

Amendment Form for Changes to Protocol, ICF, Investigator Brochure

To be used for modifications to protocol, consent, and/or Investigator Brochure

Note: if requesting a change to the informed consent due to a change in staff or research location, submit only the "Informed Consent Revision" form.

MWMCIRB must be notified (in writing) of all proposed changes to the protocol and all proposed changes to the informed consent form(s). It must be clear to the Board exactly what changes are requested, the rationale for those changes, and how the revised document differs from the document that received prior approval from the Board

Except where necessary to eliminate apparent immediate hazards to the study subjects, changes may not be implemented until approved by MWMCIRB

Instructions for Submission

- The requested changes via a memo, a formal amendment document, or a "tracked changes" version of the protocol.
- A rationale for the changes.
- The revised protocol (with no changes tracked).
- The revised consent form (with changes tracked).
- Any other modified items, such as study instruments, recruitment materials, etc.

Documents for amendments should be submitted to
MWMCIRB@mwmc.com

A. Study and Amendment Information	
Date:	
1.	MWMC Study Number: Protocol Number:
2.	Name of Study:
3.	Name of Principal Investigator: <i>NOTE: If you are submitting on behalf of multiple investigators, please provide a complete listing of all investigators.</i>

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B. Modifications to Protocol and/or IB			
1.	Does this change include a protocol change (i.e., amendment, revised protocol, administrative change, etc.)? If yes please provide if applicable: <ul style="list-style-type: none"> • Amendment/ Version Number _____ • Date of Amendment _____ • Revised Protocol Date: _____ <p><i>*If yes, submit a copy of a tracked version of the revised protocol or a detailed summary of changes.</i></p>	<input type="checkbox"/> *Yes	<input type="checkbox"/> No

C. Revised Consent Information			
1.	Does this change include a revision to the consent? <i>*If yes, be sure to include each revised or new document in MS Word, with all changes tracked</i>	<input type="checkbox"/> *Yes	<input type="checkbox"/> No
2.	List the revised Informed Consent or Assent document(s) being submitted for review, including relevant version dates or numbers		
	Document Title:		
	(New) Version date/number		

D. New Informed Consent Information			
1.	List any new Informed Consent, Assent or Addendum document(s) being submitted for review, including relevant version dates or numbers:		
2.	Document Title		
	Version date/number		

E. Re-consenting Information			
1.	Is this study open to enrollment of new subjects?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2.	Is the sponsor requiring re-consenting?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3.	Is the consent revision applicable only to new subjects?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4.	Is the consent revision applicable only to a sub-population of the research subjects? <i>*If yes, please specify:</i>	<input type="checkbox"/> *Yes	<input type="checkbox"/> No

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F. Modifications to Investigator Brochure			
1.	Does this change include a revision to the Investigator Brochure? *If yes: <ul style="list-style-type: none"> Indicate Version Number and Date _____ <p><i>If yes Submit a copy of a tracked version of the revised brochure or a detailed summary of changes.</i></p>	<input type="checkbox"/> *Yes	<input type="checkbox"/> No

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

INCLUDE THE FOLLOWING WITH ALL SUBMISSIONS	
	Word document with all tracked changes for the amendment that has been submitted
	Revised Protocol with no tracked changes
	Rationale for amendment
	Revised IB and/or ICF with tracked changes if applicable
	Clean copy of IB and/or ICF with if applicable