

Participant Information Sheet and Informed Consent Assessment Form

Study Protocol Title:			
Principal Investigator:			
Study Protocol Submission Date:			
Essential Elements (as applicable to the study)	Indicate if the study protocol has the specified element		REVIEWER'S COMMENTS
	YES	N/A	
List of all investigators involved			
Research title			
Statement that the participant involves research			
Introduce study scope			
Approximate number of participants			
Description of the study purpose			
Eligibility criteria to participate			
Study procedures and expectation			
Expected duration of participation			
Foreseeable or potential risks (including psychological, physical and emotional)			
Expected or absence of direct benefit to participants			
Community sensitivities and expected benefits to the community or to society, or contributions to scientific knowledge			
Statement that the Review Panel and regulatory authorities may review study data			
Assurance of confidentiality unless required by law			
Specimen/data handling including storage and destruction/disposal of specimen/data at the end of the study			
Statement of possible future use, affirming participant's right to refuse future storage and use of collected specimen/data			
Plans to develop commercial products and whether the participant will receive monetary or other benefit from such development			
Statement describing feedback of study finding whether provided or not			
Information of person(s) to contact in the study team for further information			
Statement on the approval by and contact of the MREC UNIMAS			
Appropriate language versions			

RECOMMENDATION

- ☐ APPROVED
- ☐ MINOR MODIFICATIONS
- ☐ MAJOR MODIFICATIONS
- ☐ DISAPPROVED

Reasons:

REVIEWER

	Signature _____
Date:	Name _____

SECRETARY

	Signature _____
Received Date:	Name _____