



CARDINAL SANTOS  
MEDICAL CENTER

**APPENDIX - FLOW CHART**  
**APPROVAL OF NEW PROTOCOL – INDUSTRY-SPONSORED**

**CSMC RESEARCH ETHICS REVIEW COMMITTEE**  
**STANDARD OPERATING PROCEDURES**

Document Control No.  
MED-01-028

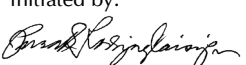
Revision No.  
04

Effectivity Date  
July 1, 2018

Page  
1 of 1

THIS DOCUMENT IS A PROPERTY OF CARDINAL SANTOS MEDICAL CENTER (CSMC). NO PART OF THIS DOCUMENT OR ITS CONTENTS SHALL BE REPRODUCED, COPIED, MODIFIED, ADAPTED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS, ELECTRONIC, MECHANICAL OR OTHERWISE, INCLUDING PHOTOCOPYING AND RECORDING, WITHOUT PRIOR WRITTEN PERMISSION FROM CSMC, FOR ANY PURPOSE OTHER THAN FOR ITS INTENDED USE. THIS VERSION IS AN UNCONTROLLED COPY. ALL OFFICIAL/CONTROLLED COPIES CAN BE ACCESSED VIA RESOURCE CENTER

FLOWCHART	PERSON RESPONSIBLE	TIME FRAME
<p>Principal Investigator submits protocol and other requirements to CSMC Research Ethics Review Committee (RERC).</p> <p>New protocol is sent to the RERC Vice Chair to decide if the protocol will undergo full board or expedited review and assign primary reviewers.</p> <p><b>EXPEDITED REVIEW</b></p> <p><b>FULL BOARD REVIEW</b></p> <p>Protocol is distributed to assigned reviewers.</p> <p>Protocol is scheduled for deliberation during the regular RERC meeting. <i>RERC meetings are scheduled every 4<sup>th</sup> Wednesday of the month.</i></p> <p>Primary reviewers present the protocol to the RERC. RERC will deliberate approval of the protocol.</p> <p>Protocol Approved</p> <p>With Modification</p> <p>Major</p> <p>Minor</p> <p>Approval letter is issued to the Principal Investigator.</p> <p>Principal Investigator conducts study in the hospital.</p> <p>Post Approval Process</p> <p>Principal Investigator shall submit the following for RERC monitoring and continuing review.</p> <ul style="list-style-type: none"> <li>• Protocol Amendment</li> <li>• Protocol Deviations</li> <li>• Safety Reports</li> <li>• Progress Reports</li> </ul> <p>RERC Chair reports decision during RERC regular meeting.</p>	<p>Principal Investigator</p> <p>Secretariat</p> <p>RERC Reviewers</p> <p>Secretariat</p> <p>Principal Investigator</p>	<p>1 week from date of receipt</p> <p>2 weeks</p> <p>1 week</p> <p>During the conduct of study</p>

Initiated by:  
  
 PURA R. CAISIP, MD / PATRICIA KHU, MD

Reviewed by:  
  
 ZENAIDA M. JAVIER-UY, MD

Approved by:  
  
 ATTY PILAR NENUCA P. ALMIRA

