Informed Consent Assessment Form

STUDY PROTOCOL INFORMATION

UPCHE REC Code:[1] (to be filled by the REC staff)	
Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date: (to be filled by the REC staff)	

INSTRUCTIONS

To the Principal Investigator: Please indicate in the space provided below whether or not the specified element is addressed in the informed consent form (ICF) by ticking on the appropriate box. To facilitate the evaluation of the assessment point, indicate in the gray column 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". 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/RP		**To be filled out by the Primary Reviewer**	
Essential Elements (as applicable to the study)	Page and paragraph where element is found	**REVIEWER COMMENTS**	**RECOMMENDATIONS**
1. Statement that the study involves research ☐Yes ☐No ☐N/A			
2. Statement describing the purpose of the study ☐Yes ☐No ☐N/A			
3. Study-related treatments and probability for random assignment ☐Yes ☐No ☐N/A			
4. Study procedures including all invasive procedures ☐Yes ☐No ☐N/A			
5. Responsibilities of the participant ☐Yes ☐No ☐N/A			

[1] To be issued upon initial processing by UPCHE REC

6. Expected duration of participation in the study ☐Yes ☐No ☐N/A			
7. Approximate number of participants in the study ☐Yes ☐No ☐N/A			
8. Study aspects that are experimental ☐Yes ☐No ☐N/A			
9. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner ☐Yes ☐No ☐N/A			
10. Risks from allowable use of placebo (as applicable) ☐Yes ☐No ☐N/A			
11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable ☐Yes ☐No ☐N/A			
12. Expected benefits to the community or to society, or contributions to scientific knowledge ☐Yes ☐No ☐N/A			
13. Description of post-study access to the study product or intervention that have been proven safe and effective ☐Yes ☐No ☐N/A			
14. Alternative procedures or treatment available to participant ☐Yes ☐No ☐N/A			
15. Compensation or insurance or treatment entitlements of the participant in case of study-related injury ☐Yes ☐No ☐N/A			
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 ☐Yes ☐No ☐N/A			

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 ☐Yes ☐No ☐N/A			
18. Anticipated expenses, if any, to the participant in the course of the study ☐Yes ☐No ☐N/A			
19. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled ☐Yes ☐No ☐N/A			
20. Statement that the study monitor(s), auditor(s), the UPCHE REC Ethics Review Committee, and regulatory authorities will be granted direct access to participant's medical records for purposes **ONLY** of verification of clinical trial procedures and data ☐Yes ☐No ☐N/A			
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 ☐Yes ☐No ☐N/A			
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 ☐Yes ☐No ☐N/A			

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 ☐Yes ☐No ☐N/A			
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 ☐Yes ☐No ☐N/A			
25. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development ☐Yes ☐No ☐N/A			
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 ☐Yes ☐No ☐N/A			
27. Statement describing access of participant to the result of the study ☐Yes ☐No ☐N/A			
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) ☐Yes ☐No ☐N/A			
29. Foreseeable circumstances and reasons under which participation in the study may be terminated ☐Yes ☐No ☐N/A			

30. Sponsor, institutional affiliation of the investigators, and nature and sources of funds ☐Yes ☐No ☐N/A			
31. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider ☐Yes ☐No ☐N/A			
32. 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 ☐Yes ☐No ☐N/A			
33. Comprehensibility of language used (English, Filipino, etc.) ☐Yes ☐No ☐N/A			
34. Statement that the UPCHE REC Ethics Review Committee (specify) has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: ☐Yes ☐No ☐N/A **Name of UPCHE REC Chair** Room 217 Alonso Hall, College of Home Economics, UP Diliman Ma. Regidor Street, Diliman, 1101 Quezon City Tel. No.: +63 2 9818500 loc 3407; Email: upcherec.upd@up.edu.ph			

TYPE OF REVIEW:

☐ Expedited ☐ Full Review

COMMENT(S)

SUMMARY OF RECOMMENDATION(S) (Note: Please see sections with comments/recommendations for the required modifications)

RECOMMENDED ACTION: ☐ APPROVAL ☐ MINOR MODIFICATIONS ☐ MAJOR MODIFICATIONS ☐ DISAPPROVAL

The criteria for Major and Minor Modifications are as follows:

Major Modification – recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research; examples: major revisions in protocol design or method or ICF, inclusion/exclusion criteria, safety issues, data privacy issues

Minor modification – recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g., incomplete documentation, informed consent elements, unsatisfactory informed consent format), administrative corrections like typo or grammar errors, minor changes on items not related to the procedure to be done

REVIEWER Date:	Signature Name Position	 Non-scientist/Scientist Member