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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 DEVIATION & VIOLATION 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 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:** |

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|[ ]  **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** |

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| **REC REVIEWER:** | Name & Signature:**CLICK TO ENTER TEXT**  | Review Date:   |