



### APPLICATION FORM FOR PROTOCOL REVIEW

CGHMC RERB Protocol Number		Sponsor Protocol No:	
Submission Date			
Protocol Title:			
Principal Investigator			
Study Site			
Contact details:	 :		
	Mobile:		
	Fax:		
	Email address:		
Sponsor:			
PI Conflict of Interest/ Declaration (Relationship with Sponsor)	Are you a regular employee of the sponsor? <input type="checkbox"/> Yes <input type="checkbox"/> No		
	Did you do consultancy or part time work for the sponsor? <input type="checkbox"/> Yes <input type="checkbox"/> No		
	In the past year, did you receive P250,000 or more from the sponsor? <input type="checkbox"/> Yes <input type="checkbox"/> 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:		
Study Site		

Documents submitted: (Please check all applicable)

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



**PROTOCOL SUMMARY SHEET**

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



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**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:	
Study Site: (Name & Address)			
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: <input type="checkbox"/> New Protocol <input type="checkbox"/> Amended Protocol (Pls state version number/date)	
Reviewers:			



<b>Type of the Study</b>	<input type="checkbox"/> Intervention	<input type="checkbox"/> Epidemiology
	<input type="checkbox"/> Observational study	<input type="checkbox"/> Genetic
	<input type="checkbox"/> Document review	<input type="checkbox"/> Social Survey
	<input type="checkbox"/> Individual based	<input type="checkbox"/> Others, specify
<b>Review Status</b>	<input type="checkbox"/> Full Board	<input type="checkbox"/> Expedited
<b>Description of the study in brief: (Mark whatever applies to the study.)</b>		
<input type="checkbox"/> Randomized	<input type="checkbox"/> Drug	<input type="checkbox"/> Use of Genetic materials
<input type="checkbox"/> Double blind	<input type="checkbox"/> Medical device	<input type="checkbox"/> Multicenter study
<input type="checkbox"/> Single blind	<input type="checkbox"/> Vaccine	<input type="checkbox"/> Global protocol
<input type="checkbox"/> Open label	<input type="checkbox"/> Diagnostics	<input type="checkbox"/> Sponsor initiated
<input type="checkbox"/> Observational	<input type="checkbox"/> Questionnaire/Survey	<input type="checkbox"/> Investigator Initiated

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

ASSESSMENT POINTS	YES	NO	N/A	REVIEWER COMMENTS
<b>1. SCIENTIFIC DESIGN</b>				
<b>1.1 Objectives</b> Review of viability of expected output				
<b>1.2 Literature Review</b> 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				
<b>1.3 Research Design</b> Review of appropriateness of design in view of objectives				
<b>1.4 Sampling Design</b> Review of appropriateness of sampling methods and techniques				
<b>1.5 Sample Size</b> Review of computation of sample size				
<b>1.6 Statistical Plan</b> Review of appropriateness of statistical methods to be used and how participant data will be summarized				
<b>1.7 Data Analysis Plan</b> Review of appropriateness of statistical and non-statistical methods of data analysis				
<b>1.8 Inclusion criteria</b>				



Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection				
<b>1.9 Exclusion criteria</b> Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion				
<b>1.10 Withdrawal criteria</b> Review of criteria precision both for scientific merit and safety concerns				
<b>2. CONDUCT OF THE STUDY</b>				
<b>2.1 Specimen handling</b> Review of specimen storage, access, disposal, and terms of use				
<b>2.2 PI qualifications</b> Review of CV and relevant certifications to ascertain capability to manage study related risks				
<b>2.3 Suitability of Site</b> Review of adequacy of qualified staff and infrastructure				
<b>2.4 Duration</b> Review of length/extent of human participant involvement in the study				
<b>3. ETHICAL CONSIDERATIONS</b>				
<b>3.1 Conflict of Interest</b> Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site				
<b>3.2 Privacy and confidentiality</b> Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans				
<b>3.3 Informed consent process</b> 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				



<b>3.4 Vulnerability</b> 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				
<b>3.5 Recruitment</b> Review of manner of recruitment including appropriateness of identified recruiting parties				
<b>3.6 Assent</b> 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				
<b>3.7 Risks</b> 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)				
<b>3.8 Benefits</b> 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				
<b>3.9 Incentives or compensation</b> Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses				
<b>3.10 Collaborative study terms of Reference</b> 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				
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B. Recommendation

DECISION:	<input type="checkbox"/> Approval	<input type="checkbox"/> Minor Revision
	<input type="checkbox"/> Major Revision/ Resubmission	<input type="checkbox"/> Disapproved
Comments (Identify items for revision)		
Reviewer's Name		Date
Signature		





### 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? <input type="checkbox"/> verbal assent (7 – 11 y/o) <input type="checkbox"/> simplified assent (12 -14 y/o)				



<input type="checkbox"/> co-sign (15 – 17 y/o)				
12. Is there a description of any reasonably foreseeable 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:	<input type="checkbox"/> Approval	<input type="checkbox"/> Minor Revision
	<input type="checkbox"/> Major Revision/ Resubmission	<input type="checkbox"/> Disapproved
Comments (Identify items for revision)		
Reviewer's Name		Date
Signature		