	UP OPEN UNIVERSITY Institutional Research Ethics Committee		
	HEALTH-RELATED ASSESSMENT FORM	REC Form No.	6 (E1)
		Version No:	02
		Date of Effectivity:	

STUDY PROTOCOL INFORMATION

Reference Number:[1]	
UPOU IREB Code:[2]	
Study Protocol Title:	
Principal Investigator:	<Title, Name, Surname>
Study Protocol Submission Date:	<<dd/mm/yyyy>>

INSTRUCTIONS

To the Principal Investigator:

Does your research involve human participants?

- Yes
- No

If yes, please proceed in accomplishing this form. 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 applying research ethics** 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.

Essential Elements (as applicable to the study)	**To be filled out by the PI**		**REVIEWER COMMENTS**
	Indicate if the ICF has the specified element		Page and paragraph where element is found
	YES	**N/A**	
1. Statement that the study involves research	•	•	
2. Statement describing the purpose of the study	•	•	

[1] To be issued upon RPC registration/submission
[2] To be issued upon initial processing by UPOU IREC

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 (e.g. study products of clinical trials)	•	•	
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 UPOU IREB, 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.	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		
33.	Statement that the UPOU 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 UPOU IREC Chair** **Address:** UPOU HQ **Email:** **Tel:** **Mobile:**	•	•
34.	Comprehensibility of language used		
35.	Other comments not addressed by items 1-34		

RECOMMENDED ACTION:

- APPROVE
- MINOR MODIFICATIONS
- MAJOR MODIFICATIONS
- DISAPPROVE
- PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

JUSTIFICATION FOR RECOMMENDED ACTION

PRIMARY REVIEWER Signature _____

Date: <dd/mm/yyyy> Name <Title, Name, Surname>