INFORMED CONSENT FORM (ICF) 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*) ☐ Full Board ☐ Expedited	

ASSESSMENT POINTS		
2.10. Provision for the following Information in the ICF		
2.8. Language of the Informed Consent/Assent document	☐ Clear ☐ Unclear	
2.10.1. Title of the Study	☐ Yes ☐ No ☐ NA	
2.10.2. Name of PI, Sponsor	☐ Yes ☐ No ☐ NA	
2.10.3. Investigative nature of the study	☐ Yes ☐ No ☐ NA	
2.10.4. Purpose of the Study	☐ Yes ☐ No ☐ NA	

2.10.5. Study Procedures/ Methods	☐ Yes ☐ No ☐ NA	
2.10.6. Number of participants involved in the study, in this site	☐ Yes ☐ No ☐ NA	
2.10.7. Nature of participation (treatment or control)	☐ Yes ☐ No ☐ NA	
2.10.8. Possibility of random allocation	☐ Yes ☐ No ☐ NA	
2.10.9. Expected duration of study participation	☐ Yes ☐ No ☐ NA	
2.10.10. Freedom to withdraw from the study at anytime without prejudice to appropriate medical care	☐ Yes ☐ No ☐ NA	
2.10.11. Time to consider whether to participate or not in the study	☐ Yes ☐ No ☐ NA	
2.10.12. Circumstances under which subject's participation may be terminated without regard to subject's consent	☐ Yes ☐ No ☐ NA	
2.10.13. Information about Study Product	☐ Yes ☐ No ☐ NA	
2.10.14. Responsibilities of the participant	☐ Yes ☐ No ☐ NA	
2.10.15. Possible benefits to the participant	☐ Yes ☐ No ☐ NA	
2.10.16. Foreseeable risks, discomforts, if any, to the participant	☐ Yes ☐ No ☐ NA	

2.10.17. Possible adverse effects of study drug/ procedure	☐ Yes ☐ No ☐ NA	
2.10.18. Free contraceptive choice	☐ Yes ☐ No ☐ NA	
2.10.19. Available alternative procedures/ treatment, if any	☐ Yes ☐ No ☐ NA	
2.10.20. Medical/ psychological support	☐ Yes ☐ No ☐ NA	
2.10.21. Participants to receive information relevant to their participation	☐ Yes ☐ No ☐ NA	
2.10.22. Participants to be informed of results of the tests/study	☐ Yes ☐ No ☐ NA	
2.10.23. Post-trial access to study product (drug/device) shown to be beneficial	☐ Yes ☐ No ☐ NA	
2.10.24. Financial cost to participants which are likely to result from participation	☐ Yes ☐ No ☐ NA	
2.10.25. Treatment/ compensation of study-related injury/ disability/ death	☐ Yes ☐ No ☐ NA	
2.10.26. Compensation/ reimbursement for time, inconvenience, travel and other similar costs	☐ Yes ☐ No ☐ NA	
2.10.27. Insurance/ Indemnity Arrangement, where applicable	☐ Yes ☐ No ☐ NA	
2.10.28. Extended access to, emergency use of, and/or compassionate use of study	☐ Yes ☐ No ☐ NA	

product		
2.10.29. Whom to contact for queries/ complaints about the research, participant's rights, and in the event of trial-related injury	☐ Yes ☐ No ☐ NA	
2.10.30. Name and contact numbers PI/ Study coordinator	☐ Yes ☐ No ☐ NA	
2.10.31. Name and contact number Chair of DLSMHSI-IEC	☐ Yes ☐ No ☐ NA	
2.10.32. Name of Impartial Witness	☐ Yes ☐ No ☐ NA	
2.10.33. Participants to be given duplicate copy of signed ICF	☐ Yes ☐ No ☐ NA	

RECOMMENDATION	**Justification for the Recommendation**
☐ APPROVAL ☐ MINOR MODIFICATIONS ☐ MAJOR MODIFICATIONS ☐ DISAPPROVAL	

Reviewer ☐ Primary ☐ Secondary	_____ *Reviewer's Signature Over Printed Name*	_____ *Date*