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| logo copy **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 |

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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:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (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:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | |  | | 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:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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**: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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**: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **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: | | | | | | | | | | | | |