**INSTITUTIONAL REVIEW BOARD**

**IRB CHECKLIST FOR INITIAL SUBMISSION (FORM 2.0)**

**Protocol package for Clinical trial and/or Sponsor-initiated studies:**

* Letter of Application & Complete Protocol
* Protocol Summary
* Investigator’s Brochure (for Clinical Trials)
* Data collection form/s
* Informed Consent Forms (English, Tagalog, and local dialect (Hiligaynon))
* CV (for clinical trials- Principal Investigator and his/her co-investigators),

(for Researcher Initiated protocol-Researcher and Adviser).

* GCP Certificate of the Principal Investigator (PI) and his/her co-investigators
* Declaration of No Conflict of Interest for Principal Investigators/Researchers (Form 2.2)
* Valid PRC License
* COI Declaration and Confidentiality Agreement
* GANTT Chart (as necessary)
* Advertisement, Diary card and other related documents (for Clinical Trials)
* Case report form/s, trial Materials (for Clinical Trials)
* Certificate of Technical Review (for Researcher Initiated protocol)
* Insurance Certificate (for Clinical Trials)
* Technical review approval/endorsement of the Department
* Decision of Ethics Review if reviewed by other Research Ethics Committee/s
* Material Transfer Agreement (for Clinical Trials if applicable)
* Budget
* Clinical Trial Agreement- Draft is acceptable (for Clinical Trials)
* Letter of Approval from Hospital Administrator and Data Protection Officer
* Waiver of Informed Consent Form (if applicable)

***\* Note: Three (3) hard copies of this protocol package should be submitted to the IRB and electronic copy through sphirbresearch@gmail.com***

* ***For submissions you may submit your application at SPH-IRB office located at 4th Floor Cancer Center Building and look for Sr. Gertrude Caryls Kuebler, SPC or Ms. Queenie Crisostomo. You may contact us also through our telephone number 337-2742 local 7306.***