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

Site Submission Form

Date: _____

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			
A1	Study Title:		
A2	Sponsor Protocol Number:	Sponsor Name if Applicable:	
A3	Will this study be federally funded?	☐ Yes	☐ No

B. **INVESTIGATOR AND RESEARCH STAFF INFORMATION**: **** Attach a CV and a license for the Principal Investigator*** ***In addition to initial disclosure, the Investigator must notify MetroWest Medical Center IRB whenever his/her financial interests in the study change. Financial conflict of interest should be disclosed to the IRB in writing via a letter from the Investigator to the IRB Chairman.**				
B1	Principal Investigator Name:			
B2	Principal Investigator email address:			
B3	Study Coordinator Name:			
B4				
B5	Study Coordinator Phone Number			
	Study Coordinator email			
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

Site Submission Form

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
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 ☐ NA	☐ No
B13	While this protocol is active, how many of the following will the PI supervise: Sub-Investigators: ____ Sites: ____		
B14	How many of the following does the PI currently supervise: Open Research Studies: _____ Approximate Number of Active Subjects: _____		
B15	Does the principal Investigator have sufficient time to conduct and complete the research?	☐ Yes	☐ No
B16	Does the Principal Investigator have adequate facilities to conduct the research?	☐ Yes	☐ No
B17	Does the Principal Investigator have access to a population that will allow recruitment of the necessary number of subjects?	☐ Yes	☐ No
B18	Does the Principal Investigator have access to medical or psychological resources that participants might require as a consequence of the research?	☐ Yes	☐ No

Site Submission Form

B19	How long has the PI been conducting research? ☐ New Site ☐ < 1 year ☐ 1-5 years ☐ >5years		
B20	Does the Principal Investigator have adequate numbers of qualified staff to perform research related activities?	☐ Yes	☐ No
B21	Indicate number of research coordinators. _____		
B22	Does the Principal Investigator have a process in place to ensure that all persons assisting with research are adequately informed about the protocol and their research related duties and functions?	☐ Yes	☐ No
B23	Does the PI oversee multiple locations for this study? * ***If so, you must submit the Additional Research Location Form.***	☐*Yes	☐ No
B24	Does the site have a Site Management Plan to explain how the PI will manage the multiple locations? ***If yes, please provide a copy.*** **A Site Management Plan for this purpose should explain how the PI manages multiple locations, multiple Sub-Investigators and whether the sites are in a drivable distance. The PI is ultimately responsible for the study conduct.**	☐*Yes ☐ NA	☐ No
B25	Does the Principal Investigator have a process in place for storage, control, and dispensing of unlicensed test articles so that they are used only in approved research protocols and under the direction of approved investigators?	☐ Yes ☐ N/A	☐ No
B26	How many studies has the PI conducted in the past year? _____		
B27	How many studies is the PI currently conducting? _____		

C. INVESTIGATIVE SITE INFORMATION			
C1	Name of Primary Research Site:		
	Address of site:		
	**List all additional research sites on Additional Research Location Form*		
C2	What type of facility is this site? ☐ Research Clinic ☐ Medical Office ☐ Hospital Office		
C3	Has this site or Principal Investigator been inspected by FDA or OHRP within the past 5 years? ****If yes, attach all documents relating to the inspections, including the current status***	☐*Yes	☐ No
C4	Has an IRB ever suspended or terminated a study at this site? * ***If yes, attach a summary of the event and resolution.***	☐*Yes	☐ No
C5	How close is the nearest emergency facility?	☐ Less than 1 Mile ☐ 1 to 10 miles ☐ More than 10 Miles	
C6	If the site is more than 10 mile away from an emergency facility, briefly describe how a medical emergency is handled. _____		
C7	Is there emergency equipment at your site? Check all that apply. ☐ Crash cart ☐ Defibrillator ☐ Oxygen ☐ Other: _____		

D. SUBJECT INFORMATION			
D1	How many subjects do you anticipate enrolling at this site? _____ ***After the study has begun at your site, if you are anticipating on enrolling more than this number of subjects, MWMC IRB approval must be obtained prior to enrolling additional subjects.***		
D2	Do you anticipate enrolling more of one gender than the other?	☐*Yes	☐ No
D3	*If you answered yes to D2 above, please provide an explanation: ☐ Not applicable ☐ Reflective of practice demographic ☐ Per inclusion/exclusion of protocol ☐ Reflective of disease demographic ☐ Other _____		

Site Submission Form

D4	Which of the following types of subjects will be recruited at your site? ☐ In- Patients ☐ Private Practice Patients ☐ Out -Patients ☐ General Population		
D5	Will any subjects from potentially vulnerable populations be enrolled?	☐*Yes	☐ No
D6	*If you answered yes to question D5 please select all that apply: ☐ Nursing Home Residents ☐ Seriously/Terminally Ill ☐ Economically Disadvantaged ☐ Mentally Impaired ☐ Homeless/Shelter ☐ Pregnant Woman ☐ Children ☐ Prisoners ***When some or all participants are vulnerable, please attach a description of additional safeguards included to protect their rights and welfare***		
D7	Describe the population to be recruited for this research: ***(These numbers should add up to 100%)*** _____ % African American/Black _____ % Asian _____ % Pacific Islander _____ % Native American _____ % Middle Eastern _____ % Aboriginal peoples of Canada _____% Caucasian _____ % Other (list) _____ *Note: This information may be estimated based on practice location.* Ethnicity: ***(These numbers should add up to 100%)*** _____ % Hispanic or Latino _____ % Not Hispanic or Latino		
D8	Please indicate the language(s) of the subjects the PI intends to enroll. *(The consent form must be in a language easily understood by the subject, and all consent form translations must be approved by MWMC IRB.)* ☐ English ☐ Spanish ☐ French ☐ Other (specify) _____		

E. CONSENT
The investigator must obtain the legally effective informed consent of the subject or the subjects legally authorized representative.

Site Submission Form

E1	Who will discuss the study with and get consent of potential study subjects? ***(MWMC IRB reviews qualification of all staff and investigators obtaining consent, please provide CV's for all individuals unless previously submitted).*** ☐ PI ☐ Sub-Investigator ☐ Study Coordinator		
E2	Will consent be obtained from a legally authorized representative for some or all of the patients?	☐*Yes	☐ No
E3	If question E2 is answered yes, describe which individuals are authorized under state or other law to consent on behalf of a prospective subject to his or her participation in the procedures involved in this proposed research**.** ***(Note: All persons deemed to be "legally authorized representatives" must meet this criterion prior to signing the informed consent.)***		
E4	What methods will be used to ensure that the study subject understands the information provided during the consenting process (check all that apply)? ☐ Subjects are allowed as much time as they need to consider participation ☐ Subjects are asked questions about the study ☐ All study procedures and risks are carefully explained ☐ Medical jargon is not used during the discussion ☐ Other: _____		
E5	Privacy refers to being free from being observed or disturbed by other people. Please note the site-specific steps taken to protect the privacy interests of subjects (Check all that apply) ☐ Consenting and research activities are performed in a private room ☐ Subjects are given time alone or only with family if requested ☐ Subject is free from being observed or disturbed by other people ☐ Separate room or drapes used when subjects must disrobe ☐ Only necessary information is collected ☐ Other privacy precautions: _____		

E6	Please note the site-specific steps taken to maintain the confidentiality of data *(i.e. where the data will be stored, how it is stored, and how access to the data is controlled)* ***(Check all that apply)*** ☐ When feasible, identifiers will be removed from study-related information ☐ Data stored in paper format will be kept in a secure location; access is limited to only those individuals required to access for study requirements ☐ Electronic file access is limited to only those individuals required to access for study requirements ☐ Other confidentiality precautions:
E7	Which of the following mechanisms are used to minimize potential coercion (check all that apply): ☐ If the investigator is also the subject's physician, the differences between research and standard of care are carefully explained. ☐ If the study includes payment to subjects, this payment is not emphasized during the consenting discussion ☐ Any potential benefit of the study is not overstated during the consenting Discussion ☐ The voluntary nature of the study is carefully explained ☐ Subjects are informed that their decision to participate or not participate will have no effect on their normal care ☐ Other: Provide description: _____

E8	Are the Investigator and sub-investigators aware that although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights?	☐ Yes	☐ No
E9	Indicate if any of the following methods will be used for subject recruitment: ☐ Practice patient population ☐ Referrals ☐ External database ☐ Advertising *(All recruitment materials must be IRB approved)* ☐ Other, please describe: ***All direct advertising must be approved by MWMCIRB***		

Site Submission Form

The consenting process will not include any exculpatory language that waives, or appears to waive subject rights or releases any entity involved in the research (sponsor, investigator, etc.) from liability or negligence *Examples of exculpatory language:* • You understand that no compensation for lost wages will be provided to you • You agree the sponsor is not responsible for any injuries you suffer from participation in this study • You understand the investigator and sponsor are not responsible for any study-related injuries you suffer if you do not follow the protocol			
E10	Is the plan for treatment and compensation of a research related injury carefully explained? ****If no please explain:*** _____	☐ Yes	☐ *No
E11	Does the person obtaining consent refrain from using exculpatory language? ****If no please explain:*** _____	☐ Yes	☐ *No
Regulatory Issues			
E12	Do you agree that all potential subjects will be consented prior to conducting any study related procedures?	☐ Yes	☐ No
E13	Do you agree to consent subjects using the only the MWMCIRB-approved, site-specific, most recent version of the informed consent form?	☐ Yes	☐ No
E14	Do you agree that only the Principal Investigator, Sub-investigators and Research Nurse/Study Coordinator(s) identified in item E1 will consent subjects at your site?	☐ Yes	☐ No
Compensation Information			
E15	Are subjects being paid for participation (including all types of reimbursement, such as parking)? ****If yes, check all that apply*** ☐ Cash ☐ Check ☐ Gift Certificate ☐ Other:_____	☐ *Yes	☐ No
E16	Provide the amount of payment to each subject, per visit: $ _____ ***The payment must be pro-rated per visit***		

E17	When will subjects be paid? ☐ Each visit ☐ Study completion ☐ Other: _____		
E18	For studies 6 months or longer, MWMCIRB recommends that payment occurs throughout the study rather than at study completion. If the study is longer than 6 months and the subjects will not be paid until study completion, confirm that the subjects who withdrew early will be paid for the visits they completed. ☐ Confirmed ☐ NA		
E19	Are you aware of any bonus payments or other incentives, beyond the original agreement, being offered for additional subject recruitment? ***If yes, explain*** _____	☐ *Yes	☐ No
E20	During the course of the study, do you agree to inform MWMCIRB of any proposed bonus payments or other incentives, beyond the original contractual agreement, be offered by the sponsor for additional subject recruitment?	☐ Yes	☐ No
Confidentiality			
E21	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
E22	Who will have access to study records? ☐ Research Personnel Only ☐ Other: _____		
E23	For how long will the study records be stored? _____		
E24	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

Site Submission Form

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.
- No subjects will be consented or enrolled into this study at this study site until final MetroWest Medical Center Institutional Review Board (MWMCIRB) approval has been granted.
- 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. Refer to MWMCIRB's website for Investigator Responsibilities and Investigator Guidance.
- 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 confirm that your Department Chair has been notified regarding this study.**

METROWEST MEDICAL CENTER

Site Submission Form

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:	
	Submission letter signed by Principal Investigator (Optional)
	Completed Site Submission Form
	Financial Disclosure signed by PI
	Current Curriculum Vitae for Principal and Sub Investigators
	Copy of Medical License for Principal and Sub Investigators
	Financial Disclosure signed by Sub-I
	Evidence of Human Subject Protection Training (CITTI, NIH or equivalent) for Principal Investigator
	Copy of Protocol and any applicable amendments
	Copy of proposed informed consent Must be a word document **(Note: Be sure consent has a version date. This consent must contain Tenet required language)**
	Copy of Form 1572 signed by Principal Investigator; If applicable
	Most current version of Investigator Brochure
	Additional Research Location Form *(if indicated)*
	Advertisement Submission Form *(if indicated)* Copy of all advertisements to be used in this study
	Waiver of Consent (if Applicable)
	HIPAA Waiver (if Reviewing patient data as part of the study)
	FDA Letter granting IND approval; if applicable

FOR DEVICE STUDIES, INCLUDE THE FOLLOWING:	
	FDA Letter granting IDE approval; **or**
	Letter from study sponsor stating why study is non-significant risk; **or**
	Letter explaining why device is exempt from IDE requirements

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Staff Qualifications					
MWMC IRB requires all research staff to be qualified by training and experience to conduct research. Clinical research training should include training on National Institute of Health (NIH) or Collaborative Instructional Training Initiative (CITI), and training on Good Clinical Practice (GCP) **Please indicate whether or not training was completed by each of the following.**					
Name	**Role PI, Sub-I Coordinator**	**NIH/CITI**	**Date Training Completed**	**GCP Training**	**Date Completed**

***Massachusetts only must present a copy of Researcher Drug and Controlled Substance License**