FOR PRINCIPAL INVESTIGATOR-INITIATED PROTOCOLS

The Principal Investigator initiates the process by submitting an application for review letter to the IRB office. The letter should accompany the documents being submitted and include the following:

- ❑ Three (3) copies of **Research Protocol** or its amendments. (If it is an initial submission, the protocol should include its title, background of the study, rationale, literature review, objectives, research design, methodology, inclusion and exclusion criteria, recruitment process, safety information on drug and/or procedures, data analysis (including dummy tables when applicable)
- ❑ Three (3) copies of **Informed Consent Forms** (*as applicable*) and Assent Forms when applicable, and their translations to Cebuano or dialect spoken or understood by research participants. (If participants are 7- 14 years of age, an assent form is required).
- ❑ Three (3) 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*).
- ❑ 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 completed and duly signed **IRB APPLICATION FORM**
- ❑ Signed **Confidentiality Agreement**

Approved by **Department Research Committee**

_____	_____
Name of Authorized Person	**Signature and Date**

IRB APPLICATION INFORMATION SHEET

The investigator initiates the process of review by submitting an application form to the IRB office.

- For resident/staff initiated Studies the review fee shall be waived.
- 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 henceforth will use this IRB reference number for tracking purposes.
- 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.
- 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.
- 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.

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