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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 |   **SITE VISIT REPORT FORM** | |
|  | |
| **Instructions to the Researcher:**  The REC Site Visit Team shall conduct this action for a cause on selected sites of approved protocols that fall within the following established criteria for such: (a) high-risk studies, (b) significant violation reports (c) receipt of complaints from participants and families, (d) nonreceipt of required after-approval reports and (e) multiple studies conducted by a researcher. | **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. | | |
| **Ethical clearance effectivity period:**  Click to enter text. | | | | | | | | | | **Study Site:**  Click to enter text. | | | | |
| 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 Number of participants withdrawn from the study: | | | | | | | | | | | Click to enter text.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 onsite SAEs/SUSARS: | | | | | | | | | | | | | Click to enter text. | |
| 1. Amendments to the original protocol including dates of approval:   Click to enter text. | | | | | | | | | | | | | | |
| 1. Deviations from the approved protocol: | | | | | | | | | | | | | | |
| Click to enter text. | | | | | | | | | | | | | | |
| 1. Onsite SAE reports:   Click to enter text. | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | Name & Signature:  **CLICK TO ENTER TEXT.** | | | | | | | | | | Date: |
| **To be filled-out by the Site Visit Team** | | | | | | | | | | | | | | |
| 1. Reasons for site visit: | | | | | | | | | | | | | | |
| Click to enter text. | | | | | | | | | | | | | | |
| 1. Person/s present during visit:   Click to enter text. | | | | | | | | | | | | | | |
| 1. Findings:   Click to enter text. | | | | | | | | | | | | | | |
| 1. Recommendations:   Click to enter text. | | | | | | | | | | | | | | |
| **Site Visit Team Head** | | | Name & Signature:  **CLICK TO ENTER TEXT.** | | | | | | | | | | | Review Date: |
| **Member 1** | | | Name & Signature:  **CLICK TO ENTER TEXT.** | | | | | | | | | | | Review Date: |
| **Member 2** | | | Name & Signature:  **CLICK TO ENTER TEXT.** | | | | | | | | | | | Review Date: |