

### SERIOUS ADVERSE EVENT FORM

Participant ID number: **SUBJID**

1 0 2 - 0 -

Age at time of event: **AE\_AGE** Years

1. Adverse Event: **AE\_EVENT**

2. Date of event: **AE\_EVENTDAT**

Day / Month / Year

Time of onset (24h clock): **AE\_TMON**

Hours : Minutes

3. Date of awareness: **AE\_AWAREDAT**

Day / Month / Year

Time of awareness (24h clock): **AE\_TMAWARE**

Hours : Minutes

4. Severity classification: **AE\_SEVERITY**

- ☐ Death
 ☐ Life Threatening
 ☐ Disability
 ☐ Hospitalization
 ☐ Required intervention to prevent permanent impairment/damage
- ☐ Other, specify: **AE\_SEVERITYO**

5. Relationship to study: **AE\_RELATION**

- ☐ Unrelated
 ☐ Probably not
 ☐ Possibly
 ☐ Probably
 ☐ Definitely

6. Event Summary: Describe study procedure performed and cause of death if applicable **AE\_SUMMARY**

**AE\_STATUS**

7. Status of event: ☐ Ongoing ☐ Unknown

☐ Resolved WITHOUT sequelae, date:

Day / Month / Year

☐ Resolved WITH sequelae, date:

Day / Month / Year

☐ Death, date:

Day / Month / Year

**AE\_WOUDAT**

**AE\_WITHDAT**

**AE\_DEATHDAT**

Completed by: **AE\_SIGN**

Date: Day / Month / Year

signature and print

**AE\_COMPDAT**