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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 |   **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: |