INFORMED CONSENT ASSESSMENT FORM

STUDY PROTOCOL INFORMATION

RIHS ERC Code:	
Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date:	

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." 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			
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	**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. Reason for inclusion of subject				
6. Responsibilities of the participant				
7. Expected duration of participation in the study				
8. Approximate number of participants in the study				
9. Study aspects that are experimental				
10. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; including ways to mitigate these risks.				
11. Risks from allowable use of placebo (as applicable)				
12. Reasonably expected benefits; or absence of direct benefit to participants, as applicable				
13. Expected direct or indirect benefits to the community or to society, or contributions to scientific knowledge are maximized				
14. Description of post-study access to the study product or intervention that have been proven safe and effective				
15. Alternative procedures or treatment available to participant				
16. Compensation or insurance or treatment entitlements of the participant in case of study-related injury				
17. Is there a provision for medical/psychosocial support?				
18. Anticipated prorated 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				
19. 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				
20. Anticipated expenses, if any, to the participant in the course of the study				

21. Appropriateness of language used: accurate, simple and concise content				
22. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled				
23. Statement that the study monitor(s), auditor(s), the RIHS ERC 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				
24. 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				
25. 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				
26. 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				
27. 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				
28. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development				
29. 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				
30. Statement describing access of participant to the result of the study				
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. Foreseeable circumstances and reasons under which participation in the study may be terminated				
33. Sponsor, institutional affiliation of the investigators, and nature and sources of funds				
34. a. The role of the investigator is serving only as an investigator				
b. The investigator is serving as both investigator and the participant's healthcare provider				
35. 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				
36. Statement that the RIHS ERC has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: **Maria Milagros U. Magat, MD, MEd** **Chair, RIHS ERC** **Address:** 2/F JMC Bldg. Aurora Blvd. Quezon City **Email:** ethicsreviewcommittee@uerm.edu.ph **Tel:** +63 2 87150861 local 358				

RECOMMENDED ACTION:

- ☐ APPROVE
- ☐ MINOR MODIFICATIONS

  (*(any revision not included as major revision, any clarification)*
- ☐ MAJOR MODIFICATIONS

  (*Revision of ICF except for typographical and administrative revisions, change in study design, change in sample size, adding or removing procedure to improve study methods)*
- ☐ DISAPPROVE
- ☐ DEFERRED, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER	Signature
Date:	Name