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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 |   **APPLICATION FOR CONTINUING REVIEW & PROGRESS REPORT FORM** | |
|  | |
| **Instructions to the Researcher:**  This form must be submitted four weeks before the expiration date.  Please complete this form accurately and add additional rows if necessary. Submit it along with a cover letter addressed to the REC Head. Submit this F19 Form as a Word document and the cover letter as PDF file 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:** | Click to enter text. | | | | | | | | | **CRO:** | | | | Click to enter text. | | | |
| **Duration of study: (months)** | | | | | | | | | | **Study Site:** | | | | | | | |
| Tick the appropriate box | | **Application for Continuing Review** | | | | | | | |  | | **Progress Report Submission** | | | | |  |
| 1. Date of Initial REC Approval: | | | | | | | | | **Click to enter text.** | | | | | | | | |
| 1. Start of study: | | | | **Click to enter text.** | | | | | | | | | | | | | |
| 1. Expected end of study: | | | | | **Click to enter text.** | | | | | | | | | | | | |
| 1. Number of required participants: | | | | | | | | | **Click to enter text.** | | | | | | | | |
| 1. Number of enrolled participants: | | | | | | | | | **Click to enter text.** | | | | | | | | |
| 1. Number of randomized participants: | | | | | | | | | **Click to enter text.** | | | | | | | | |
| 1. Number of participants who completed the study: | | | | | | | | | | | **Click to enter text.** | | | | | | |
| 1. Number of participants withdrawn from the study: | | | | | | | | | | | **Click to enter text.** | | | | | | |
| 1. Number of participants who are lost to follow-up: | | | | | | | | | | | **Click to enter text.** | | | | | | |
| 1. Number of participants who experienced SAEs/SUSARS | | | | | | | | | | | | | **Click to enter text.** | | | | |
| 1. Amendments to the original protocol including dates of approval: 2. **Click to enter text.** | | | | | | | | | | | | | | | | | |
| 1. Deviations from the approved protocol:   **Click to enter text.** | | | | | | | | | | | | | | | | | |
| 1. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio:   **Click to enter text.** | | | | | | | | | | | | | | | | | |
| 1. Issues/problems encountered:    1. **Click to enter text.** | | | | | | | | | | | | | | | | | |
| 1. Progress Status (Provide a short description and indicate completion status, e.g., 50% complete, 75% complete):   **Click to enter text.** | | | | | | | | | | | | | | | | | |
| 1. Action Requested | | |  | | | | | **Renew** - New participant accrual to continue | | | | | | | | | |
|  | | | | | **Renew** - Enrolled participant follow-up only | | | | | | | | | |
|  | | | | | **Others** - Specify: | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | Name & Signature:  **CLICK TO ENTER TEXT.** | | | | | | | | | | | | Date: | | |
| **To be filled-out by the REC Primary Reviewer** | | | | | | | | | | | | | | | | | |
| Is the risk-benefits ratio still favorable? | | | | | | | | | | **Yes** | | | | | | **No** | |
| **Additional comments:** | | | | | | | | | | | | | | | | | |
| **RECOMMENDATION:** | | |  | | | | **APPROVAL** | | | | | | | | | | |
|  | | | | **ADDITIONAL INFORMATION REQUIRED** | | | | | | | | | | |
|  | | | | **SUBMISSION OF AN EXPLANATION FOR FAILURE TO SUBMIT REQUIRED REPORTS** | | | | | | | | | | |
|  | | | | **DISAPPROVAL** | | | | | | | | | | |
| **REC REVIEWER:** | | | Name & Signature:  **CLICK TO ENTER TEXT.** | | | | | | | | | | | | Review Date: | | |