Requirements for Clinical Trial:

a. An application for review requires the following submissions:

- Completed Initial Review Submission Form (PHC-IERB 03-21-02) and Document receipt form (PHC-IERB 03-14-02)
- Letter of Intent (addressed to Dr. Marcelito L. Durante, IERB Chair, and to
- Dr. Gilbert C. Villela –Department Manager, DETR

b. Protocol w/ the following attachments (10 copies)

- Informed Consent Form (English and Tagalog Versions)
- Investigator's Brochure (IB)
- If any, Pharmacogenetics ICF (English and Tagalog Versions)
- **If any**, Subject Worksheets/Patient Diary /Alert Cards (English and Tagalog Versions)
- **If any**, Questionnaire (English and Tagalog Versions)
- Philippine Food and Drug Administration **(PFDA) Approval** or **letter of request for protocol review**
- Curriculum Vitae of Investigator/s
- **Updated** Good Clinical Practice (GCP) Certificates
- Certificate of Insurance (if applicable)
- Ethics Review Fee *(P40,000 net of tax)* and Technical/Institutional Fee (*P100,000 net of tax)*(To be paid upon submission of the above)