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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 DEVIATION & VIOLATION 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 other relevant documents in relation to the deviation/violation. Submit this F16 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. | | | | | | | | | | | | | |
| **Ethical clearance effectivity period:**  Click to enter text. | | | | | | | | | | **Study Site:**  Click to enter text. | | | | | | |
| **Protocol Deviation & Violation:** | | | | | | | | | | | | | | | | |
| 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 participants who withdrew: | | | | | | | | Click to enter text. | | | | | | | | |
| 1. **Description of Reported Deviation/Violation:** *(Describe/explain the reported deviation/ violation. Identify who committed the deviation - i.e. Patient, Investigator, Sponsor, Research Coordinator)*   **Click to enter text.** | | | | | | | | | | | | | | | | |
| 1. Nature of Deviation/Violation: | | | | | | | | | **MAJOR** | |  | | | **MINOR** | |  |
| 1. Investigator’s assessment on Impact of deviation/violation on participants’ risks/harms and integrity of data:   **Click to enter text.** | | | | | | | | | | | | | | | | |
| 1. Investigator’s assessment on impact of deviation on credibility of data:   **Click to enter text.** | | | | | | | | | | | | | | | | |
| 1. Description of Investigator’s corrective action and preventive action (CAPA):   **Click to enter text.** | | | | | | | | | | | | | | | | |
| 1. Sponsor assessment of severity: | | | | | | | | | **MAJOR** | | |  | | **MINOR** | |  |
| 1. Description of Sponsor corrective action:   **Click to enter text.** | | | | | | | | | | | | | | | | |
| 1. Actions taken to prevent future deviation/violation:   **Click to enter text.** | | | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | Name & Signature:  **CLICK TO ENTER TEXT.** | | | | | | | | | | | | Date: | |
| **To be filled-out by the REC Primary Reviewer** | | | | | | | | | | | | | | | | |
| **Reviewer’s comments on the following:** | | | | | | | | | | | | | | | | |
| Impact of Deviation on Participant’s risks or harms: | | | | | Click to enter text. | | | | | | | | | | | |
| Impact of deviation on integrity and credibility of data: | | | | | Click to enter text. | | | | | | | | | | | |
| Corrective actions: | | | | | Click to enter text. | | | | | | | | | | | |
| **RECOMMENDATION:** | | | | | |  |  | | --- | --- | |  | **REQUIRE ADDITIONAL INFORMATION** | |  | **REQUIRE CORRECTIVE & PREVENTIVE ACTION** | |  | **INVITATION TO A CLARIFICATORY INTERVIEW** | |  | **REQUIREMENT FOR AN AMENDMENT** | |  | **SITE VISIT** | |  | **SUSPENSION OF RECRUITMENT** | |  | **WITHDRAWAL OF ETHICAL CLEARANCE** | | | | | | | | | | | | |
| **REC REVIEWER:** | | | Name & Signature:  **CLICK TO ENTER TEXT** | | | | | | | | | | | | Review Date: | |