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

Chart Review Site Submission Form

Please provide information about the Investigator and the Research Site. All fields on this form must be completed, failure to do so may result in a delay of IRB review. Please refer to the end of this form for a checklist of required documentation that must accompany your submission.			
A. GENERAL STUDY INFORMATION			**Date of Submission:**
A1	Study Title:		
A2	Sponsor Protocol Number:		

B. **INVESTIGATOR AND RESEARCH STAFF INFORMATION**: **** Attach a CV and a license for the Principal Investigator***				
B1	Principal Investigator Name:			
B2	Principal Investigator email address:			
B3	Study Coordinator Name: ****if applicable***			
B4	Study Coordinator Phone Number:			
	Study Coordinator email:			
B5	Is this Resident Research?		Yes ☐	No ☐
B6	Does the PI have an obligation to use another IRB for any site in this study? ****If yes, please complete Waiver of Authorization Form***		*Yes ☐	No ☐
B7	Has PI ever been convicted of a crime, disciplined by public or private medical organization, disciplined by a licensing authority, or is the PI currently involved in any such proceeding? **** If yes, provide explanation***		*Yes ☐	No ☐
B8	Has the PI ever been disciplined/sanctioned by the FDA, OHRP or by an IRB? **** If yes, please provide explanation***		*Yes ☐	No ☐
B9	Is this a multi-site study in which the investigator is the lead investigator		*Yes ☐	No ☐

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B9a.	*If yes please include a description of the management of information obtained in multi-site research that might be relevant to the protection of subjects, such as: • Unanticipated problems involving risks to subjects or others. • Interim Results • Protocol Modifications		
B10	Will there be any Sub-Investigators participating in this trial?	Yes ☐	No ☐
B11	Sub-Investigator Name(s):		
B12	Has any Sub-Investigator ever been convicted of a crime, disciplined by public or private medical organization, disciplined by a licensing authority, or is the Sub---Investigator currently involved in any such proceeding? * ***If yes, provide explanation***	*Yes ☐	No ☐
B13	Name of Research Site		
	Address of Site		

Confidentiality			
E1	Are the subject's names, social security numbers, hospital record numbers, or any identifier (other than subject initials and study number) being sent off site?	Yes ☐	No ☐
E2	Who will have access to study records? ☐ Research Personnel Only ☐ Other: _____		
E3	For how long will the study records be stored? _____		
E4	Will this data be used for any other purpose other than that for which the subjects will be consented? ***If yes, please explain*** _____	*Yes ☐	No ☐

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Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	

Investigator Statement

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.
- MWMCIRB has the authority to suspend the study if necessary to protect the rights and welfare of the study subjects.
- I will provide MWMCIRB with the information required to conduct initial and continuing review of this study on a timely basis and that if the information is not provided, MWMCIRB may suspend the study.
- I will conduct the study in accordance with the conditions of approval required by MWMCIRB and in accordance with all applicable regulations and ethical guidelines.
- 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)

For Resident studies, Resident Department Chair signature is required.

_____ _____
Department Chair (signature) Date

_____
Department Chair (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.**

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	INCLUDE THE FOLLOWING WITH ALL SUBMISSIONS
	Submission letter signed by Principal Investigator (Optional)
	Current Curriculum Vitae for Principal Investigator *(signed and dated)*
	Current Curriculum Vitae for Sub- Investigator *(signed and dated)*
	Copy of Medical License for Principal Investigator and Sub Investigators
	Evidence of Human Subject Protection Training (CITTI, NIH or equivalent)
	Completed Protocol Summary Form and or protocol