Instructions to Principal Investigators/researchers (Consultants, Fellows, Nurses, etc.)

Submit protocol and relevant documents to the Technical Review Committee (TRC) for review and approval. The TRC will then forward the protocol file to the IERB once it is approved. The IERB will notify the researcher/Principal Investigator when the protocol is scheduled for full board review and when attendance is required.

Requirements for Clinical Trial:

1. An application for review requires the following submissions:
   1.1 Completed Initial Review Submission Form (FM-E-IRB-2019-021 Rev. 07) and Document receipt form (FM-E-IRB-2019-014 Rev. 05)
   1.2 Letter of Intent (addressed to Dr. Rafael Tenorio, IERB Chair, and to Dr. Alexander A. Tuazon –Department Manager, Clinical Research Department

2. Protocol w/ the following attachments (3 paper copies and digital copy)
   2.1 Informed Consent Form (English and Tagalog Versions)
   2.2 Investigator's Brochure (IB)
   2.3 If any, Pharmacogenetics ICF (English and Tagalog Versions)
   2.4 **If any**, Subject Worksheets/Patient Diary /Alert Cards (English and Tagalog Versions)
   2.5 **If any**, Questionnaire (English and Tagalog Versions)
   2.6 Philippine Food and Drug Administration **(PFDA)Approval** or **letter of request for protocol review**
   2.7 Curriculum Vitae of Investigator/s
   2.8 **Updated** Good Clinical Practice (GCP) Certificates
   2.9 Certificate of Insurance (if applicable)
   2.10 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)Continuing review fee (*P10,000*).

Note: For 3 or more study sites need to submit to SJREB