REQUIREMENT CHECKLIST FOR INITIAL SUBMISSION

STUDY PROTOCOL INFORMATION

RIHS ERC Code: (*to be assigned by the ERC*)	
Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date:	

Basic Documents (must submit) (*to be checked and verified by the ERC Secretariat*):

- ☐ **[RIHS ERC FORM 2(B)]** Requirement Checklist for Initial Submission
- ☐ **[RIHS ERC FORM 2(C)]** Printed Registration and Application
- ☐ **[RIHS ERC FORM 2 (J)]** Review of Resubmitted Protocol
- ☐ **[RIHS ERC FORM 2(D)]** Study Protocol Assessment
- ☐ Study Protocol
- ☐ Study Protocol Synopsis
- ☐ **[RIHS ERC FORM 2(E)]** Informed Consent Assessment (for studies with human participants)
- ☐ Data Collection Forms (including CRFs)
- ☐ CV of PI and study team members
- ☐ Informed consent form in English (for studies with human participants)
- ☐ Informed consent form in local language (for studies with human participants)
- ☐ Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
- ☐ Electronic copy of study protocol, **RIHS ERC FORM 2(B), RIHS ERC FORM 2(C), RIHS ERC FORM 2(D),** and **RIHS ERC FORM 2(E)** for initial submission
- ☐ Electronic copy of study protocol and **RIHS ERC FORM 2(J), RIHS ERC FORM 2(D),** and **RIHS ERC FORM 2(E)** for resubmission

Study-specific Documents (submit as needed)

- ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV) and other clinical trials outside of Phase 1 - 4
- ☐ Summary of all safety, pharmacological, pharmaceutical, and toxicological data (for study product such as pharmaceutical or device under investigation)
- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, etc.)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ **[RIHS ERC FORM 2(F)]** Site Resources Checklist for Clinical Trial Outside UERMMMCI By UERMMMCI Personnel
- ☐ **[RIHS ERC FORM 2(G)]** Site Resources Checklist for Clinical Trial Outside UERMMMCI By non-UERMMMCI Personnel
- ☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- ☐ Disclosure of previous ethical and/or scientific board reviews (with attached copy of conclusions, recommendations and incorporated changes)
- ☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while RIHS ERC review is on-going)
- ☐ Declaration of Conflict of Interest of the Principal Investigator/Co-investigators
- ☐ Disclosure of funding sources, sponsors, institutional affiliations and other possible sources of conflicts of interest
- ☐ Any additional materials submitted for approval (pls. specify)