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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 COMMITTE** |
| 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 |

**Research Protocol & Informed Consent Assessment Form**

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| **INSTRUCTIONS:** |  |
| *To the Principal Investigator:* | *Kindly indicate in the spaces provided if the specified assessment parameters have been addressed by your research protocol. Further, kindly indicate the page and paragraph number where the information can be found.*  |
| *To the Primary Reviewer:* | *Kindly evaluate how the specified assessment parameters outlined below have been appropriately addressed in the research protocol and informed consent form(s). Confirm the submitted information and indicate your comments, suggestions, and/or recommendations under the “Reviewer’s Comments” column. In your comments for the informed consent, ensure that the vulnerability, the recruitment process, and the process of obtaining informed consent are always assessed within the context of the research protocol and the participant. Kindly summarize your comments, suggestions, and/or recommendations in the “Overall Evaluation” section and finalize your review by indicating your conclusion under the “Recommended Action” section. Finally, kindly sign in the space provided for the primary reviewer and date your signature.*  |
| **Protocol Code:** | Click here to enter text. | **Date of Submission:**  | Click here to enter a date. |
| **Protocol Title** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Co-Investigator(s):** | Click here to enter text. |
| **Adviser** *(if applicable):* | Click here to enter text. |
| **Contact No:** | Click here to enter text. | **Email Address:** | Click here to enter text. |
| **Affiliation:** | Click here to enter text. |

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| **ASSESSMENT PARAMATERS** | **TO BE FILLED OUT BY THE INVESTIGATOR** | **TO BE FILLED OUTBY THE REVIEWER** |
| **PART IRESEARCH PROTOCOL** | *Indicate if protocol addressed the specified parameters* | *Indicate page & paragraph number* | **REVIEWER’S COMMENTS** |
| YES | N/A |
| 1. **SCIENTIFIC DESIGN**
 |
| * 1. **Research Objectives**

*Scientific soundness and feasibility of research and expected output* |  |  |  |  |
| * 1. **Literature Review**

*Comprehensive and updated review of results of previous animal or human researches showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials* |  |  |  |  |
| * 1. **Research Design**

*Appropriateness of research design in view of research objectives* |  |  |  |  |
| * 1. **Sampling Design**

*Appropriateness of sampling methods and techniques* |  |  |  |  |
| * 1. **Sample Size**

*Justification of sample size with statistical computation and parameters or sound basis/references* |  |  |  |  |
| * 1. **Statistical and/or Data Analysis**

*Appropriateness of statistical and non-statistical plans for data analysis and how data will be summarized* |  |  |  |  |
| * 1. **Inclusion Criteria**

*Criteria for participant eligibility for scientific merit, safety concerns, and equitable selection* |  |  |  |  |
| * 1. **Exclusion Criteria**

*Criteria for participant eligibility for scientific merit, safety concerns, and justifiable exclusion* |  |  |  |  |
| * 1. **Withdrawal Criteria**

*Criteria for participant withdrawal for scientific merit and safety concerns* |  |  |  |  |
| * 1. **Data Collection Forms**

*Appropriateness of technical-soundness, language, and semantics of data collection forms that uphold participant anonymity* |  |  |  |  |
| 1. **CONDUCT OF STUDY**
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| * 1. **Data/Specimen Handling**

*Review of specimen and/or data collection, storage, access, disposal, and usage* |  |  |  |  |
| * 1. **Investigator Qualifications**

*Review of curriculum vitae, updated GCP certification, and other research-relevant certifications of all research members (investigators, research associates and assistants, data collectors, etc.) to ascertain capability to conduct the research and to appropriately address study-related risks* |  |  |  |  |
| * 1. **Suitability of Site**

*Adequacy and capability of qualified staff and infrastructures in the study sites* |  |  |  |  |
| * 1. **Study Duration**

*Length and extent of human participant involvement in the study**Timeline of research activities* |  |  |  |  |
| 1. **ETHICAL CONSIDERATIONS** *(Provide the following subsections in the Ethical Considerations section of the protocol)*
 |
| * 1. **Conflict of Interest**

*Declaration and management of conflicts arising from financial, familial, and/or proprietary considerations of the investigator(s), sponsor, and/or study site* |  |  |  |  |
| * 1. **Privacy and Confidentiality**

*Measures and safeguards to protect privacy and confidentiality of participant information, as indicated in the research methodology, including, but not limited to, data protection plans, anonymization plans, and data de-identification* |  |  |  |  |
| * 1. **Informed Consent Process**

*Application of the principle of respect for persons, who will provide consent, and how and when it will be secured**Who will provide consent in the case of special populations (e.g. minors) and those who are not legally competent to consent, or indigenous people which require additional clearances* |  |  |  |  |
| * 1. **Recruitment Process**

*Detailed manner of recruitment process including the appropriateness of identified recruiting parties* |  |  |  |  |
| * 1. **Vulnerability**

*Involvement of vulnerable populations and impact on informed consent. Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group.* |  |  |  |  |
| * 1. **Assent**

*Feasibility of obtaining assent vis à vis incompetence to consent. Applicability of the assent age brackets in children:*

|  |  |  |
| --- | --- | --- |
| *Under 7 y/o* | : | *No assent but with**parental consent* |
| *7 – 12 y/o* | : | *Verbal Assent (provide script) & parental consent* |
| *12 – under 15y/o* | : | *Simplified Assent with parental consent* |
| *12 – under 15y/o* | : | *Co-signed informed consent with parents* |

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| * 1. **Risks**

*Level of risk (including physical, psychological, social, and economic) and measures to mitigate these risks, including plans for adverse event management**Justification for allowable use of placebo as per the Declaration of Helsinki (as applicable)* |  |  |  |  |
| * 1. **Benefits**

*Potential direct benefit to participants; the potential to yield generalizable knowledge about the participants’ condition or problem**Non-material compensation to participant (health education or other creative benefits) where no clear, direct benefit will be received by the participant* |  |  |  |  |
| * 1. **Incentives or Compensation**

*Amount and method of compensations (for travel expenses, loss of income, etc.), financial incentives, or reimbursement of study-related expenses* |  |  |  |  |
| * 1. **Community Considerations**

*Impact of the research on the community where the research occurs and/or to whom findings can be linked including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community and its leaders in decisions about the study* |  |  |  |  |
| * 1. **Collaborative Study Terms of Reference**

*Memorandum of Agreement or Terms of Reference for collaborative studies, especially for multi-country or multi-institutional studies**Include statements of authorship, intellectual property rights, publication rights, information and responsibility sharing, transparency, site-specific rules and regulations, and capacity building* |  |  |  |  |
| * 1. **Other Ethics-Related Issues**

*Other ethical issues not subsumed in from item 3.1 to 3.11* |  |  |  |  |
| **ASSESSMENT PARAMATERS** | **TO BE FILLED OUT BY THE INVESTIGATOR** | **TO BE FILLED OUTBY THE REVIEWER** |
| **PART IIINFORMED CONSENT FORM(S)** | *Indicate if protocol addressed the specified parameters* | *Indicate page & paragraph number* | **REVIEWER’S COMMENTS** |
| YES | N/A |
| 1. Statement that the study involves research
 |  |  |  |  |
| 1. Statement describing the purpose of the study
 |  |  |  |  |
| 1. Study-related treatments and probability for random assignment, as applicable
 |  |  |  |  |
| 1. Study procedures including all invasive procedures, as applicable
 |  |  |  |  |
| 1. Responsibilities of the participant
 |  |  |  |  |
| 1. Expected duration of participation in the study
 |  |  |  |  |
| 1. Approximate number of participants in the study
 |  |  |  |  |
| 1. Study aspects that are experimental
 |  |  |  |  |
| 1. Foreseeable risks to participant, embryo, fetus, or nursing infant including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks
 |  |  |  |  |
| 1. Risks from allowable use of placebo, as applicable
 |  |  |  |  |
| 1. Reasonably expected benefits or absence of direct benefit to participants, as applicable
 |  |  |  |  |
| 1. Expected benefits to the community or to society or contributions to scientific knowledge
 |  |  |  |  |
| 1. Description of post-study access to the study product or intervention that have been proven safe and effective
 |  |  |  |  |
| 1. Alternative procedures or treatment available to participant
 |  |  |  |  |
| 1. Compensation or insurance or treatment entitlements of the participant in case of study-related injury
 |  |  |  |  |
| 1. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount
 |  |  |  |  |
| 1. Compensation (or no plans of compensation) for the participant or the participant’s family or dependents in case of disability or death resulting from study-related injuries
 |  |  |  |  |
| 1. Anticipated expenses, if any, to the participant in the course of the study
 |  |  |  |  |
| 1. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled
 |  |  |  |  |
| 1. Statement that the study monitor(s), auditor(s), the USTCON ERC, and regulatory authorities will be granted direct access to participant’s records for purposes ONLY of verification of clinical trial procedures and data
 |  |  |  |  |
| 1. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity will remain confidential in the event the results are published; including limitations to the investigator’s ability to guarantee confidentiality
 |  |  |  |  |
| 1. Description of policy on the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without participant consent
 |  |  |  |  |
| 1. Possible direct or secondary use medical records and biological specimens of the participant taken during the course of clinical care or in the course of this study
 |  |  |  |  |
| 1. Plans to destroy collected biological specimen at the end of the study; if not, details on the storage (*duration, type of storage facility, location, access information*) and possible future utilization; affirming the participant’s right to refuse future use, refuse storage, or to have the materials destroyed
 |  |  |  |  |
| 1. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development
 |  |  |  |  |
| 1. Statement that the participant or the participant’s legally acceptable representative will be informed in a timely manner if the information becomes available that may be relevant to willingness of the participant to continue his or her participation
 |  |  |  |  |
| 1. Statement describing access of participant to the result of the study
 |  |  |  |  |
| 1. Statement describing the extent of participant’s right to access his or her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure)
 |  |  |  |  |
| 1. Foreseeable circumstances and reasons under which participation in the study may be terminated
 |  |  |  |  |
| 1. Sponsor, institutional affiliation of the investigators, and nature and sources of funds
 |  |  |  |  |
| 1. Statement whether the investigator is serving only as an investigator or as both investigator and the participant’s healthcare provider
 |  |  |  |  |
| 1. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury
 |  |  |  |  |
| 1. Statement that the USTCON Ethics Review Committee has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:

**Prof. Lily F. Famadico, Ph.D., R.N., *USTCON Ethics Review Committee Chair*****Address**: 1st Floor, Room 108, St. Martin de Porres Building, University of Santo Tomas, España Boulevard, Sampaloc, Manila 1015**Email:** erc-nursing@ust.edu.ph**Tel**: +63 2 406 – 1611 local 8362**Mobile**: \_\_\_\_\_\_ |  |  |  |  |
| 1. Informed consent form version number and date
 |  |  |  |  |
| 1. Comprehensibility of language used (understandable to a layman)
 |  |  |  |  |
| 1. Consent form must include the name, date, and signature of the following:
2. Participant
3. Person administering the informed consent
4. Impartial witness
5. Parents or legal guardians for participants who are minors
6. Legally acceptable representative of participants who are incapacitated
 |  |  |  |  |
| 1. Other comments or issues not addressed in items 1-36
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| **OVERALL EVALUATION*(To be filled out by the Reviewer)*** |
| **CRITERIA FOR APPROVAL** | **REVIEWER COMMENTS** |
| 1. **Scientific Soundness of Research Protocol**

*The research and its objectives are scientifically-sound and can contribute to the solution of the problems.* |  |
| 1. **Technical Soundness of Research Protocol**

*The research methodology is technically-sound and applies the scientific principles of research methods, sample size and sampling technique, statistical and/or data analytic techniques, data collection, data collection forms, etc.*  |  |
| 1. **Ethical Soundness of Research Protocol**
 |  |
| * 1. **Justifiable Risk-Benefit Ratio**

*There is an acceptable balance of the study risks and benefits. All risks (physical, psychological, emotional, economical, etc.) are minimized with technically-appropriate research methods which limits exposure to study-related risks. Standard of care or procedures are employed to the participants, as applicable. Likewise, there are appropriate direct and/or indirect benefits to the participants.*  |  |
| * 1. **Equitable Selection of Participants**

*Participants are selected by virtue of the principle of justice and were fairly selected and recruited.*  |  |
| * 1. **Acceptable Safeguards for Privacy, Confidentiality and Monitoring of Participant Safety**

*Research safeguards to ensure privacy, confidentiality, and anonymity of research participants during and after data collection were clearly delineated and acceptable.* |  |
| * 1. **Appropriate Protection of Vulnerable Populations**

*Appropriate measures to protect the rights and welfare of vulnerable populations have been imposed in the study, including no undue influence, coercion, or manipulation of participant.*  |  |
| * 1. **Declaration of Conflict of Interests**

*Conflict of interests arising from financial, familial, and/or proprietary considerations, signed by the Principal Investigator, and may compete with the obligation to protect the rights and welfare of human participants have been adequately reported.*  |  |
| * 1. **Acceptable Qualification of Research Team**

*The Principal Investigator and his or her research team have met the necessary qualification to conduct the study and to protect the rights of human participants. These individuals are qualified by education, training, and experience, and all have updated and valid Good Clinical Practice certifications.*  |  |
| 1. **Suitable Quality of Informed Consent and/or Assent Forms**

*Informed consent forms are age-appropriate and appropriately stated in the both English and vernacular (as applicable) languages. The informed consent forms have all the necessary elements; conform with regulations and ethical standards; are complete, accurate, consistent, and comprehensible; and, give participants a clear description of the risks and discomfort and anticipated benefits of the study.*  |  |
| **ADDITIONAL COMMENTS, SUGGESTIONS, AND/OR RECOMMENDATIONS:** |
|  |
| **RECOMMENDED ACTION:** | * APPROVE
* MINOR MODIFICATIONS
* MAJOR MODIFICATIONS
* DISAPPROVE
* PENDING UPON CLARIFICATORY INTERVIEW
 |
| **PRIMARY REVIEWER:** | **Signature over Printed Name:** | **Date (DD | MM | YYYY)** |