MetroWest Medical Center IRB

85 Lincoln Street, Framingham, MA 01702

Protocol Submission Form

General Information		
1	Protocol Name: Click here to enter text.	
2	Protocol Number : Click here to enter text.	Study Sponsor: Click here to enter text.
3	For the initial approval process, MWMCIRB should communicate with (check one) ☐ Sponsor ☐ CRO ☐ Site	
4	Contact Information for Entity Listed Above: Name: Click here to enter text. Company: Click here to enter text. Address: Click here to enter text. City, State, Zip: Click here to enter text. Phone: Click here to enter text. Fax: Click here to enter text. Email Address: Click here to enter text.	

5.	*Check as Applicable:* ☐ Data from this study are subject to FDA regulation and oversight, either through submission or inspection. ☐ This study is federally funded. (If checked, a copy of the entire grant must be submitted) ☐ This study is not subject to FDA regulation, nor is it federally funded.		
6.	Drug or Biologic Study: **** If yes check all that apply*** ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ IND #, if applicable ☐ No IND #; provide explanation:	*Yes ☐	No ☐

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7.	Device Study: **** If yes check all that apply*** ☐ Investigational ☐ Class I ☐ Class II ☐ Class III ☐ Significant Risk: submit IDE #, letter from FDA and device specifications ☐ Non-Significant Risk: submit justification, including regulatory citations and 510k# if applicable) ☐ HUD – submit HDE# and FDA letter ☐Marketed; being in accordance with approved labeling (submit approved labeling) ☐ IDE exemption: provide category as per 21 CFR 812.2 ☐ This study does not involve a drug, biologic or device	*Yes ☐	No ☐

8.	Approximate number of investigative sites to be submitted to MWMCIRB Click here to enter text.			
9.	Is the language in the submitted ICF that addresses compensation for research-related injury language consistent with the language in the investigative site's contracts?	N/A ☐	Yes ☐	No ☐
10.	Have any other IRBs (local or central) reviewed this study? **** If yes, describe the outcome of the review, including any issues that required*** resolution prior to final approval:	N/A ☐	*Yes ☐	No ☐

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

Name of Person Completing Form (contact person for questions):	
Name:	Click here to enter text.
Title:	Click here to enter text.
Phone Number:	Click here to enter text.
Fax Number:	Click here to enter text.
Email Address:	Click here to enter text.
	Principal Investigator Signature
Date: Click here to enter text.	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
	Protocol
	Current Curriculum Vitae for Principal Investigator *(signed and dated)*
	Evidence of Human Subject Protection Training (CITTI, NIH or equivalent)
	ICF If Applicable