NATIONAL CHILDREN'S HOSPITAL-INSTITUTIONAL REVIEW BOARD (NCH-IRB)
PHREB Accreditation No: L3-2019-018-02 and FERCAP Recognized
Room 514, 5th Floor, NCH MAB Bldg., 264 E. Rodriguez Sr. Avenue., Quezon City, 1102
Telephone Nos.: +63 2 87240656 to 87240659 59 loc.102 *Telefax No.*: +63 2 87254533
Email: nchirb@gmail.com *Website*: www.nch_doh.gov.ph

FORM 2.3

PROTOCOL EVALUATION FORM

NCH-IRB Protocol No.		Date:	
Protocol Title:			
Principal Investigators:			
Institution		Contact no./ Email	
Co – PI/ Members of the Research Team:		Contact no./ Email	
Total No. of Participants: Expected no. from your site/s		No. of Study Sites:	
Sponsor		Contact No/ Email	
Duration of the Study:		Status:	☐ New ☐ For renewal of approval

For NCH-IRB USE

Primary Reviewers:	

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

Review Type ☐ Full Board ☐ Expedited ☐ Exempt

Description of the Study in brief: Mark (✓) whatever applies to the study.

☐ Randomized ☐ Drug ☐ Use of genetic materials
☐ Double-blind ☐ Medical Device ☐ Multi-center study

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☐ Single-blind	☐ Vaccine	☐ Global protocol
☐ Open-label	☐ Diagnostics	☐ Sponsor-initiated
☐ Observational	☐ Questionnaire	☐ Investigator-initiated

A. PROTOCOL DOCUMENT REVIEW

	Comments of Primary Reviewer ***What should be improved?***
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 ☐ Negligible ☐ Low-medium ☐ High	
10. Risks assessment ☐ Appropriate ☐ Not appropriate	
11. Benefits Assessment ☐ 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	

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	☐ Appropriate ☐ Not appropriate	
17.	Voluntary, Non-Coercive recruitment of participants ☐ Yes ☐ No	
18.	Are the qualifications and experience of the 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 ☐ NA	
22.	Involvement of local researchers and communities in the protocol preparation and implementation ☐ Yes ☐ No ☐ NA	
23.	Contribution to local capacity building ☐ Yes ☐ No ☐ NA	
24.	Benefit to local communities ☐ Yes ☐ No ☐ NA	
25.	Sharing of study results ☐ Yes ☐ No ☐ NA	
26.	Are blood/tissue samples sent abroad ☐ Yes ☐ No ☐ NA	

B. RECOMMENDATION

DECISION	☐ Approval	☐ Minor Revision
	☐ Major Revision	☐ Disapproval
Comments (Identify items for revision)		
Primary Reviewer's Name		Date:
Signature :		

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