

Study Protocol and Informed Consent Self-Assessment Checklist

Our Lady of Fatima University
Institutional Ethics Review Committee

Reference Number
as assigned by the OLFU-IERC

Principal Investigator	Last Name	First Name	Middle Name
College/Affiliation			
Date Received			
Research Title			

Assessment Points	To be filled out by the Principal Investigator		
	Indicate if the specified assessment point is stated on the study protocol		Page and the paragraph where the said point is discussed
A. Proposal (Scientific and Technical Issues)	YES	N/A	
A.1. Are the objectives/aims of the study protocol clearly and concisely defined?			
A.2. Is the question/issue or general problem of the study protocol clearly stated?			
A.3. Is the research question related to the objective/purpose of the research study?			
A.4. Does the literature review section of the research protocol provide foundation knowledge of the topic?			
A.5. Are the review results in the literature review section relevant to the proposed study protocol?			
A.6. Does the chosen research design effectively address the research problem in a logical way?			
A.7. Are the specific sampling methods and procedure in the study protocol fully described?			
A.8. Is the research approach or type of analysis clearly described?			
A.9. Are the types of sources used clearly discussed? (primary or secondary texts, interviews, surveys, diaries, journals, etc.)			
A.10. Is the sample size appropriate and well justified?			
A.11. Is the statistical method used appropriate?			
A.12. Are the statistical and non-statistical methods relevant to the data analysis and data summary?			
A.13. Are the inclusion and exclusion criteria complete and appropriate?			

B. Research Handling	YES	N/A	
B.1. Do provisions exist in the specimen storage, access, disposal, and terms of use? (If applicable)			
B.2. Are the copies of the CV of the research investigator included?			

B.3. Is the duration/length of the respondents' involvement in the study clearly discussed?			
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C. Ethical Issues	YES	N/A
C.1. Is a vulnerable population being studied?		
C.2. Is the justification for studying this vulnerable population adequate?		
C.3. Do adequate provisions exist to ensure that the vulnerable population is not being exploited?		
C.4 Are the risks and benefits for the research participants been discussed in the research protocol?		
C.5 Does the protocol describe how the communities from which the participants are to be drawn likely benefit from the research?		
C.6 Is the design free of undue inducements to participate in the research?		
C.7. Does the recruitment procedure include adequate protection for the privacy and psychosocial needs of the individuals?		
C.8. Do provisions exist in the protocol for counseling research participants during and after the research?		
C.9. Are the research participants free not to participate or to leave the research at any time, without penalty?		
C.10. Do provisions exist in the proposal to recruit participants incapable of giving personal consent, (e.g., because of cultural factors, children, or adolescents less than the legal		

D. Informed Consent Form	YES	N/A
D.1 Is the attached informed consent form written in English or in a language that the respondents can understand?		
D.2 Is the information sheet free of technical terms, written in lay-persons' language, easily understandable, complete & adequate?		
D.3 Is the Informed Consent Form patterned after the WHO template?		
D.4 Are all the sections in the ICF completely and clearly explained?		

E. Participant Recruitment	YES	N/A
E.1. Will recruitment material (e.g., advertisements, notices, media articles, transcripts of radio messages) be used to recruit participants?		
E.2. Is the Participant Recruitment Material provided both in English and in the local language?		
E.3. Do these materials make claims that may not be true? (e.g., provide undue incentives or emphasize remuneration)		

SUBMITTED BY	RECEIVED BY	DATE RECEIVED
	For OLFU-IERC use only	
_____ Signature over printed name Principal Investigator	_____ Signature over printed name OLFU-IERC staff	