Protocol Evaluation Form

MMERC Protocol No.		Date (Day/Month/Year)	
Protocol Title			
Principal Investigators			
Department		Contact No./Email	
Co-investigator(s)		Contact No./Email	
Total No. of Participants		No. of Study Sites	
Sponsor		Contact No./Email	
Duration of Study		Status	☐ New ☐ Amended
Reviewers			

Type of the Study

☐ Intervention	☐ Epidemiology	☐ Genetic
☐ Document review	☐ Individual based	☐ Others, specific
☐ Social Survey	☐ Observational Study	_____

Review Status

☐ Full Board ☐ Expedited

Description of the Study in brief: Mark whatever applies to the study.

☐ Randomized	☐ Drug	☐ Use of Genetic Materials
☐ Double Blind	☐ Medical Device	☐ Multicenter Study
☐ Single Blind	☐ Vaccine	☐ Global Protocol
☐ Open Label	☐ Diagnostics	☐ Sponsor Initiated
☐ Observational	☐ Questionnaire	☐ Investigator Initiated

A. PROTOCOL DOCUMENT REVIEW

		YES	NO	COMMENTS
1.	With social value?			
2.	With clear objectives of the study?			
3.	With need for human participants?			
4.	With sufficient background information and data?			
5.	With Background Information and Data			
6.	With acceptable inclusion of criteria			
7.	With appropriate exclusion of criteria			
8.	With appropriate withdrawal of criteria			
9.	With sufficient number of participants?			
10.	With control arms (placebo, if any)			
11.	With statistical analysis?			
12.	With voluntary, non-coercive recruitment of participants?			
13.	With risk and benefits assessment?			
14.	With involvement of vulnerable participants?			
15.	With data protection plan, privacy and confidentiality?			
16.	With appropriate qualifications and experience of the participating investigators?			
17.	With disclosure or declaration of potential conflict of interest?			
18.	With appropriate facilities and infrastructure of participating sites?			
19.	With community consultation?			
20.	With involvement of local researchers and communities in the protocol preparation and implementation?			
21.	With contribution to local capacity building?			
22.	With benefit to local communities?			
23.	With sharing of study results?			
24.	With blood/tissue samples sent abroad?			

B. RECOMMENDATION

Decision	☐ Approved	☐ Minor Modification
	☐ Disapproved	☐ Major Modification

Comments *(Identify items for revision)*	

Reviewer's Name		**Date**	
Signature			