ANGELES UNIVERSITY FOUNDATION
Angeles City
Office of the Vice President for Research and Innovation

Study Protocol Assessment Form[1]

Protocol Number:	
Type of Review	
Type of Research:	
Study Protocol Title:	
Principal Investigator/s (PIs):	
Study Protocol Submission Date:	

	To be filled out by PI			REVIEWER'S COMMENTS
ASSESSMENT POINTS	Indicate if the study protocol contains the specified assessment point		Indicate the Page and paragraph where it is found***(please highlight the paragraph)***	
1. SCIENTIFIC DESIGN	**YES**	**N/A**		
1.1 Objectives *Review of viability of expected output*	/			
1.2 Literature Review *Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials*	/			
1.3 Research Design *Review of appropriateness of design in view of objectives*	/			
1.4 Sampling Design *Review of appropriateness of sampling methods and techniques*	/			
1.5 Sample Size *Review of computation of sample size*	/			
1.6 Statistical Analysis Plan (SAP) *Review of appropriateness of statistical methods to be used and how participant data will be summarized*	/			
1.7 Data Analysis Plan *Review of appropriateness of statistical and non-statistical methods of data analysis*	/			
1.8 Inclusion Criteria *Review of precision of criteria both for scientific merit and safety concerns; and equitable selection*	/			

[1] **Adapted from: PHREB Guidelines**

1.9 Exclusion Criteria *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion*	/			
1.10 Withdrawal Criteria *Review of criteria precision both for scientific merit and safety concerns*	/			
2. CONDUCT OF STUDY				
2.1 Specimen handling *Review of specimen storage, access, disposal and terms of use*	/			
2.2 PI Qualifications *Review of CV and relevant certifications to ascertain capability to manage study related risks*				
2.3 Suitability of Site *Review of adequacy of qualified staff and infrastructures*	/			
3. ETHICAL CONSIDERATIONS				
3.1 Conflict of Interests *Review of management of conflict arising from financial, familial, or proprietary conditions of the PI, sponsor, or the study site*	/			
3.2 Privacy and Confidentiality *Review of measures or guarantee to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans*	/			
3.3 Informed consent process *Review of application of the principle of respect for persons who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who not legally competent to give consent, or indigenous people which require additional clearances*	/			
3.4 Vulnerability *Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic, and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members, of a hierarchical group*	/			
3.5 Recruitment *Review of manner of recruitment including handling appropriateness*	/			

of identified recruiting parties				
3.6 Assent *Review of feasibility of obtaining assent vis a vis incompetence to consent; Review of applicability of assent age brackets in children:* *0-under 7: No assent* *7-under 12: Verbal assent* *12-under 15: Simplified assent form* *15- under 18: Co-sign informed consent from parents*		/		
3.7 Risks *Review of level of risk and measures to mitigate these risks (including physical, psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable)*		/		
3.8 Benefits *Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant*	/			
3.9 Incentives and compensation *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses*		/		
3.10 Community considerations *Review of impact of the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of the study.*	/			
3.11 Collaborative study terms of reference *Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building.*		/		

RECOMMENDED ACTION APPROVAL MINOR MODIFICATIONS (to be reviewed by chair) MAJOR MODIFICATIONS DISAPPROVAL	
JUSTIFICATION FOR RECOMMENDATION	
PRIMARY REVIEWER Date: <dd/mm/yyyy>	Signature _____ Name <Title, Name, Surname>
PANEL SECRETARY Date: <dd/mm/yyyy>	Signature _____ Name <Title, Name, Surname>
PANEL CHAIR Date: <dd/mm/yyyy>	Signature _____ Name <Title, Name, Surname>