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

Protocol Summary Non-Industry

Instructions: Complete each section as instructed and submit this form with your protocol. Also, make sure all information provided on this worksheet is included in the protocol document.

Date: _____

Section A: Rationale/ Purpose (Briefly Explain)	
A1.	Study Rationale: Click here to enter text.
A2.	Study Objective(s) and/or hypothesis Click here to enter text.

Section B: Study Design and Procedures	
B1.	☐ Randomized trial ☐ Non-randomized trial testing new or experimental procedures or interventions ☐ Survey, interview ☐ Focus groups ☐ Database review, record review ☐ Epidemiological research ☐ Secondary analysis of previously collected data ☐ Chart Review (complete Chart Review Protocol) ☐ Other (specify):
B2.	List the inclusion criteria for subjects or criteria for selection of records to review:
B3.	List the exclusion criteria for subjects or criteria for selection of records to review:
B4	Briefly describe the anticipated outcomes of the study:

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C. Recruitment, Screening and Consenting Subjects	
C1	Describe in detail the planned method for recruiting / contacting potential subjects, including how initial contact will be made with potential subjects and by whom:
C2	Indicate if/how any screening procedures will be done to determine subject eligibility:
C3	Describe in detail in the box below your plans for obtaining informed consent from subjects, including how consent will be obtained (in person, by telephone, by mail, by internet, etc.:

D. Potential Risks and Benefits	
D1	List the possibilities for risk or harm to subjects as a result of participation in the research, including physical harms, social harms, discomforts, hazards, or inconveniences.
D2	List any potential benefit to the subject or society.

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E. Costs	
E1	Please explain the costs/potential cost that subjects might/will incur as part of the study. Include costs of travel, parking, medication, equipment, internet service fees, etc. How will the costs of research be covered? Will the subjects have to pay any out of pocket expenses? Will the subject's insurance be billed for any research related activities? If yes, indicate specifically which items the subjects (or subject's insurance) will be responsible for and the cost of each. Be sure to include any co-pays, deductibles, out of pocket expenses, etc.

F. Confidentiality of Data	
F1	Data is considered identifiable if • It contains any subject identifiers, OR • The data can be linked to subject identifiers via a master code OR • Subjects can be identified via deductive disclosure (combination of the data elements). In the space below, clearly specify whether any subject data will be recorded in a way that it is identifiable (even temporarily). Specify whether study data will be identified by specific subject identifiers (name, medical record numbers, etc.) or by any study IDs that can be linked to subjects via master-codes. Also describe who will have access to the master-code and how it will be stored to ensure that unauthorized individuals do not gain access to the master-code. _____ _____ _____

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G. Data Analysis	
	Provide a description of the plan for data analysis. • State the types of comparisons that are planned (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). • How will the analyses proposed relate to the primary purposes of the study? • If the research is qualitative, state how comparisons will be made. _____ _____ _____

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:	
	Principal Investigator Signature
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.**

Checklist

INCLUDE THE FOLLOWING WITH SUBMISSION	
	Copy of Protocol
	Copy of CV and Medical License
	ICF word document **if applicable*
	Waiver of consent **if applicable*