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

**For office use only** protocol number

**INSTRUCTIONS:**

1. Please complete all sections and submit 1 hardcopies to the CBAS Ethics Office
2. Send a soft copy to ethicscbas@.ug.edu.gh to facilitate the review process.
3. Use very clear font size such as Times New Roman or Arial

**SECTION A – BACKGROUND INFORMATION**

1. Project Title:
2. Proposed Date of Commencement:
3. Indicate status:

 Undergraduate Master’s Doctorate If other specify

**SECTION B – PROJECT INFORMATION**

1. Proposed Project Duration – From: To:
2. Source of Funding:
3. Research location(s):

 **SECTION C – SUBJECT OUTCOME AT TIME OF REPORT**

**Please tick where appropriate**

|  |  |
| --- | --- |
| 1.Complete recovery |  |
| 2.Recovery with consequence |  |
| 3.Events not yet resolved |  |
| 4.Death |  |
| 5.unknown |  |
| 6.other |  |

**SECTION - D – SERIOUS ADVERSE EVENT**

Subject reference:

1. Name:
2. Initials:
3. Age:
4. Sex:
5. Medical history

|  |
| --- |
|  |

1. Current treatment

|  |
| --- |
|  |

1. Nature of SAE

|  |
| --- |
|  |

1. Type of SAE (e.g. initial, follow up, etc.):
2. Frequency (e.g. one episode, intermittent, continuous etc.):
3. Seriousness:

**Please tick where appropriate**

|  |  |
| --- | --- |
| Death  |  |
| Life threatening |  |
| hospitalization |  |
| Disability  |  |
| Other medical condition  |  |

**SECTION – E – SUSPECTED RELATIONSHIP TO STUDY**

**Please tick where appropriate**

|  |  |
| --- | --- |
| 1.Definite |  |
| 2.Not related |  |
| 3.Probable |  |

**SECTION – F –REMEDIAL ACTION ON AFFECTED SUBJECTS**

**Please tick where appropriate**

|  |  |
| --- | --- |
| 1.None |  |
| 2.Adjusted dosage |  |
| 3.Interrupted temporarily |  |
| 4.Terminated study |  |

5.remedial actions for all subjects:

|  |
| --- |
|  |

**SECTION – G – SIGNATURE PAGE**

|  |
| --- |
| Name of person completing the form:Role on the study:Signature:Date: |