

ETHICS REVIEW BOARD
College of Social Sciences and Philosophy
University of the Philippines Diliman

CSSP-ERB INFORMED CONSENT ASSESSMENT FORM

STUDY PROTOCOL INFORMATION

CSSP-ERB Code:	
Study Protocol Title:	
Principal Investigator:	<Title, Name, Surname>
Study Protocol Submission Date:	<DD/MM/YYYY>

INSTRUCTIONS

To the Principal Investigator: Please indicate in the space provided below whether or not the specified element is addressed by the informed consent form (ICF). To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

To the Primary Reviewer: Please evaluate how the elements outlined below have been appropriately addressed by the informed consent form (ICF), as applicable, and by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." In your comments, ensure that **vulnerability, recruitment process, and process of obtaining informed** consent are always assessed in the context of the study protocol and the participant. Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

	To be filled out by the PI			To be filled out by the Primary Reviewer	
Essential Elements (as applicable to the study)	Indicate if the ICF has the specified element		Page and paragraph where element is found	**REVIEWER COMMENTS**	**REVIEWER RECOMMENDATIONS**
	YES	**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; and integrating risks as detailed in the investigator's brochure					
10. Risks from allowable use of placebo (as applicable)					
11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable					

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, interventions, or treatment available to participant					
15. 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					
16. 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					
17. Anticipated expenses, if any, to the participant in the course of the study					
18. Statement that participation is voluntary and may be withdrawn anytime without penalty or loss of benefit to which the participant is entitled					
19. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study					
20. Statement that the study monitor(s), auditor(s), the CSSP-ERB 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 data protection plan and details about storage (including who has access to the study-related documents, how long identifying data will be stored, and manner of storage) (*NEGHHR 2017)*					
23. 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					
24. 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					
25. 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					
26. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development					
27. 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					
Data Privacy Issues (28-33) in compliance with the Data Privacy Act of 2012					
28. Statement describing that consent for participation is time-bound					
29. Statement describing the data subject's right to be informed that his/her personal data will be collected and processed					
30. Statement describing the data subject's right to object or withhold consent to processing in case of changes or any amendment to the information supplied					
31. 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)					
32. Compensation or insurance or treatment entitlements of the participant in case of study-related injury					
33. Statement describing access of participant to the result of the study including details on what data will be shared and available, duration, and access criteria for data sharing					
34. Foreseeable circumstances and reasons under which participation in the study may be terminated					
35. Sponsor, institutional affiliation of the investigators, and nature and sources of funds					
36. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider					
37. 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					
38. Statement that the CSSP-ERB Ethics Review Panel (specify) has approved					

the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: **Name of CSSP-ERB Panel Chair** **Address:** **Email:** csspethicsboard.upd@up.edu.ph **Tel:**					
39. Comprehensibility of language used					
40. Other comments not addressed by items 1-34					

RECOMMENDED ACTION:

- ☐ APPROVE
- ☐ FOR MODIFICATION
- ☐ DISAPPROVE
- ☐ PENDING, IF CLARIFICATIONS ARE REQUIRED OR ADDITIONAL DOCUMENTS ARE NEEDED BEFORE A DECISION CAN BE MADE.

ADDITIONAL REMARKS:

PRIMARY REVIEWER Signature _____

Date: <DD/MM/YYYY> Name <Title, Name, Surname>

Panel <Name of Panel>