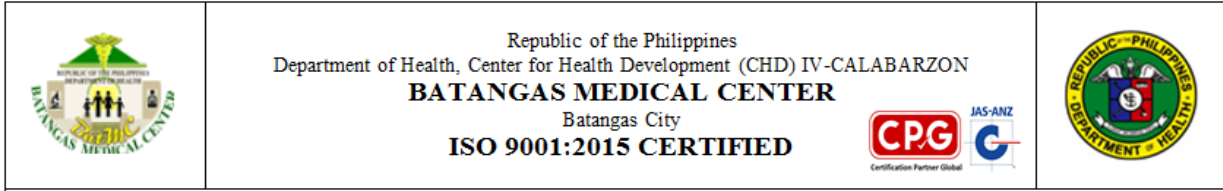


**BATANGAS MEDICAL CENTER
RESEARCH ETHICS REVIEW COMMITTEE**

**DEVIATION / NON-COMPLIANCE / VIOLATION REPORT/ SUMMARY REPORT
Form 3.18.1**

Title of Study			
REC Code (To be provided by REC)		Study Site	
Name of Researcher)		Contact Information	Tel No:
Co-researcher (if any)			Mobile No:
			Fax No:
			Email:
Institution			
Address of Institution			
Ethical clearance effectivity period			
Progress Report			
Start of study		Expected end of study	
Number of enrolled participants		Number of required participants	
Number of participants who withdrew			
Indicate each protocol deviation/violation:		Actions taken to prevent future deviation/violation	



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1. 2. 3.	1. 2. 3.
Impact of deviation/violation on participants' risks/harms and integrity of data	How would you address these factors?

**BATMC RERC Protocol Noncompliance
 (Deviation or Violation) SUMMARY Report**

(FOR BATMC RERC USE ONLY)

BATMC-RERC Code:	
Project Title:	
Principal Investigator:	Email:
	Telephone:
	Mobile:
Approval Date:	Report Submission Date:
Study Site Name:	Study Site Address:






Republic of the Philippines
 Department of Health, Center for Health Development (CHD) IV-CALABARZON
BATANGAS MEDICAL CENTER
 Batangas City
ISO 9001:2015 CERTIFIED



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NATURE OF REPORT	
MINOR PROTOCOL DEVIATION - (non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature) MAJOR PROTOCOL DEVIATION - Persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk)	
DESCRIPTION OF REPORTED DEVIATION/VIOLATION:	
DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:	
Found by:	
Principal Investigator/Study Team Sponsor/Monitor BATMC-RERC	
Date: _____	
Reported by: _____	
Date: _____	
Recommended Action:	
UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION REQUEST INFORMATION: (specify) RECOMMEND FURTHER ACTION Suspend the study (until additional information is made available) Suspend the study (until recommendations are implemented by the P.I. and found to be satisfactory)	

	<p>Republic of the Philippines Department of Health, Center for Health Development (CHD) IV-CALABARZON BATANGAS MEDICAL CENTER Batangas City ISO 9001:2015 CERTIFIED</p>	 
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**BATANGAS MEDICAL CENTER
RESEARCH ETHICS REVIEW COMMITTEE**

Revoke approval of the current study Reprimand the Principal Investigator		
PRIMARY REVIEWERS	Signature	Date signed
1.		
2.		
Other Reviewers		
1.		
2.		
3.		
BATMC-RERC SECRETARY Date: < mm/dd/yy > BATMC-RERC CHAIR Date: < mm/dd/yy > Signature Name: Signature Name: Signature Name: <hr/> <Title, Name, Surname> <hr/> <Title, Name, Surname> <hr/> <Title, Name, Surname>		