Review Checklist

STUDY PROTOCOL INFORMATION	
Reference Number:	
UVIRB Code:	
Study Protocol Title:	
Proponent:	
Other Authors:	
Study Protocol Submission Date: *(to be accomplished by UVIRB Staff)*	
Verified Complete by: *(to be accomplished by UVIRB Staff)*	
Classification of Review: *(to be accomplished by UVIRB)*	☐ **EXEMPTED** ☐ **EXPEDITED** ☐ **FULL BOARD**
Classified by the: ☐ **UVIRB Chair** ☐ **UVIRB IRB Officer 1** ☐ **UVIRB IRB Officer 2**	

Basic Documents (must submit) – 3 PHOTOCOPIES (prescribed folder)

- ☐ IRB PROCEDURE
- ☐ Review Checklist **[UVIRB FORM II(A)]**
- ☐ Printed Registration and Application Form **[UVIRB FORM II(B)]**
- ☐ Study Protocol (Chapters 1 to 3) for Quantitative studies; or (Chapter 1 and 2) for Qualitative Studies
- ☐ Complied Panel's Recommendations with signature of all panel members
- ☐ Records of Proceedings
- ☐ Approved Title Study
- ☐ Application for Design Hearing
- ☐ CV of PI and study team members and adviser – **[UVIRB FORM III]**
- ☐ Technical Soundness: – IRB OFFICE
  - ☐ Quantitative and Evaluation Research – **[UVIRB FORM Form II(C1)]**
  - ☐ Phenomenology – **[UVIRB FORM Form II(C2.1)]**
  - ☐ Grounded Theory – **[UVIRB FORM Form II(C2.2)]**
  - ☐ Ethnography and Thematic Research – **[UVIRB FORM Form II(C2.3)]**
  - ☐ Case Study and Narrative Research – **[UVIRB FORM Form II(C2.4)]**
- ☐ Ethical Soundness:
  - ☐ Ethical Consideration Assessment Form **[UVIRB FORM II(D1)]**
  - ☐ Inform Consent Assessment Form **[UVIRB FORM II(D2)]**, when applicable

For those applying for Exempt for IRB Review:

- ☐ IRB PROCEDURE
- ☐ Review Checklist **[UVIRB FORM II(A)]**
- ☐ Printed Application for IRB Review **[UVIRB FORM II(B)]**
- ☐ Study Protocol (Chapter 1 to 3) for Quantitative studies; or (Chapter 1 and 2) for Qualitative Studies
- ☐ Records of Proceedings
- ☐ CV of PI and study team members and adviser – **[UVIRB FORM III]**

Corner Colon & Jakosalem Streets, Cebu City 6000, Philippines *Telephone: +63 (32) 416.8607; Email: uvirb2017@gmail.com*

Review Checklist

☐ UVIRB Form 2.1F Request For Exempt from IRB Review
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) ☐ 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) ☐ 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) ☐ Site Resources Checklist (for Clinical Trial) ☐ 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 UVIRB review is ongoing) ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable; can be processed while UVIRB review is ongoing)
This portion is applicable once Notice to Proceed is released ☐ **FINAL REPORT** ☐ **Project Closure Form (UVIRB FORM V)** ☐ CD-RW copy of **ALL BASIC DOCUMENTS and UVIRB Forms** (properly labelled) – • Sticker Label must follow the colour coding of your College • Reference Number (leave it blank) • UVIRB Code: (leave it blank) • Study Protocol Title: • Principal Investigator:

Corner Colon & Jakosalem Streets, Cebu City 6000, Philippines *Telephone: +63 (32) 416.8607; Email: uvirb2017@gmail.com*