崇華醫院
Chong Hua Hospital
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IRB APPLICATION INFORMATION SHEET

Form HRP-IRB-009

The investigator initiates the process of review by submitting an application to the IRB office. A formal letter for review of a research should accompany the ff. documents:

- ❑ Nine (9) copies of **Research Protocol** or its amendments. This may include the title of the proposal, background of the study, rationale, objectives, research design, inclusion and exclusion criteria, and safety information, including the process of recruitment.
- ❑ Nine (9) copies of **Investigators' Brochure** if applicable
- ❑ Nine (9) copies **Informed Consent Forms** and its translations to Cebuano or dialect spoken or understood by research participants
- ❑ Nine (9) copies of **additional information sheet** *(any information not included in the above documents)* in English and Cebuano or dialect spoken and understood by research participants.
- ❑ Investigators' **Curriculum Vitae** (latest updated, signed and dated).
- ❑ Recent **PRC License**.
- ❑ A copy of the latest **GCP certification** of the Principal Investigator (at least for the past 2 years) or schedule of planned GCP training.
- ❑ A copy of PI's **declaration of no Conflict of Interest**.
- ❑ A completed and duly signed duplicate copy of page 1 of the **IRB APPLICATION FORM** is attached.
- ❑ Duly signed **letter of consent** approved by the COO/Medical Director for the proposal to conduct clinical trials in Chong Hua Hospital.
- ❑ A **review fee** of 50,000 Php and **institutional fee** of 50,000 Php in two separate checks (for New Protocol) or 10,000 Php (for Protocol Amendment) is required to be submitted together with the application letter and the required documents stated above.

- IRB staff will screen the application and may request additional information or revisions if it is incomplete or contains inconsistencies.
- Once the application is complete, the IRB will set the schedule of IRB meetings and final disposition. Scheduling starts only after all the application requirements have been completed.
- Once the application meets all criteria for approval, the IRB will issue an approval letter not later than 4 weeks upon receipt of complete requirements.
- If the protocol fails to meet the criteria for approval, clarification to include more information or revisions will be requested. Should significant changes be needed, the revised protocol will require a new review.

The investigator may be invited to provide information on any aspect of the trial, but are not allowed to participate in the deliberation of the IRB or in the vote opinion of the IRB.

- The investigator initiates the process of review by submitting an application form to the IRB office.
- The application letter should be accompanied by a duly signed letter of consent approved by the COO/Medical Director to conduct clinical trials in Chong Hua Hospital.
- A review fee shall be paid together with the application letter.
- IRB staff will screen the application and may request additional information or revisions if it is incomplete or contains inconsistencies.
- Once the application requirements have been completed, the IRB will set the schedule of a convened IRB meeting not later than 2 weeks from submission. Scheduling starts only after the application requirements have been completed.
- The investigator or his designate may be invited to provide information on any aspect of the trial but are not allowed to participate in the deliberation of the IRB.
- Once the application meets all criteria for approval the IRB will issue an approval letter not later than 4 weeks after receipt of complete requirements.
- If the protocol fails to meet the criteria for approval, more information or revisions may be requested before an unfavorable decision will be issued.
- Unfavorable board decisions may be appealed not later than 2 weeks from receipt of the written decision.

***** Please keep this copy for your guidance *****