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| |  |  | | --- | --- | | logo copy*p* **UNIVERSITY OF SANTO TOMAS HOSPITAL** RESEARCH ETHICS COMMITTEE 6th Floor St. John Macias O.P. Building  A.H. Lacson St., Sampaloc, Manila 1015 Philippines  Telephone: +63 2 8731-3001 local 2610  Email: [*usth\_irb@yahoo.com.ph*](mailto:usth_irb@yahoo.com.ph)Website*: usthrec.online*  **UNIVERSITY OF SANTO TOMAS HOSPITAL** España Blvd., Manila | *1* **UNIVERSITY OF SANTO TOMAS HOSPITAL** RESEARCH ETHICS COMMITTEE 6th Floor St. John Macias O.P. Building  A.H. Lacson St., Sampaloc, Manila 1015 Philippines  Telephone: +63 2 8731-3001 local 2610  Email: *usth\_irb@yahoo.com.ph*  **UNIVERSITY OF SANTO TOMAS HOSPITAL** España Blvd., Manila logo copy |   **RESEARCH PROTOCOL & INFORMED CONSENT ASSESSMENT FORM** | | | | | | | | | |
|  | | | | | | | | | |
| **Instructions:**  **To the Principal Investigator:** Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.  **To the REC Primary Reviewer:** Kindly evaluate how the assessment points outlined below have been addressed by the clinical trial/research protocol & Informed Consent Form (ICF). Confirm the submitted information by putting your comments in the space provided under “Reviewers Comments”. Summarize your comments in the space provided and finalize your review by indicating your conclusions under “Recommendation”. Sign and date the space provided for the reviewers. | | | | | | **Receiving Stamp/**  **Date of Submission:** | | | |
| **3** | | | | | | | | | |
| **REC Protocol Reference. No.**  *\*to be assigned by USTH-REC* | **CLICK TO ENTER TEXT.** | | | | | | | | |
| **Protocol No./Title:** | Click to enter text. | | | | | | | | |
| **Principal Investigator:** | Click to enter text. | | | | | | | | |
| **Sponsor / CRO:** | Click to enter text. | | | | | | | | |
| **PART I: RESEARCH PROTOCOL CHECKLIST**  **Guide questions for reviewing the proposal/ protocol** | | **TO BE FILLED-UP BY THE**  **PRINCIPAL INVESTIGATOR/ PROPONENT** | | | | **TO BE FILLED-UP BY THE**  **REC REVIEWER** | | | |
| **Indicate If the protocol contains the specified point** | | | Page & paragraph where it is found | **Type of Review:** | | | |
| Expedited  Review |  | Full Review |  |
| **Yes** | **No** | **Unable to assess** | **Reviewer’s Comments & Recommendations** | | | |
| 1. Does the study have social value? | |  |  |  |  |  | | | |
| 1. Are the research questions supported by the Review of Literature? | |  |  |  |  |  | | | |
| 1. Are the study objectives Specific, Measurable, Attainable, Realistic, Time-bound? | |  |  |  |  |  | | | |
| 1. Is the research design appropriate? | |  |  |  |  |  | | | |
| * Is the population identified and defined? | |  |  |  |  |  | | | |
| * Is the selection of study participants described? | |  |  |  |  |  | | | |
| * Is the sample size justified? | |  |  |  |  |  | | | |
| * Is the plan for data analysis described? Are there dummy tables? | |  |  |  |  |  | | | |
| * Does the protocol include Ethical Considerations section? | |  |  |  |  |  | | | |
| * Does the research need to be carried out with human participants? | |  |  |  |  |  | | | |
| * Does the study have a vulnerability issue? | |  |  |  |  |  | | | |
| * Are appropriate mechanisms/ interventions in place to address the vulnerability issue/s? | |  |  |  |  |  | | | |
| * Are there risks/ probable harms to the human participants in the study? | |  |  |  |  |  | | | |
| * Are there measures to mitigate the risks? | |  |  |  |  |  | | | |
| * Is the informed consent procedure / form adequate and culturally appropriate? | |  |  |  |  |  | | | |
| * Is/are the investigator/s adequately trained and do they have sufficient experience to undertake the study? | |  |  |  |  |  | | | |
| * Is there a disclosure of conflict of interest? | |  |  |  |  |  | | | |
| * Are the research facilities adequate? | |  |  |  |  |  | | | |
| * Are there any other concerns in the study? | |  |  |  |  |  | | | |
| **PART II: INFORMED CONSENT CHECKLIST**  **Guide questions for reviewing the informed consent process and form** | | **TO BE FILLED-UP BY THE**  **PRINCIPAL INVESTIGATOR/ PROPONENT** | | | | **TO BE FILLED-UP BY THE**  **REC REVIEWER** | | | |
| **Indicate If the protocol contains the specified point** | | | Page & paragraph where it is found |
| **Yes** | **No** | **Unable to assess** | **Reviewer’s Comments & Recommendations** | | | |
| Is it necessary to seek the informed consent of the participants? | |  |  |  |  |  | | | |
| **If NO, please explain.** | | | | | | | | | |
| **If YES, are the participants provided with sufficient information regarding:** | | | | | | | | | |
| * Purpose of the study? | |  |  |  |  |  | | | |
| * Expected duration of participation? | |  |  |  |  |  | | | |
| * Procedures to be carried out? | |  |  |  |  |  | | | |
| * Discomforts and inconveniences? | |  |  |  |  |  | | | |
| * Risks (physical, emotional, financial, legal, including possible discrimination)? | |  |  |  |  |  | | | |
| * Random assignment to the trial treatments? | |  |  |  |  |  | | | |
| * Benefits to the participants? Direct and indirect benefits? | |  |  |  |  |  | | | |
| * Alternative treatments/ procedures? | |  |  |  |  |  | | | |
| * Compensation and/or medical treatments in case of injury? | |  |  |  |  |  | | | |
| * Who to contact for pertinent questions and / or for assistance in a research- related injury? | |  |  |  |  |  | | | |
| * Refusal to participate or discontinuance at any time will involve penalty or loss of benefits to which the subject is entitled? | |  |  |  |  |  | | | |
| * Extent of confidentiality? | |  |  |  |  |  | | | |
| * Is the informed consent written or presented in simple language that participants can understand? | |  |  |  |  |  | | | |
| * Does the protocol include an adequate process for ensuring that consent is voluntary? | |  |  |  |  |  | | | |
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| **TO BE FILLED-UP BY THE USTH- REC REVIEWER:** | | | | |
| *Summarize your assessment review comments in this space provided:* | | | | |
| **RECOMMENDATION:** | |  | FOR CLARIFICATORY INTERVIEW | |
|  | APPROVED | |
|  | MINOR REVISIONS | |
|  | MAJOR MODIFICATIONS | |
|  | DISAPPROVED  State Reasons for Disapproval: | |
| **REC REVIEWER:** | Name & Signature: | | | Review Date: |