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| logo copy*p***UNIVERSITY OF SANTO TOMAS HOSPITAL**RESEARCH ETHICS COMMITTEE6th Floor St. John Macias O.P. BuildingA.H. Lacson St., Sampaloc, Manila 1015 PhilippinesTelephone: +63 2 8731-3001 local 2610Email: *usth\_irb@yahoo.com.ph*Website: *usthrec.online***UNIVERSITY OF SANTO TOMAS HOSPITAL**España Blvd., Manila |

**PROTOCOL AMENDMENT FORM** |
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| **Instructions to the Researcher:** Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Attach the amended Protocol, ICFs, and any other relevant documents requiring amendment. Submit this **F14 Form** as a Word document and other documents as PDF files via **usthrec.online** | **Receiving Stamp/****Date of Submission:****CLICK TO ENTER TEXT.** |
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| **REC Protocol Reference No.:** | **CLICK TO ENTER TEXT.** |
| **Protocol No./Title:** | Click to enter text. |
| **Name of Investigator:** | Click to enter text. |
| **Contact No.:** | Click to enter text. | **Email** **address:** | Click to enter text. |
| **Department:** | Click to enter text. | **Section:** | Click to enter text. |
| **Sponsor/CRO:** | Click to enter text. |
| **Current REC Approved Protocol/ICF:** (ProtocolVersion No. & Date)**Click to enter text.** | **Proposed Amendments:**(Protocol/ICF Amendment Version No. & Date)**Click to enter text.** |
| **To be filled-out by the Principal Investigator** |
| **Current REC Approved Protocol/ICF/Others** *List the document(s) and specific portions that are approved by the REC* | **Proposed Amendments:***Explain & specify the exact document and section/portion that needs to be amended. Include page number/s.* | **Reason/Justification** **for the Amendments:***Provide a clear and detailed explanation for why these amendments are necessary* |
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| **Type of Amendments** (check all that apply):[ ]  Revision to currently approved *Protocol* [ ]  Revision to currently approved *Consent Forms* change[ ]  Other (e.g., advertisement)  | [ ]  Minor[ ]  Major |
| **Effect on Risks** (check one):[ ]  This amendment ***does not*** increase risks to participants enrolled in the study[ ]  This amendment ***does*** increase risks to participants enrolled in the study |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:**CLICK TO ENTER TEXT** | Date:   |
|  |
| **To be filled-out by the REC Primary Reviewer** |
| Does the amendment increase the risks to participants? | [ ]  Yes [ ]  No |
| Does the amendment increase the benefits to participants? | [ ]  Yes [ ]  No |
| Is there favorable benefit/risk ratio? | [ ]  Yes [ ]  No |
| **Additional comments:** |
| **RECOMMENDATION:** |[ ]  **APPROVAL** |
|  |[ ]  **REQUEST FOR FURTHER INFORMATION/MODIFICATION** |
|  |[ ]  **RECONSENT REQUIRED** |
|  |[ ]  **DISAPPROVAL** |
| **REC REVIEWER:** | Name & Signature:**CLICK TO ENTER TEXT**  | Review Date:   |