

Republic of the Philippines Department of Health

JOSE R. REYES MEMORIAL MEDICAL CENTER

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INSTITUTIONAL REVIEW BOARD

Form 3.4

FINAL REPORT

IRB Protocol No.			Initial Approval Date		
Protocol Title					
Principal Investigator					
Email				Mobile	
Study Sites					
Sponsor					
Sponsor Contact Person				E-mail	
1. Study Arms:					
2. Summary of Recruitment: Accrual ceiling set by REC					
New participants accrued since last					
review					
Total number of participants					
accrued since protocol began No. of participants who are lost to					
follow up					
No. of participants withdrawn from the study					
No. of participants who experienced					
SAEs/SUSARs 3. Number of participants who					
completed the study:					
4. Amendments to the original protocol					
(including dates of a					
5. Summary of onsite SAEs reported:6. Summary of participants' complaints					
or grievances documented regarding					
conduct of study:					
7. Summary of benefits to participants:					
8. Summary of indemnifications of					
study related injury (if applicable): 9. If terminated early, specify reason					
for termination					
10. Progress reports submitted					
(with dates of approval)					

11. Dur	ation of the study						
versi	rmed consent form used (with ion no./date) and attach the recent version						
13. Stud	ly objectives						
14. Summary of results							
	Signature of PI						
	Date Submitted						
	Received by						
	Report Submission Date (to be filled out by IRB)						
			_				
For IRB U	JSE ONLY						
Comments of Primary Reviewer (i.e. compliance with the terms of the approved protocol including post-approval							
review re	equirements, and overall assessment	of risks against benefits in the conduct	t of study)				
	Dogommondations		True of marriague				
Recommendations: Type of review: Approve Exempted							
Request further action. Specify. Expedited							
Paguage further information Charify							
Request further information. Specify. Others comments:							
·	·						
	Name of Reviewer:	Signature:	Date:				
	Final Decision						
	IRB Chair:	Signature:	Date:				