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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 |

**REPORTABLE NEGATIVE EVENT (RNE) FORM** |
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| **Instructions to the Researcher:** RNEs are occurrences during the implementation of a research that impact safety, dignity and well-being of participants and /or the study team and the integrity of data. These events need to be reported to the REC as essential to the continuing concern for a favorable balance of risks and benefits from the study. Submit at the latest 5 days after the event has come to the attention of the researcher along with a cover letter addressed to the REC Head. Submit this F23 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. |
| **RNE Report:** |
| 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. Description of Negative (harm, risks) Events:
 |
| * 1. Involving participants

**Click to enter text.** |
| * 1. Involving members of the Study Team

**Click to enter text.** |
| * 1. Involving Data safety & integrity

**Click to enter text.** |
| 1. Actions taken to prevent future RNEs, interventions and outcomes:

**Click to enter text.** |
| 1. Recommendations of PI:

**Click to enter text.** |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:**CLICK TO ENTER TEXT.** | Date:   |
| **To be filled-out by the REC Primary Reviewer** |
| **Comments of REC Reviewer:** |
| **REC REVIEWER:** | Name & Signature:**CLICK TO ENTER TEXT.** | Review Date:   |