APPLICATION FORM FOR PROTOCOL REVIEW (FORM 6A)

CGHMC RERB Protocol Number		Sponsor Protocol No:	
Submission Date			
Protocol Title:			
Principal Investigator			
Contact details:	☏:		
	Mobile:		
	Fax:		
	Email address:		
Sponsor:			
PI Conflict of Interest/ Declaration (Relationship with Sponsor)	Are you a regular employee of the sponsor? ☐ Yes ☐ No		
	Did you do consultancy or part time work for the sponsor? ☐ Yes ☐ No		
	In the past year, did you receive P250,000 or more from the sponsor? ☐ Yes ☐ No		
	Other ties with the sponsor		
By signing the application form, I undertake to address my competing interests, uphold scientific integrity, respect and protect human subjects during the conduct of my research in this institution.			
PI Signature:			

CHECKLIST OF DOCUMENTS SUBMITTED FOR PROTOCOL REVIEW

CGHMC RERB PROTOCOL NO:		**Sponsor Protocol No.**
PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		

Documents submitted: (Please check all applicable)

Documents
☐ **Protocol**
☐ **Patient information form**
☐ **Informed consent form (English and Tagalog Version)**
☐ **Assent Form in English and Tagalog (for studies involving minor and relevant subjects incompetent to sign an ICF**
☐ **Advertisement**
☐ **Investigator's brochure**
☐ **Protocol summary**
☐ **Ethical Considerations – description/statement of compliance with ethical principle**
☐ **Data Protection Plan**
☐ **Data Collection Forms/ Case report forms (CRFs)**
☐ **Research team list**
☐ **Curriculum vitae (CV) (all team members)**
☐ **valid GCP certificates (team) updated (3 years validity)**
☐ **Study budget**
☐ **Revised protocol**
☐ **Revised consent form**
☐ **Amendments**
☐ **Technical Review Approval**
☐ **Insurance certificate (if applicable)**
☐ **FDA approval (if applicable)**
☐ **Others (Please specify)**

PROTOCOL SUMMARY SHEET

CGHMC RERB Protocol No.		**Sponsor Protocol No.**	
Date Submitted			
Title:			
Principal Investigator		**Sponsor**	
Rationale			
Objectives			
Study Design/ Methodology			
Inclusion Criteria			
Exclusion Criteria			
Data Analysis Plan			
Study Outcomes			

CHINESE GENERAL HOSPITAL AND MEDICAL CENTER
DEPARTMENT OF MEDICAL EDUCATION AND RESEARCH
RESEARCH ETHICS REVIEW BOARD (RERB)

REVIEWER'S PROTOCOL EVALUATION FORM

CGHMC RERB Protocol No.		**Sponsor Protocol No.**	
Date Submitted			
Protocol Title			
Principal Investigators:		Contact details:	
Department:			
Co-investigator(s):		**Contact details:**	
Overall/Total No. of Participants (onsite and off-site):	**Total no. of onsite participants:**	**No. of Study sites (if applicable):**	
Sponsor		**Contact Person/ contact details:**	
Clinical Research Organization		**Contact Person/ contact details**	
Duration of the Study (mos/years):		**Status:** ☐ New Protocol ☐ Amended Protocol (Pls state version number/date)	
Reviewers:			
Type of the Study	☐ Intervention ☐ Observational study ☐ Document review ☐ Individual based	☐ Epidemiology ☐ Genetic ☐ Social Survey ☐ Others, specify	
Review Status	☐ Full Board	☐ Expedited	
Description of the study in brief: (Mark whatever applies to the study.)			
☐ Randomized	☐ Drug	☐ Use of Genetic materials	
☐ Double blind	☐ Medical device	☐ Multicenter study	
☐ Single blind	☐ Vaccine	☐ Global protocol	
☐Open label	☐ Diagnostics	☐ Sponsor initiated	
☐ Observational	☐ Questionnaire/Survey	☐ Investigator Initiated	

A. PROTOCOL DOCUMENT REVIEW (to be filled up by reviewer)

ASSESSMENT POINTS	YES	NO	N/A	REVIEWER COMMENTS
1. SCIENTIFIC DESIGN				
1.1 Objectives Review of viability of expected output				
1.2 Literature Review Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials				
1.3 Research Design Review of appropriateness of design in view of objectives				
1.4 Sampling Design Review of appropriateness of sampling methods and techniques				
1.5 Sample Size Review of computation of sample size				
1.6 Statistical Plan Review of appropriateness of statistical methods to be used and how participant data will be summarized				
1.7 Data Analysis Plan Review of appropriateness of statistical and non-statistical methods of data analysis				
1.8 Inclusion criteria Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection				
1.9 Exclusion criteria Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion				
1.10 Withdrawal criteria Review of criteria precision both for scientific merit and safety concerns				
2. CONDUCT OF THE STUDY				
2.1 Specimen handling				

Review of specimen storage, access, disposal, and terms of use				
2.2 PI qualifications Review of CV and relevant certifications to ascertain capability to manage study related risks				
2.3 Suitability of Site Review of adequacy of qualified staff and infrastructure				
2.4 Duration Review of length/extent of human participant involvement in the study				
3. ETHICAL CONSIDERATIONS				
3.1 Conflict of Interest Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site				
3.2 Privacy and confidentiality Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans				
3.3 Informed consent process Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances				
3.4 Vulnerability Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group				

3.5 Recruitment Review of manner of recruitment including appropriateness of identified recruiting parties				
3.6 Assent Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children: 0-under 7: No assent; 7-under 12; Verbal Assent 12-under15; Simplified Assent Form 15-under18; Co-sign informed consent form with parents				
3.7 Risks Review of level of risk and measures to mitigate these risks (including physical ,psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable)				
3.8 Benefits Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant				
3.9 Incentives or compensation Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses				
3.10 Collaborative study terms of Reference Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building				

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision	
	☐ Major Revision/ Resubmission	☐ Disapproved	
Comments (Identify items for revision)			
Reviewer's Name		Date	
Signature			

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RESEARCH ETHICS REVIEW BOARD (RERB)

INFORMED CONSENT EVALUATION FORM

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Protocol Title:			
Principal Investigators:		Co-investigator/s:	

INFORMED CONSENT DOCUMENT REVIEW	YES	NO	N/A	REVIEWER COMMENTS
1. Does the Informed Consent document state that the procedures are primarily intended for research?				
2. Are procedures for obtaining Informed Consent appropriate?				
3.Does the Informed Consent document contain comprehensive and relevant information?				
4. Is the information provided in the protocol consistent with those in the consent form?				
5. Is the expected duration of the study stated?				
6. Is the approximate number of participants stated?				
7. Are study related risks mentioned in the consent form?				
8. Is the language in the Informed Consent document understandable?				
9. Is the Informed Consent translated into the local language/dialect?				
10. Is there adequate protection of vulnerable participants?				
11. Are the different types of consent				

forms (assent, legally acceptable representative) appropriate for the types of study participants?				
Should assent be required? ☐ verbal assent (7 – 11 y/o) ☐ simplified assent (12 -14 y/o) ☐ co-sign (15 – 17 y/o)				
12. Is there a description of any reasonably forseeable risks or discomfort to the subject?				
13. Is there a description of any benefits to the subject or to others which may reasonably be expected from the research?				
14. Is there a disclosure of appropriate alternative procedures or courses of treatment, if any, might be advantageous to the subject?				
15. Are names and contact numbers from the research team and the RERB in the informed consent?				
16. Does the ICF mention privacy & confidentiality protection?				
17. Is there any inducement for participation?				
18. Is there provision for medical / psychosocial support?				
19. Is there provision for treatment of study-related injury?				
20. Is there provision for compensation?				

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision	
	☐ Major Revision/ Resubmission	☐ Disapproved	
Comments (Identify items for revision)			
Reviewer's Name		Date	
Signature			