**SERIOUS ADVERSE EVENT REPORT FORM**

All SAE/SUSAR events in any research approved by the MCU-FDTMF Institutional Review Board must be reported by the Principal Investigator (PI) to the MCU-FDTMF IRB.

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| --- | --- | --- |
| **SECTION 1** (*To be filled up by the PI*) | **Date** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **MCU-FDTMF IRB PROTOCOL CODE** |  | **Sponsor****Protocol Number** |  |

|  |  |
| --- | --- |
| **Protocol Title** |  |
| **Principal Investigator** |  |

|  |  |
| --- | --- |
| **Name of the Study Medicine/Device** | **Report Date** |
|  | □ | Initial | □ | Follow –up (No.) |
| Onset Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |

|  |  |
| --- | --- |
| **Sponsor** | **Date of Randomization** |
|  |  |
| **Title of the Report** | **Date of the Report** |
|  |  |

|  |  |  |
| --- | --- | --- |
| **Subjects’ Initial Number** | **Age** | **Gender** |
|  |  | □ | Male | □ | Female |

|  |  |
| --- | --- |
| **Subjects’ History** |  |
| **Laboratory Findings** |  |
| **SAE** |  |
| **Treatment** | Outcome: | □ | Resolved | □ | On-going |

|  |  |
| --- | --- |
| **Seriousness** | **Relation to** |
| □ | Death | □ | Drug | □ | Study |
| □ | Hospitalization | □ | Not related |  |  |  |
|  | □ | Initial | □ | Prolonged | □ | Possibly |  |  |  |
| □ | Disability/Incapacity | □ | Probably  |  |  |  |
| □ | Congenital Anomaly | □ | Definitely related |  |  |  |
| □ | Life Threatening | □ | Unknown |  |  |  |
| □ | Others: (Specify) | □ | Device |  |  |  |
| **NOTE:** *PI should attach standard SAE report form (CIOMS) to this MCU-FDTMF IRB Form* |

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator’s Signature** |  | **Date** |  |

**SECTION 2** *(To be filled up by the MCU-FDTMF IRB)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Received by****(***Signature over Printed Name***)** |  | **Date Received** |  |

|  |
| --- |
| **Assessment by the SAE Subcommittee Primary Reviewer** |
| **Comments** |  |
| **Recommendations** |  |  |  |  |  |  |
|  |  | No further action/report on file |  |  | Amendment to the  |
|  |  |  |  |  | protocol/ICF |
|  |  | Request further information |  |  |  |
|  |  |  |  |  | Suspend enrolment of new  |
|  |  | Take Note and continue  |  |  | Participants until further review |
|  |  | monitoring |  |  |  |
|  |  |  |  |  | Suspend all trial related  |
|  |  | Conduct Site Visit |  |  | procedures |
|  |  |  |  |  |  |
|  |  | Termination of the study |  |  |  |
|  |  |  |  |  |  |

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| --- | --- | --- |
| **Primary Reviewer** | **Signature** | **Date** |
|  |  |  |
| **SAE Subcommittee Chair** | **Signature** | **Date** |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **MCU-FDTMF IRB Final Decision** |  | Type of Review□ Expedited review□ Full board review |
| Date of Meeting |  |

|  |  |  |
| --- | --- | --- |
| **MCU-FDTMF IRB Chair** | **Signature** | **Date** |
|  |  |  |