

Site Visit Report Form

MMERC Protocol No.	Sponsor Protocol No	Date of submission
Study Title:		
Investigator		Contact No.:
Sponsor:		Contact No.:
Type of Review	<input type="checkbox"/> Full board <input type="checkbox"/> Expedited	
Initial Approval Date		Date of last continuing review approval
Study Site Name and Address		
Site Visit Date	<input type="checkbox"/> Participants <input type="checkbox"/> Study Team <input type="checkbox"/> Data	
Total Participants Expected		Date:
Total Participants Enrolled		Date:

	YES	NO	COMMENTS
1. Are site facilities appropriate			
2. Are informed consent documents updated to the version approved by the MMERC?			
3. Are there any SAE/SUSAR reports not previously reported to the MMERC?			
4. Are there any events of protocol noncompliance not previously reported to the MMERC?			
5. Are investigation products and study documents secured adequately?			
6. Are all other MMERC-approved documents (e.g. advertisements) used in accordance with the approved study protocol?			
7. Are there any significant findings in this visit that could affect participant's/subject's rights, safety or welfare			
8. Overall, does the study site provide adequate protection for the rights, safety or welfare of study participants/subjects?			
9. How well are study participants/subjects protected?			
10. Are there further actions or queries resulting from this site visit?			
11. Additional remarks:			
12. Duration of visit:			

Comments of Primary Reviewer: _____

FOR MMERC

RECOMMENDATION

Decision	<input type="checkbox"/> No further action <input type="checkbox"/> Request Further Information, Specific: _____ <input type="checkbox"/> Require Specific Action, (e.g. CAPA by the study team) <input type="checkbox"/> Terminate or suspend the study in case	
Reviewer's Name		Date
Signature		