|  |
| --- |
| Office Use Only Protocol Number: |

**INSTITUTIONAL REVIEW BOARD**

**FORM D – SERIOUS ADVERSE EVENT (SAE) REPORT FORM**

**INSTRUCTIONS:**

1. Please complete all sections and submit 3 hardcopies to the CU-IRB Office
2. Send a soft copy to cuirb@central.edu.gh to facilitate the review process.
3. Use very clear font size such as Times New Roman 12pt, Arial 11 pt, Calibri 12pt.

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION A – BACKGROUND INFORMATION** | |  |  |
| Study title |  |  |  |
|  | |  |  |
| REC/IRB |  | Protocol no. |  |
|  | |  |  |
| Study start date |  | Anticipated end date |  |
|  | |  |  |
| Maximum number of subjects/samples/records planned (local) | |  |  |

|  |  |
| --- | --- |
| **SECTION B – STUDY SITE(S) INVOLVED** | |
|  | Overseas site(s) ( |

Submit report(s) from sponsor and omit section 3-5)

|  |  |  |
| --- | --- | --- |
|  | Local site(s) Name of study site: |  |

# SECTION C – SUBJECT OUTCOME AT TIME OF REPORT

Complete recovery Recovery with sequelae Events not yet resolved

|  |
| --- |
|  |

|  |  |  |
| --- | --- | --- |
|  | Unknown |  |

Death; cause:

|  |  |  |
| --- | --- | --- |
| **SECTION D – SERIOUS ADVERSE EVENT** | | |
| Subject reference: Code |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Age |  | Sex |  |

Initials

|  |
| --- |
|  |

1. Relevant medical history & current treatments:

|  |
| --- |
|  |

1. Nature of SAE: (Describe temporal relationship with intervention & other concomitant therapies)

CU-IRB Form D 1

Version Date: August 2023



**INSTITUTIONAL REVIEW BOARD**

|  |  |  |
| --- | --- | --- |
|  | SAE stop date |  |

SAE start date /not resolved\*

|  |  |  |
| --- | --- | --- |
|  | initial |  |

Type of SAE follow up

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | One episode |  | Intermittent |  |
|  |  |  |

Frequency Continuous

|  |
| --- |
|  |

|  |
| --- |
|  |

Seriousness Death Life threatening

|  |
| --- |
|  |
|  |
|  |
|  |
|  |
|  |
|  |

|  |
| --- |
|  |

|  |
| --- |
|  |

|  |
| --- |
|  |

Significant disability/incapacity Required hospitalisation

Persistent disability/incapacity Prolonged hospitalisation

Congenital anomaly/birth None of the above defect

Other medically important condition

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION E – SUSPECTED RELATIONSHIP TO STUDY** | | | | | | | |
|  | Definite |  | Probable |  | Possible |  |  |

|  |
| --- |
|  |

Not related Not assessable

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | **SECTION F – REMEDIAL ACTIONS** | | | | On the affected |  | None | | |  | | --- | |  | |

Adjusted dosage

subject:

|  |  |  |
| --- | --- | --- |
|  | Interrupted temporarily |  |

Discontinued/ terminated study

|  |
| --- |
|  |

For all subjects/ study design:

# SECTION G – SIGNATURE

|  |  |  |
| --- | --- | --- |
| Name | Signature | Date |
|  |  |  |

**Report by**

CU-IRB Form D 2

Version Date: August 2023