is accurate.
- MWMCIRB has the authority to oversee this study and there is no other IRB with jurisdiction of this study at this study site.
- Any and all delegation of my responsibilities as Principal Investigator will be made to individuals qualified and appropriately licensed to carry out the delegated duties.

_____ _____

Principal Investigator (Signature) Date

_____

Principal Investigator (printed name)

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

Checklist

INCLUDE THE FOLLOWING WITH SUBMISSION	
	Completed Site Submission form with required documents
	A complete copy of correspondence between the Investigator and IRB, including minutes if available. All documents should be organized in chronological order and can be provided by the investigator or IRB
	A written agreement from the previous IRB transferring jurisdiction to the MWMCIRB
	Study Protocol
	Last approved ICF word version
	Copy of last IRB Continuing Review Approval Letter