Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 2
PROTOCOL ASSESSMENT FORM

To be filled up by primary reviewer
Instructions: Please do literature search to update your knowledge about this protocol

SJREB Protocol No.:		Date (D/M/Y.):	
Protocol Title:			
Coordinating Investigator:			
Institution:			
Total No. of Participants:		No. of Study Sites:	
Expected no. from Philippine sites:			
Sponsor:			

Duration of the Study:		Status:		New		For Renewal of Approval
Reviewers:						

☐ Intervention	☐ Epidemiology	☐ Observational study
☐ Document review	☐ Case study	☐ Genetic
☐ Social Survey	☐ Others *(specify):*	

Review Type: ☐ Full Board ☐ Expedited ☐ Exempted

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 (*please put an X before your choice and N/A on the comments if there are no further comments)*

Questions	Comment/s:
1. Objectives of the study	

	Clear		Not clear	
2. Need for human participants				
	Clear		Not clear	
3. Background information				
	Sufficient		Not sufficient	
4. Methodology				
	Clear		Not clear	
5. Sufficient number of participants				
	Yes		No	
6. Control arms (placebo, if any)				
	Yes		No	
7. Data analysis plan				
	Appropriate		Not Appropriate	
8. Study outcomes				
	Defined		Incomplete	Not defined
9. Level of risk				
	Low		Medium	High
10. Risk mitigation in the protocol				
	Appropriate		Not Appropriate	
11. Benefits of the participants in the protocol				
	Appropriate		Not Appropriate	
12. Inclusion criteria				
	Appropriate		Not Appropriate	
13. Exclusion criteria				
	Appropriate		Not Appropriate	
14. Withdrawal criteria				
	Appropriate		Not Appropriate	
15. Involvement of vulnerable participants				
	Yes		No	
16. Protection of vulnerable participants				
	Appropriate		Not Appropriate	
17. Voluntary, non-coercive recruitment of participants				
	Yes		No	
18. Are the qualifications and experience of the coordinating investigators/participating investigators, research team appropriate?				

	Yes		No			
19. Disclosure of potential conflicts of interest						
	Yes		No			
20. Facilities and infrastructure of participating sites						
	Yes		No			
21. Community consultation						
	Yes		No		N/A	
22. Involvement of local researchers and communities in the protocol preparation and implementation						
	Yes		No		N/A	
23. Contribution to local capacity building						
	Yes		No		N/A	
24. Benefit to local community						
	Yes		No		N/A	
25. Sharing of study results						
	Yes		No		N/A	
26. Are blood or tissue samples sent abroad						
	Yes		No		N/A	

B. RECOMMENDATION

Decision:		Approval		Minor Revision
		Major Revision		Disapproval

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	