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| logo copy  **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  |

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| **SERIOUS ADVERSE EVENT SAE & SUSARS 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 SAE/SUSARS. Submit the F15 Form as a Word document and other documents as PDF files via **usthrec.online** | **Receiving Stamp/****Date of Submission:****CLICK TO ENTER TEXT.** |
| **REC Protocol Reference No.:** | **CLICK TO ENTER TEXT.** |
| **Protocol No./Title:** | Click to enter text. |
| **Name of Investigator:** | Click to enter text. |
| **Sponsor:** | Click to enter text. | **CRO:** | Click to enter text. |
| **Study Site:** | Click to enter text. | **On-site** |[ ]  **Off-site** |[ ]
|  |
| Name of the study drug/device:  | Date of first use: |
| Onset Date:  |[ ]  Initial Report |[ ]  Follow-up Report | Report Date:  |
| Patient’s Code:Click to enter text. | Age: Click to enter text. |[ ]  Male |[ ]  Female |
| Patient’s Date of Birth:Click to enter text. | Weight:  kg | Height:  cm |
| Relevant medical history and concurrent conditions: Click to enter text. |
| 1. **REACTION INFORMATION:**
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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (use CIOMS definition)List all relevant tests/ lab data: | **Check all appropriate:** |
|  |[ ]  Resulting in death |
|  |[ ]  Required in-patient hospitalization/prolonged hospitalization |
|  |[ ]  Persistent or significant disability or incapacity |
|  |[ ]  Life threatening |
|  |[ ]  Pregnancy |
| 1. **SUSPECT DRUG/S INFORMATION:**
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| Suspect drug/s (include generic name):Click to enter text. | **Did reaction abate after stopping drug?** |
|  |[ ]  Yes |[ ]  No |[ ]  NA |
| Daily dose/s:Click to enter text. | Route of administration:Click to enter text. | **Did reaction appear after reintroduction?** |
|  |  |[ ]  Yes |[ ]  No |[ ]  NA |
| Indication/s for use:Click to enter text. |
| Therapy date/s: (from/to) | Therapy duration: |
| Is this reaction  |[ ]  **Expected** |[ ]  **Unexpected** |[ ]  **Related** |[ ]  **Not related** |
| Treatment Given for Adverse Event:Click to enter text. |
| Causality Assessment by Investigator: |[ ]  Certain  |[x]  Probable |[ ]  Possible |[ ]  Unlikely |[ ]  Unclassifiable |
| Outcome of reaction/event at the time of last observation: |[ ]  Recovered |[ ]  Recovering  |[ ]  Recovering with sequelae  |
|  |[ ]  Not recovering |[ ]  Death |[ ]  Unknown |
| 1. **NARRATIVE DESCRIPTION OF THE EVENT:**

Click to enter text. |
| 1. **CONCOMITANT DRUG/S AND HISTORY:**
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| Concomitant drug/s and dates of administration (exclude drug used to treat reaction)Click to enter text. |
| Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)Click to enter text. |
| 1. **MANUFACTURER’S INFORMATION**:
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| Name and address of manufacturer: | Click to enter text. |
| Manufacturer control no.: | Click to enter text. |
| Date received by manufacturer:Click to enter text. | Report source: |[ ]   Study  |[ ]  Literature  |[ ]  Health professional |
| Date of this report:Click to enter text. | Report type:  |[ ]  Initial  |[ ]   Follow-Up  |  |
| **PRINCIPAL INVESTIGATOR:** | Name & Signature:**CLICK TO ENTER TEXT.** | Date:   |
| 1. **CURRENT STATUS OF PARTICIPANT**:
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| **TO BE FILLED-UP BY THE BY THE USTH-REC SAE SUBCOMMITTEE TEAM:** |
| **TYPE OF REVIEW** | **FULL REVIEW** |[ ]  **EXPEDITED REVIEW**  |[ ]
| Causality Assessment by SAE Subcommittee Team: |[ ]  Certain  |[ ]  Probable |[ ]  Possible |[ ]  Unlikely |[ ]  Unclassifiable |
| **REVIEWER’S COMMENTS:** *(Must determine causality of SAE independent of the PI’s judgement)* |
| **RECOMMENDED****ACTION:** |[ ]  **NOTATION WITH NO FURTHER ACTION REQUIRED** |
|  |[ ]  **REQUIRE FURTHER INFORMATION: (indicate information)** |
|  |[ ]  **REQUIRE FURTHER ACTION: (indicate action)** |
|  |[ ]  **SITE VISIT** |
|  |[ ]  **SUSPENSION OF RECRUITMENT** |
|  |
| **SAE SUB COMMITTEE HEAD:** | Name & Signature:**CLICK TO ENTER TEXT.** | Review Date:   |
| **PRIMARY REVIEWER:** | Name & Signature:**CLICK TO ENTER TEXT.** | Review Date:   |
| **PHARMACIST:** | Name & Signature:**CLICK TO ENTER TEXT.** | Review Date:   |