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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 |   **PROTOCOL AMENDMENT FORM** | |
|  | |
| **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: |