ETHICS REVIEW BOARD
College of Social Sciences and Philosophy
University of the Philippines Diliman
csspethicsboard.upd@up.edu.ph

CSSP-ERB RVW Form 10

PROTOCOL DEVIATION REPORT

General Information			
Title of Study			
Protocol Code		Study Site	
Name of Primary Investigator		Contact Information	Tel No.:
Name of Co-investigator/s (if any)			Mobile No.: Email:
Institution			
Address of Institution			
Ethical clearance effectivity period			
Start of study		Expected end of study	
Report on Deviation			
		Reviewer Comments	Reviewer Recommendations
Number of currently enrolled participants			
Number of required participants			
Number of participants who withdrew			

State the non-compliance from the approved protocol			
Explain reasons for non-compliance			
State the impact of the deviation on 1) potential risks/harms and 2) integrity of the study			
State the actions taken to protect the rights and well-being of the research participants			

RECOMMENDED ACTION:

Note: If **for modification**, indicate if minor or major modification by putting a check next to the appropriate choice. Also, highlight the justification for the recommended action from the choices provided.

___ APPROVE

Specify:
_____

___ FOR MODIFICATION/AMENDMENT

___ Minor Modification/Amendment
Justification:
___ Incomplete Documentation
___ Incomplete ICF/PIS Elements
___ Unsatisfactory IC Format
___ Others:
_____

___ Major Modification/Amendment
Justification:
___ Change of Study Objectives
___ Change in the Recruitment Process
___ Revision of exclusion/inclusion Criteria
___ Change of Data Collection Method
___ Change in the process of mitigation of risk/harm
to participants and the integrity of the research
___ Others:
_____

___ DISAPPROVE

ADDITIONAL REMARKS:

PRIMARY REVIEWER Signature _____

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

Panel <Name of Panel>

ETHICS REVIEW BOARD

College of Social Sciences and Philosophy

University of the Philippines Diliman

csspethicsboard.upd@up.edu.ph