**Serious Adverse Event/s Report**

*Instructions: Please fill out this form COMPLETELY and attach all related forms and documents from the Sponsor.*

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator: | FEU-NRMF IERC Code: | | |
| Study Protocol Title: | | | |
| Name of the study medicine/device | | Report Date: dd/mm/yyyy   * Initial * Follow-up # \_\_\_   Onset date: dd/mm/yyyy | |
| Sponsor: | | Date of first use: | |
| Patient’s Initial/Number: | | Age: | * Male * Female |
| Patient’s Date of Birth: mm/dd/yyyy | | Weight: kg | Height: cm |
| Relevant medical history and concurrent conditions: | | | |

1. **REACTION INFORMATION:**

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (use CIOMS definition)  List all relevant tests/ lab data: | Check all appropriate to adverse reaction:   * Patient died * Involved or prolonged inpatient hospitalization * Involved persistence or significant disability or incapacity * Life threatening |
| Narrative of SAE (Describe the events, including dates, leading up to the reporting of the SAE, as well as the actions of the investigators to ensure the safety of the participant): | |

1. **SUSPECT DRUG/S INFORMATION:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Suspect drug/s (include generic name) | | | Did reaction abate after stopping drug?   * Yes * No * NA | |
| Daily dose/s: | | Route/s of administration: | Did reaction appear after reintroduction?   * Yes * No * NA | |
| Indication/s for use: | | |
| Therapy date/s: (from/to) | | Therapy duration: | | |
| Is this reaction 🞏Unexpected 🞏 Expected | | | | |
| Treatment given for Adverse Event: | | | | |
| Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System)   * Certain * Probable * Possible * Unlikely * Unclassifiable | | | | |
| Basis of Causality Assessment: | | | | |
| Outcome of reaction/event at the time of last observation: | | | | |
| * Recovered * Recovering | * Recovering with sequelae * Not recovering | | | * Death * Unknown |

1. **CONCOMITANT DRUG/S AND HISTORY:**

|  |
| --- |
| Concomitant drug/s and dates of administration (exclude drug used to treat reaction) |
| Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) |

1. **MANUFACTURER’S INFORMATION**:

|  |  |  |
| --- | --- | --- |
| Name and address of manufacturer | |  |
| Manufacturer control no. |  |  |
| Date received by manufacturer: mm/dd/yyyy | Report source   * Study * Literature * Health professional |  |
| Date of this report: mm/dd/yyyy | Report type   * Initial * Follow-up # \_\_\_ |  |

1. **FUTURE PLANS:**

|  |
| --- |
| Plans for participant (monitoring, withdrawal from study, continued participation, etc.): |

|  |  |  |  |
| --- | --- | --- | --- |
| **RECOMMENDED ACTION: (for FEU-NRMF IERC use only)**   * UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION (*No modifications required, study to continue)* * REQUEST INFORMATION: (indicate information) * RECOMMEND FURTHER ACTION:   + Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks (specify)   + Recommend implementation of additional procedures for protecting/safeguarding participants (specify)   + Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency)   + Request an amendment to the protocol or the consent form (specify)   + Recommend suspension of the entire study   + Others: | | | |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <mm/dd/yyyy> |  | Name | <Title, Name, Surname> |
| **SECRETARY** |  | Signature |  |
| Date: <mm/dd/yyyy> |  | Name | <Title, Name, Surname> |
| **CHAIR** |  | Signature |  |
| Date: <mm/dd/yyyy> |  | Name | <Title, Name, Surname> |