



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
<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)