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| C:\Users\NURSING\Desktop\UST Logo.jpg | C:\Users\NURSING\Desktop\UST CON Logo.png | **UST COLLEGE OF NURSING**  **ETHICS REVIEW COMMITTEE** |
| 1st Floor Room 105, St. Martin de Porres Building, España, Manila, Philippines 1015  *Telephone*: (632) 406-1611 local 8362 | (632) 731-5738  *Email*: erc-nursing@ust.edu.ph |

**Protocol Registration and Application Form**

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| **INSTRUCTION:** |  |
| *The protocol registration and application form is required for all initial study protocol submission and all study protocol resubmission. Upon completing this form, print this form in* ***Letter size paper****, sign this form, and date your signature prior to submission.* | |

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| **SECTION I: APPLICATION INFORMATION** | | | | | |
| 1. **Study Protocol Code:** |  | | | | |
| 1. **Type of Submission:** | 2.1 Initial Review  2.2 Resubmission (*responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval*).   **NOTE**: version and date of version must be inserted as a document footer for all resubmissions  2.3 Application for Exemption from USTCON ERC Review (*for official declaration of study exemption from ethics review)* | | | | |
| 1. **Date of Submission:** | [DD/MM/YYYY] | | | | |
| 1. **Study Category:** | 4.1 Research involving human participants  4.2 Research involving non-human living vertebrates  4.3 Others (*please indicate*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 1. **Type of Study:** | 5.1 Experimental/Interventional Research  5.2 Non-Experimental/Interventional Research (*choose one*):  5.2.1 Correlational Research  5.2.2 Comparative Research  5.2.3 Methodological/Scale Development Research  5.2.4 Historical Research  5.2.5 Evaluative Research  5.2.6 Epidemiological Study  5.2.7 Socio-Behavioral Research  5.2.8 Health Informatics  5.3 Qualitative Research  5.4 Others (*please indicate*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 1. **Category of Investigator:** | 6.1 **UST Nursing Affiliate**  6.1.1 UST Nursing Undergraduate Student  6.1.2 UST Nursing Graduate Student  6.1.3. UST Nursing Faculty  6.2 **UST Affiliate**  6.2.1 UST Undergraduate Student (*specify Faculty/College/Institute): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  6.2.2 UST Graduate Student  6.2.3. UST Faculty (*specify Faculty/College/Institute): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  6.3 **Non-UST Affiliate** (*specify institution*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  (**NOTE**: This category requires completion of *Part III: Authorization and Acknowledgement of Review* below) | | | | |
| 1. **Purpose of Study:** | 7.1 Academic Requirement (*Thesis, Dissertation, Training Requirement*)  7.2Independent Research Work  7.3 Multi-Institutional or Multi-Country Collaboration  7.4Others (*please indicate*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 1. **Study Title:** |  | | | | |
| 1. **Study Protocol Synopsis:** | *Please write a synopsis (maximum 500 words) of the study in the space provided below based on the specified components, and indicate page where such components may be found in the full study protocol or in annexes/appendices. If items are not applicable, indicate by N/A. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol.*   1. **Technical Synopsis:**    1. Objectives and/or Expected Output    2. Literature Review rationalizing the Design    3. Research Design    4. Sampling Design and Sample Size    5. Inclusion Criteria, Exclusion Criteria, and Withdrawal Criteria    6. Data Collection Plan    7. Specimen Collection and Processing Plan (*include plans for specimen storage, data storage, and duration of storage*)    8. Data Analysis Plan (*include statistical basis for design, as applicable*)    9. Rationalization for Choice of Study Site (*including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable*) (*Cross reference information with statements provided in the informed consent*) | | | | |
|  | 1. **Ethical Considerations Section**    1. Protection of Privacy and Confidentiality of Research Information including Data Protection Plan    2. Vulnerability of Research Participants    3. Risks of the Study (*include social risks*)    4. Benefits of the Study    5. Patient-Related Compensations/Reimbursements/Entitlements    6. Informed Consent Process and Recruitment Procedures    7. Terms of reference of collaborative study (*as applicable, such as intellectual property agreements and similar concerns*)    8. Terms of Available Study-Related Insurance | | | | |
| 1. **Study Duration** | (in months) | | | | |
| 1. **Use of special populations or vulnerable groups** | 11.1 Children (under 18)  1.12 Indigenous People  11.3 Elderly (≥ 65)  11.4 People on welfare/social assistance  11.5 Poor and unemployed  11.6 Patients in emergency care  11.7 Homeless persons  11.8 Refugees or displaced persons  11.9 Patients with incurable diseases  11.10 Institutionalized individuals  11.11 Others (*please indicate*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  11.12 Not applicable | | | | |
| 1. **Endorsing/Unit/ Department/ Institution:** | 12.1 UST (*specify Faculty/College/Institute*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  12.2 Non-UST (*local, please specify*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  12.3 Non-UST (*foreign institution, specify*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 1. **Study Site:** | 13.1 UST unit  13.2 Non-UST with local IRB/ERB/ERC  13.3Non-UST without local IRB**/**ERB/ERC | | | | |
| 1. **Funding Agency:** | **14.1 (NAME):** | | | | |
| * 1. **TYPE OF FUNDING AGENCY:** | | | | |
| 14.2.1 UST Unit  14.2.2 UST-CON unit  14.2.3 Investigator-Initiated  14.2.4 PHL Government Agency/Office/Entity  14.2.5 Multilateral Agency (*UN agencies & Other intergovernmental agencies*)  14.2.6 Private Company or Non-Governmental Organization (NGO)  14.2.7 Others (*please indicate*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 1. **Study Budget:** | **NOTE**: *This refers to line item amounts. However, if a separate budget sheet is available, just indicate total amount and attach budget sheet*  **TOTAL BUDGET**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 1. **Previous ethics approval or clearance issued by other sites:** | 16.1 Name of Institutional Review Board or Ethics Review Committee:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  16.2 Date of Ethics Approval [DD/MM/YYYY]: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  16.3 Date of Expiration of Approval [DD/MM/YYYY]: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  16.4 Not Applicable | | | | |
| 1. **Principal Investigator:** | [Title, Name, Surname] | | | | |
| 1. **Birthdate:** | [DD/MM/YYYY] | | | | |
| 1. **PI Address:** | [Institutional Address] | | | | |
| 1. **PI Telephone:** |  | | | | |
| 1. **PI Facsimile:** |  | | | | |
| 1. **PI Mobile:** |  | | | | |
| 1. **PI Email:** |  | | | | |
| 1. **Other Ongoing Studies:** | 24.1 Title:  24.1.1 UST ERC Code (*if applicable*): | | | | 24.3 Title:  24.3.1 UST ERC Code (*if applicable*): |
| 24.2 Title:  24.2.1 UST ERC Code (*if applicable*): | | | | 24.4 Title:  24.4.1 UST ERC Code (*if applicable*): |
| 1. **Declaration of Conflict of Interest of PI:** | 25.1 I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site. | | | | |
| 25.2 I have personal/family financial interest in the results of the study. | | | | |
|  | NATURE: | |  | |
| 25.3 I have proprietary interest in the research for which this application is being made (patent, trademark, copyright, licensing). | | | | |
|  | NATURE: | |  | |
| I have significant financial interests as defined in US 45 CFR Part 94 (*Note: This category is only for applications for which this regulation may apply. For information, refer to http://www.ecfr.gov*). | | | | |
|  | NATURE: | |  | |
| 1. **Other investigators with corresponding task description** *(add additional rows as applicable):* | Co-Investigator:  Task description: | | | | |
| Co-Investigator:  Task description: | | | | |
| Co-Investigator:  Task description: | | | | |
| 1. **Submitted By:** | [Title, Name, Surname] | | | | |
| Study Designation: | |  | | |
| 1. **PI Signature:** |  | | | | |

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| **SECTION II: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW**  *This section should be completed by the signatory official who can sign on behalf of the institution that has oversight on the research site,* ***IF the research site is OUTSIDE the scope of authority of UST-CON and the PI is a non-USTCON personnel****. If not applicable, put N/A in all fields. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.*** *In case regional IRB will opt not to review, attach letter of endorsement.* | | |
| **Study Protocol Title with Version Number and Date:** |  | |
| **Principal Investigator:** | [Title, Name, Surname] | |
| This is to certify that the **[NAME OF RESEARCH SITE]:**   * + 1. Has no local Institutional Review Board/ Ethics Review Committee; and,     2. Authorizes and acknowledges the **University of Santo Tomas College of Nursing – Ethics Review Committee (USTCON-ERC),** located at the **1st Floor Room 108, San Martin de Porres Building, España Boulevard, Sampaloc, Manila, Philippines 1015**, to perform the ethical review of the abovementioned protocol in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research which includes progress monitoring, adverse event monitoring, and site visits. | | |
| **Name of Research Site:** |  | |
| **Address of Research Site:** |  | |
| **Signatory Official:** | [Title, Name, Surname] | |
| **Position of Official:** |  | |
| **Signature:** |  | **Date of Signature**: [DD/MM/YYYY] |