PROTOCOL REVIEW APPLICATION

To the Principal Investigator:

Please obtain a copy of this form, fill-out the requested information, and make your submission both in electronic version and hard copy.

APPLICATION INFORMATION (to be filled by Principal Investigator)		
Date of Application: (mm/dd/yyyy)	Protocol No.: (if applicable)	Version No. and effectivity date:
Title:		
Principal Investigator: (Last Name, First Name)	PI Address:	
Telephone No.:	Mobile No:	Email:
Sponsor / CRO:	Study Site:	Duration of the study: (in months)
Purpose of the study: ☐ Academic requirement ☐ Collaboration / Joint venture	☐ Independent research work ☐ Others (indicate)	☐ Contract research
Category of Principal Investigator: ☐ DLSMHSI Fellow/ Resident ☐ DLSMHSI Employee	☐ DLSMHSI Faculty ☐ NON-DLSMHSI: (please specify)	☐ DLSMHSI Student
Previous Approval from other Technical / Ethics Committees: ☐ Non-Applicable	☐ Applicable *(if applicable, complete details below)*	
Start and End Date:	Name of Technical Review Committee/ Ethics Review Committee:	
Funding Source: ☐ Investigator ☐ Others (indicate)	☐ DLSMHSI	

CATEGORY OF PROTOCOL (check all that applies)

CITY OF DASMARIÑAS, CAVITE, PHILIPPINES 4114
GF, DE LA SALLE ANGELO KING MEDICAL RESEARCH CENTER
(046) 4818000 / (02) 89883100 LOC. 8042
www.dlshsi.edu.ph
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☐ Pre-clinical		
☐ Clinical		
☐ Observational	☐ Interventional (Clinical Trial phase)	
☐ Non-Clinical		
☐ Epidemiological	☐ Document-based	☐ Socio-behavioral
☐ Controlled laboratory studies	☐ Herbal/CAM Research	☐ Diagnostics
☐ Medical Device	☐ Genetic/genomic research	☐ Operations/Process Research
☐ Others (indicate)		
☐ Single-Center	☐ Multi-Center (No. of Study Sites)	
☐ Screening	☐ Interim Analysis	☐ Randomized
☐ Stratified randomized	☐ Single-blind	☐ Double blind
☐ Open-labeled	☐ Parallel	☐ Cross-over
☐ Placebo-controlled	☐ Treatment-controlled	
☐ Use of:		
☐ Blood samples	☐ Tissue samples	☐ Genetic materials

PARTICIPANT INFORMATION (check all that applies)		
Total No. of Participants:	Gender: ☐ Male	☐ Female
Age Group: ☐ <18 yrs	☐ Adults (18-65yrs)	☐ Elderly (>65yrs)
Groups of participants: ☐ Healthy Volunteers	☐ Patients	☐ Women of child-bearing potential
☐ Others (indicate)		
☐ Vulnerable Participants:		
☐ In-utero	☐ Pre-term Newborn (up to ≤37weeks)	☐ Infant & Toddlers (28 days-23 mons)
☐ Newborns (0-27days)	☐ Children (2-11years)	☐ Adolescents (12-17years)

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☐ Elderly (>65years)	☐ Pregnant women	☐ Illiterate
☐ Seriously ill	☐ Terminally ill	☐ Handicapped
☐ Mentally challenged	☐ Others (indicate)	_____

DECLARATION

I declare that I have:

- *NO Conflict of Interest in any form (personal, professional, financial, proprietary) with the sponsor, the study, or the site.*
- *NO personal / family interest in the study result*
- *NO proprietary interest in the study (patent, trademark, copyright, licensing etc.*

I declare that the above study has not commenced or been completed

I declare that the information provided is true and correct to the best of my knowledge.

I understand that it will require 30-60 days for the IEC to review and grant approval.

Signature over printed name of Principal Investigator:	Date signed:

PROTOCOL VERIFICATION AND CLASSIFICATION (to be filled up by DLSMHSI-IEC)

Decision Point: (Accepted or Rejected)

☐ Accepted ☐ Rejected

If ACCEPTED assign IEC Tracking No.:	If REJECTED indicate reason for rejection:
Verified by: (printed name and signature of Staff)	**Date verified: (mm/dd/yyyy)**

Classification of Protocol:

☐ Exempted Review ☐ Expedited Review ☐ Full-board Review

Classified by:	Date classified: (mm/dd/yyy)

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