

REQUEST FOR AMENDMENT APPROVAL

If any significant changes occur to the initial protocol reviewed by the ERB, the ERB should be informed and asked for approval. A review may be initiated on the amended protocol if warranted. This form should be duly filled out and submitted together with the amended protocol.

PROTOCOL ID:

PROTOCOL TITLE:

PI NAME:

MEDICAL DIRECTOR NAME:

EXPECTED STUDY PERIOD:

Please provide the information in the table below (indicate if not applicable)

1	Version number and date of (latest) MSF ERB approved protocol				
2	Date of original/most recent MSF ERB ethics approval				
3.	Details of changes made on the protocol and implications on participants and study outcomes. Please itemise the changes and provide justifications for the changes as needed. Rows may be added.				
	Changes	Justifications	Implications of the changes		Page number in amended protocol
			On study participants	On study outcomes	
4.	Has the amended protocol been submitted to or approved by National/ Local Ethics Review Committee(s)? <i>If not yet submitted, please indicate when and to which committee the protocol will be submitted. Please furnish the ERB a copy of the local ethics board approval.</i>				