



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) |