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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | | *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*](mailto:usth_irb@yahoo.com.ph) *Website: usthrec.online*  **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. Submit this F08 firm in Word file format.  **To the 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:**  **CLICK TO ENTER TEXT.** | | | | | |
| **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. | | | | | | | | | | | | | | | | | | |
| **Type of Review** | Full Review | | | |  | | Expedited Review | | | | | |  | | | Exempt from Review | |  | |
| **Total number of participants** | **In USTH** | | | Click to enter text. | | | | | | | **Global** | | | | | | Click to enter text. | | |
| **Duration of the study** | Click to enter text. | | | | | | | | | | | | | | | | | | |
| **Type of study** | Intervention | | | | | | |  | Epidemiology | | | | | | |  | Observational |  | |
| Document review | | | | | | |  | Case report | | | | | | |  | Genetic |  | |
| Social survey | | | | | | |  | Others: | | | | | | | | | | |
| **Description of the study in brief** (mark whatever applies to the study) | Randomized | | | |  | | Drug | | | | |  | | | Global protocol | | | |  |
| Double-blind | | | |  | | Diagnostics | | | | |  | | | Multicenter | | | |  |
| Single-blind | | | |  | | Medical Device | | | | |  | | | Use of genetic materials | | | |  |
| Open -label | | | |  | | Vaccine | | | | |  | | | Sponsor-initiated | | | |  |
| Observational | | | |  | | Questionnaire | | | | |  | | | Investigator-initiated | | | |  |
| **PART I: RESEARCH PROTOCOL CHECKLIST**  **Guide questions for reviewing the proposal/ protocol** | | **TO BE FILLED-OUT BY THE**  **PRINCIPAL INVESTIGATOR/ PROPONENT** | | | | | | | | | | | | **TO BE FILLED-OUT BY THE**  **REC PRIMARY REVIEWER** | | | | | |
| **Yes** | **No** | | | **Unable to assess** | | | | **Put page & paragraph where it is found** | | | | **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 clear? | |  |  | | |  | | | |  | | | |  | | | | | |
| 1. Is there a clear need for human   participants? | |  |  | | |  | | | |  | | | |  | | | | | |
| 1. Is the research design appropriate? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is the methodology clear? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is the population identified and defined? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is the selection of study participants described? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Are the inclusion criteria appropriate? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Are the exclusion criteria   appropriate? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is the sample size justified? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is the plan for statistical data analysis described? Are there dummy tables? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Does the protocol include Ethical Considerations section? | |  |  | | |  | | | |  | | | |  | | | | | |
| * 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? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Are there potential benefits for participants & expected societal benefits or contributions to knowledge? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is there a disclosure of conflict of interest? | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is there a dissemination of how study results will be communicated to participants & society? (publication plans) | |  |  | | |  | | | |  | | | |  | | | | | |
| * Is/are the investigator/s adequately trained and do they have sufficient experience to undertake the study? | |  |  | | |  | | | |  | | | |  | | | | | |
| * 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-OUT BY THE**  **PRINCIPAL INVESTIGATOR/ PROPONENT** | | | | | | | | | | | | **TO BE FILLED-OUT BY THE**  **REC PRIMARY REVIEWER** | | | | | |
| **Indicate If the protocol contains the specified point** | | | | | | | | Put 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-out by the REC Primary 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:  **CLICK TO ENTER TEXT.** | | | Date: |