Form 5.1 Protocol Package Checklist

**Eastern Visayas Health Research and Development Consortium - Ethics Review Committee**

***PROTOCOL PACKAGE CHECKLIST***

**PROTOCOL TITLE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROTOCOL CODE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PRIMARY INVESTIGATOR:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Submission:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Basic Documents (ALL must be submitted)

☐ Form 5.1 Protocol Package Checklist

☐ Form 5.2 Application for Initial Protocol Review

☐ Form 5.3 Protocol Summary

☐ Form 5.4 Non-disclosure Agreement (Principal Investigator)

☐ Application for Review – Request Letter addressed to the ERC Chair

☐ Study Protocol

☐ Title

☐ Significance of the study

☐ Literature Review

☐ Project Duration

☐ Objectives of the study

☐ Methodology & Procedures

☐ Description of the study population

☐ Exclusion/inclusion criteria

☐ Data analysis

☐ Dummy tables

☐ Work Plan Schedule (Gantt chart for schedule of activities)

☐ Ethical considerations (which include, but not limited to)

☐ Disclosure of Conflict of Interest

☐ Confidentiality and Data Protection Plan (in compliance with Data Privacy Act)

☐ Vulnerability Issues

☐ Risk/Benefit Statement

☐ Mitigation of Risk

☐ Research Dissemination Plan

☐ Schematic Diagram/Conceptual Framework

☐ Study Protocol Budget/Line-Item Budget

☐ Supplementary Documents (if applicable)

 ☐Questionnaire

☐Data Collection Forms

☐Product Brochure/Basic Product Information Document (for Phase IV clinical trials)

☐ Permit/s for Special Population (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ Informed Consent Forms *(preferably using the WHO template with a statement that EVHRDC-ERC reviewed the protocol and includes its contact information for possible queries and complaints from the participants (053 888-4203)*

 ☐English ☐ Vernacular ☐Others

 ☐ Assent Form (if applicable)

 ☐English ☐ Vernacular ☐Others

 ☐ Technical Review Certificate

☐ Curriculum Vitae for all members of the Study Team

☐ Proof of Payment of Initial Review Fee, if applicable

☐ Three (3) hardcopies of the study protocol

Study Specific Documents (submit as needed particularly for externally originated studies and sponsored studies)

☐ 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)

☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)

☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while ERC review is ongoing)

☐ Contracts and/or Approval of relevant offices / regulatory authorities (Written review agreement / Authorization and Acknowledgement of review)

WHO Templates for Informed Consent and Assent Forms (use as Guide only)

☐ WHO TEMPLATE: Informed Consent form in English and Local language (for studies involving adult human participants) (Use as Guide : WHO Form ICF-1)

☐ WHO TEMPLATE: Informed Consent form for Co-signature in English and Local language (for studies involving minors ages more than or equal to 15 years up to less than 18 years of age and relevant populations deemed incompetent to execute decision and signing of informed consent form) (Use as Guide : WHO Form ICF-1)

☐ WHO TEMPLATE: Assent form in English and Local language (for studies involving minors less than or equal to 12-15 years of age and relevant populations deemed incompetent to sign an informed consent form(Use as Guide : WHO Form ICF-2 )

☐ WHO TEMPLATE: Informed Consent for Qualitative Studies -research interventions that use questionnaires, in-depth interviews or focus group discussions (Use as Guide : WHO Form ICF-3)

☐ WHO TEMPLATE: Informed Parental Consent for Research Involving Children (Qualitative Studies) (Use as Guide : WHO Form ICF-4)

☐ WHO TEMPLATE: informed Consent for Storage and Future Use of Unused Sample (Use as Guide : WHO Form ICF-5)

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Submitted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_