

Informed Consent Evaluation Form

MMERC Protocol No.		Date (Day/Month/Year)	
Protocol Title			
Principal Investigators			

A. INFORMED CONSENT DOCUMENT REVIEW

		YES	NO	COMMENTS
1.	Does the Informed Consent document state that the procedures are primarily intended for research?			
2.	Are procedures for obtaining Informed Consent appropriate?			
3.	With complete Informed Consent document contain comprehensive and relevant information?			
4.	With consistent information provided in the protocol consistent with those in the consent form?			
5.	With complete study related risks mentioned in the consent form? (Include risk mitigation procedure)			
6.	With clear language in the Informed Consent document understandable?			
7.	With clear Informed Consent translated into the local language/dialect?			
8.	With adequate protection of vulnerable participants?			
9.	With complete different types of consent forms (assent, patient representative) appropriate for the types of study participants?			
10.	Requirement Details: <ul style="list-style-type: none"><li>Who: _____</li><li>How: _____</li><li>Where: _____</li></ul>			
11.	Is there data protection plan?			
12.	Informed consent process: <ul style="list-style-type: none"><li>Who: _____</li><li>How: _____</li><li>Where: _____</li></ul>			
13.	Is there sharing of study results?			
14.	Does the ICF mention privacy & confidentiality protection?			
15.	Is there any inducement for participation?			
16.	Is there appropriate provision for medical / psychosocial support?			
17.	Is there appropriate provision for treatment of study-related injuries			
18.	Is there appropriate provision for compensation?			
19.	Are names and contact numbers from the research team and the ERC in the informed consent?			

B. RECOMMENDATION

Decision	<div><input type="checkbox"/> Approved</div> <div><input type="checkbox"/> Disapproved</div>	<div><input type="checkbox"/> Minor Modification</div> <div><input type="checkbox"/> Major Modification</div>
Comments (Identify items for revision)		
Reviewer's Name		Date
Signature		