

Protocol Amendment Review			
MMERC Protocol No.	Sponsor Protocol No	Date of Submission	Date of Approval
Title			
Principal Investigator Sponsor Contact No.			Contact No.
Type of Review			
Original Provisions	Proposed Amendment	Rationale	Reviewer's Comment
Criteria for Evaluation		Assessment	
A. Effect on the safety of pa			
B. Effect on the risk-benefitC. Effect on the data integri			
D. Effect on the feasibility o	f the study		
E. D. Effect on ICF (e.g. need f	or changes, re-consent)		
Comments:			
FOR MMERC			
RECOMMENDATION			
	Approval		
Decision	Major Modification Minor Modification		
	Disapproval		
Douisurer's News		Det	
Reviewer's Name		Date	
Signature			
Jigilature			

 $\underline{\textit{MMERC FORM CODE:}}\ \textit{MMERC Form 3.1_Protocol Amendment}$