

# INSTITUTIONAL REVIEW BOARD

Office Use Only Protocol Number:

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](mailto:nirb@noguchi.ug.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** | | | | | |  | Events not yet resolved |
|  | Complete recovery |  | Recovery with sequelae | |  | |
|  | | | | | | | |
|  | Unknown |  | Death; cause: |  | | | |
|  | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION D – SERIOUS ADVERSE EVENT** | | | | | | | |
| Subject reference: | Code |  | Initials |  | Age |  | Sex |
|  |  |  |  |  |  |  |  |
| **i.** Relevant medical history & current treatments: |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **ii.** Nature of SAE: *(Describe temporal relationship with intervention & other concomitant therapies)* |  |  |  |  |  |  |  |



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| --- | --- | --- | --- | --- | --- | --- | --- |
| SAE start date |  |  |  | SA | E stop date |  | /not resolved\* |
|  |  |  |  |  |  |  |  |
| Type of SAE |  | initial |  |  | follow up |  |  |
|  |  |  |  |  |  |  |  |
| Frequency |  | One episode |  |  | Intermittent |  | Continuous |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Seriousness |  | Death |  | Life threatening |
|  |  | Significant disability/incapacity |  | Required hospitalisation |
|  |  |  |  |  |
|  |  | Persistent disability/incapacity |  | Prolonged hospitalisation |
|  |  |  |  |  |
|  |  | Congenital anomaly/birth defect |  | None of the above |
|  |  |  |  |  |
|  |  | Other medically important condition | | |

Not related Not assessable

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SECTION F – REMEDIAL ACTIONS** | | | | |
| On the affected subject: |  | None |  | Adjusted dosage |
|  |  |  |  |
|  | Interrupted temporarily |  | Discontinued/ terminated study |
|  |  |  |  |
| For all subjects/ study design: |  |  |  |  |

**SECTION G – SIGNATURE**

|  |  |  |  |
| --- | --- | --- | --- |
| **Report by** | Name | Signature | Date |
|  |  |  |