中華崇仁總醫院暨醫學中心
CHINESE GENERAL HOSPITAL AND MEDICAL CENTER
EXCEPTIONAL CARE WITHIN REACH

Department of Medical Education and Research
RESEARCH ETHICS REVIEW BOARD (RERB)
Contact#: 8711-4141 local 418 and 481
Email Address: rerb@cghmc.com.ph

APPROVAL LETTER

Date _____

This is to certify that the following protocol and related documents have been granted approval by the CGHMC RERB for implementation

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Principal Investigator		Sponsor	
Study Site			
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			
Type of review	☐ Expedited ☐ Full board Meeting date:	Duration of Approval From _____ to _____	Frequency of continuing review
RERB Chair	Name	Signature	Date

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Investigator Responsibilities after Approval:

1. Submit protocol amendment documents using CGHMC Form 3.1: Protocol Amendment Application Form for RERB approval before implementing them.
2. Submit revisions in the Informed Consent Form using CGHMC Form 3.1: Protocol Amendment Application Form.
3. Submit on-site SAE reports to the RERB using CGHMC Form 3.4: SAE report within within 72 hours from the knowledge of the event and a complete report within 14 days. For off-site SUSARs, submit a cumulative notification to RERB quarterly (every 3 months)
4. Submit progress report/continuing review application every 12/6 months or as deemed necessary. Submit 60 days before the expiration of RERB approval. Use CGHMC Form 3.3 A and 3.3B: Continuing Review Application/Progress Report Form.
5. Submit final report using CGHMC Form 3.9: Final Report Form after completion of protocol procedures at the study site
6. Report protocol non-compliance/deviation/ violation using CGHMC Form 3.5: Non-compliance/violation/deviation Report Form.
7. Submit Notice of early termination of the study and reasons for such using CGHMC Form 3.8: Early Study Termination Form.
8. Comply with all relevant international and national guidelines and regulations.
9. Abide by the principles of good clinical practice and ethical research.

Received by:
Name and Signature: _____ Date Received: _____