|  |
| --- |
| 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

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|  |  |  |
| --- | --- | --- |
|   | 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)

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

 SAE start date /not resolved\*

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

Type of SAE follow up

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

Frequency Continuous

|  |
| --- |
|   |

|  |
| --- |
|   |

Seriousness Death Life threatening

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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

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

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| --- |
| **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**

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