

**SERIOUS ADVERSE
EVENT REPORT
FORM**

PARTICIPANT STUDY NUMBER
PARTICIPANT INITIALS



Date of onset of SAE / /

Description of event (include reported signs, symptoms and diagnosis where possible)

Adverse Event described as **SERIOUS** because (tick all that apply)

- Resulted in death
- Life threatening event
- Required/prolonged hospitalisation
- Persistent/significant disability/incapacity

Outcome at time of this report (tick one box only)

- Recovered
- Recovered with sequelae
- Died

Date recovered/died / /

OR: Tick if ongoing at the time of report

COMPLETED BY (CAPITALS):

Signature:

Date of report: / /

Please fax this form to PenCTU on XXXXXXXXXX
Once faxed please file the original report with the participant's CRF

PenCTU's summary description of event

For PenCTU use only