



PROTOCOL ASSESSMENT FORM

To the IEC Reviewer:

Please describe or comment on how the assessment points were addressed by the study protocol. Indicate your conclusions under the "RECOMMENDATION".

Please obtain an electronic copy of this Form, fill-out the requested information, and submit to the Secretariat both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION (to be filled out by the Primary Investigator/s)	IEC Protocol Tracking No.
Study Protocol No.	Protocol Submission Date
Title	Version Number, Date
Name of Principal Investigator	Contact Nos.
Sponsor/CRO	
Study Site	
Type of Review (to be filled out by the DLSMHSI-IEC) <input type="checkbox"/> Full Board <input type="checkbox"/> Expedited	

ASSESSMENT POINTS		
1. SCIENTIFIC SOUNDNESS		COMMENTS
1.1. Study Objectives	<input type="checkbox"/> Clear <input type="checkbox"/> Unclear	
1.2. Background information/data	<input type="checkbox"/> Sufficient <input type="checkbox"/> Insufficient	
1.3. Study/ Sampling Design	<input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	
1.4. Use of control arm/ placebo	<input type="checkbox"/> Justifiable <input type="checkbox"/> Hardly justifiable	
1.5. Inclusion/ Exclusion/ Withdrawal Criteria	<input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	
1.6. Statistical/ Data Analysis Plan	<input type="checkbox"/> Plausible <input type="checkbox"/> Implausible	
1.7. Specimen Collection, Processing, Storage	<input type="checkbox"/> Adequate <input type="checkbox"/> Inadequate	



Procedures		
1.8. Facilities/ Infrastructure at Study Site	<input type="checkbox"/> Adequate <input type="checkbox"/> Inadequate	
1.9. PI Qualification, Competence, and Experience	<input type="checkbox"/> Suitable <input type="checkbox"/> Unsuitable	
1.10 Contribution to science, research capacity, health care, treatment	<input type="checkbox"/> Yes <input type="checkbox"/> No	
1.11. Benefit to Local Communities	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. ETHICAL SOUNDNESS		COMMENTS
2.1. Privacy and Confidentiality Safeguards	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2.2. Involvement of human participants	<input type="checkbox"/> Necessary <input type="checkbox"/> Not necessary	
2.3. Involvement of Vulnerable Populations	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2.4. Voluntary, non-coercive recruitment	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2.5. Participant Selection	<input type="checkbox"/> Equitable <input type="checkbox"/> Not equitable	
2.6. Risk - Benefit Ratio	<input type="checkbox"/> Favorable <input type="checkbox"/> Not favorable	
2.7. Informed Consent Process	<input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	
2.8. Translation(s) of the ICF	<input type="checkbox"/> Accurate <input type="checkbox"/> Inaccurate	

RECOMMENDATION	Justification for the Recommendation
<input type="checkbox"/> APPROVAL <input type="checkbox"/> MINOR MODIFICATIONS <input type="checkbox"/> MAJOR MODIFICATIONS <input type="checkbox"/> DISAPPROVAL	

Reviewer	
<input type="checkbox"/> Primary	



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INDEPENDENT ETHICS COMMITTEE

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DLSMHSI-IEC Form 2D/V2/2019

Protocol Assessment

Effective Date: November 2019

<input type="checkbox"/> Secondary	<hr/> <i>Reviewer's Signature Over Printed Name</i> <hr/><i>Date</i>
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