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INFORMED CONSENT EVALUATION FORM* (Form 3.3)

IRB Protocol No.		Date (D/M/Y):	
Protocol Title:		Type of Review:	( ) Full Board ( ) Expedited
Principal Investigators:		Sponsors:	

A. INFORMED CONSENT DOCUMENT REVIEW

	To be filled out by PI				
Essential Elements (as applicable to the study)	Indicate if the ICF has the specified element			Page and paragraph where element is found	**REVIEWER COMMENTS**
	YES	**NO**	**N/A**		
1. Statement that the study involves research					
2. Statement describing the purpose of the study					
3. Study-related treatments and probability for random assignment					
4. Study procedures including all invasive procedures					
5. Responsibilities of the participant					
6. Expected duration of participation in the study					
7. Approximate number of participants in the study					
8. Study aspects that are experimental					
9. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner;					
10. Risks from allowable use of placebo (as applicable)					
11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable					

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12. Expected benefits to the community or to society, or contributions to scientific knowledge					
13. Description of post-study access to the study product or intervention that have been proven safe and effective					
14. Alternative procedures or treatment available to participant					
15. Compensation or insurance or treatment entitlements of the participant in case of study-related injury					
16. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount					
17. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries					
18. Anticipated expenses, if any, to the participant in the course of the study					
19. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled					
20. Statement that the study monitor(s), auditor(s), the IRB Ethics Review Panel, and regulatory authorities will be granted direct access to participant's medical records for purposes **ONLY** of verification of clinical trial procedures and data					
21. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality					
22. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant					
23. Possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study					
24. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed					
25. Plans to develop commercial products from biological specimens and whether the					

participant will receive monetary or other benefit from such development					
26. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation					
27. Statement describing access of participant to the result of the study					
28. Statement describing extent of participant's right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure)					
29. Foreseeable circumstances and reasons under which participation in the study may be terminated					
30. Sponsor, institutional affiliation of the investigators, and nature and sources of funds					
31. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider					
32. Statement that the participant may choose for simple language for better comprehension (English, Tagalog and local dialect (Hiligaynon) versions)					
33. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury					
34. Statement that the Ethics Review Committee Panel has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:					

B. Recommendation

Decision

☐ Approval ☐ Minor Revision

☐ Major Revision/ Resubmission ☐ Disapproval

Comments (Identify items For revisions)

- ☐ **Informed Consent**
- ☐ **Study Methodology**
  - ☐ **Inclusion/exclusion criteria**
  - ☐ **Study Design/ sampling design**
  - ☐ **Sample size**
  - ☐ **Data collection/ data gathering instruments**
  - ☐ **Data Analysis**

Reviewer's Name & Signature _____ **Date:**

*Adapted from UPMREB Informed Consent Assessment Form Page 3 of 3