IRB APPLICATION INFORMATION SHEET

Form HRP-IRB-009

FOR SPONSOR-INITIATED PROTOCOLS

The Principal Investigator initiates the process of ethics review by submitting an application letter to the IRB office. The letter should be attached to the document package which should include the following:

- ❑ Nine (7) copies of **Research Protocol** or its amendments.
- ❑ Nine (7) copies of **Investigators' Brochure** if applicable
- ❑ Nine (7) copies **Informed Consent Forms and Consent forms (if applicable)** and their translations to Cebuano or dialect spoken or understood by research participants
- ❑ Nine (7) 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 **IRB APPLICATION FORM**
- ❑ 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 **(to be collected only after the approval and if space is available at Research Facility Unit of Chong Hua Hospital)** 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 APPLICATION INFORMATION SHEET

Form HRP-IRB-009

- 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.
- If the application is complete the IRB will assign an IRB Reference Number to your research submission. All communication from and to the principal investigator henceforth will use this IRB reference number for tracking purposes.
- 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 or in the vote opinion of the IRB.
- 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.
- Unfavorable board decisions may be appealed not later than 2 weeks from receipt of the written decision.
- The sponsor/ investigator should provide the list of laboratory/ other procedures to be done in the site.

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