



## NCMH-REC FORM 2.3 PROTOCOL EVALUATION FORM

To be filled up by the primary reviewer

Protocol Number

Instruction: Please do literatures search to update your knowledge about this protocol

Protocol Title:	Date (m/d/y):
Principal Investigator	Contact Number/Email:
Co – Principal Investigator / Members of the Research Team:	Contact Number/Email:
Institution:	Duration of the Study:
Total No. of Participants:	No. of Study Sites:
Expected No. from Philippine sites:	No. of Study Sites:
Sponsor:	Contact No./Email:
Reviewers:	

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> Intervention    | <input type="checkbox"/> Epidemiology          | <input type="checkbox"/> Observational study |
| <input type="checkbox"/> Document review | <input type="checkbox"/> Case study            | <input type="checkbox"/> Genetic             |
| <input type="checkbox"/> Social survey   | <input type="checkbox"/> others, specify _____ |  |

**Review Type:**       Full Board       Expedited       Exempt

**Description of the Study in brief: Mark whatever applies to the study.**

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> Randomized    | <input type="checkbox"/> Drug           | <input type="checkbox"/> Use of genetic materials |
| <input type="checkbox"/> Double-blind  | <input type="checkbox"/> Medical Device | <input type="checkbox"/> Multicenter study        |
| <input type="checkbox"/> Single-blind  | <input type="checkbox"/> Vaccine        | <input type="checkbox"/> Global protocol          |
| <input type="checkbox"/> Open-label    | <input type="checkbox"/> Diagnostics    | <input type="checkbox"/> Sponsor-initiated        |
| <input type="checkbox"/> Observational | <input type="checkbox"/> Questionnaire  | <input type="checkbox"/> Investigator-initiated   |

<b>A. Protocol Document Review</b>	
1. Social and Scientific Value <input type="checkbox"/> Clear <input type="checkbox"/> Not Clear	Comments/What should be improved?
2. Objectives of the Study <input type="checkbox"/> Clear <input type="checkbox"/> Not Clear	Comments/What should be improved?
3. Need for Human Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
4. Background Information <input type="checkbox"/> Sufficient <input type="checkbox"/> Not Sufficient	Comments/What should be improved?
5. Methodology <input type="checkbox"/> Clear <input type="checkbox"/> Not Clear	Comments/What should be improved?
6. Sufficient Number of Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
7. Control Arms (placebo, if any) <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
8. Data Analysis Plan <input type="checkbox"/> Appropriate <input type="checkbox"/> Not Appropriate	Comments/What should be improved?
9. Study Outcomes <input type="checkbox"/> Defined <input type="checkbox"/> Incomplete <input type="checkbox"/> Not Defined	Comments/What should be improved?
10. Level of Risk <input type="checkbox"/> Negligible <input type="checkbox"/> Low Risk <input type="checkbox"/> Minimal Risk <input type="checkbox"/> More than minimal <input type="checkbox"/> Moderate <input type="checkbox"/> High Risk	Comments/What should be improved?
11. Risk Assessment <input type="checkbox"/> Appropriate <input type="checkbox"/> Not Appropriate	Comments/What should be improved?
12. Benefits Assessment <input type="checkbox"/> Appropriate <input type="checkbox"/> Not Appropriate	Comments/What should be improved?
13. Inclusion Criteria	Comments/What should be improved?

<input type="checkbox"/> Appropriate <input type="checkbox"/> Not Appropriate	
14. Exclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Not Appropriate	Comments/What should be improved?
15. Withdrawal Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Not Appropriate	Comments/What should be improved?
16. Involvement of Vulnerable Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
17. Protection of Vulnerable Participants <input type="checkbox"/> Appropriate <input type="checkbox"/> Not appropriate	Comments/What should be improved?
18. Voluntary, non-coercive recruitment of participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
19. Are the qualifications and experience of the participating investigators, research team appropriate <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
20. Disclosure of potential Conflicts of Interest <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
21. Facilities and infrastructure of participating sites <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments/What should be improved?
22. Community consultation <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Comments/What should be improved?
23. Involvement of local researchers and communities in the protocol preparation and implementation <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Comments/What should be improved?
24. Contribution to local capacity building <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Comments/What should be improved?
25. Benefit to local communities <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Comments/What should be improved?
26. Sharing of study results <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Comments/What should be improved?
27. Are blood/tissues sample sent abroad <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Comments/What should be improved?

## B. Recommendation

