



37 MILITRAY HOSPITAL INSTITUTIONAL REVIEW BOARD

Office Use Only
Protocol Number:

FORM D - SERIOUS ADVERSE EVENT (SAE) REPORT FORM

INSTRUCTIONS:

1. Please complete all sections and submit 1 hardcopy to the 37MH-IRB Office (Postgraduate College)
2. Send soft copy to irbmilhosp@gmail.com to facilitate the review process.
3. Use very clear font size such as Times New Roman 12pt, Arial 11pt, Calibri 12pt.

SECTION A- BACKGROUND INFORMATION

Study title:

IRB/ERC

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 THE TIME OF REPORT

☐

Complete recovery

☐

Recovery with sequelae

☐

Events not yet resolved

☐

Unknown

☐

Death: cause:

SECTION D-SERIOUS ADVERSE EVENT

Subject reference: Code Initials Age Sex

- ii. Nature of SAE: (Describe temporal relationship with intervention & other concomitant therapies)

SAE start date SAE stop date /not resolved *

Type of SAE Initial Follow up

Frequency One episode Intermittent Continuous

Seriousness Death
 Significant disability/incapacity Required hospitalization
 Persistent disability/incapacity Prolonged hospitalization
 Congenital anomaly/birth defect None of the above
 Other Medically important condition

SECTION E- SUSPECTED RELATIONSHIP TO STUDY
☐ Definite ☐ Probable ☐ Possible ☐ Not assessable
SECTION F- REMEDIAL ACTIONS
On the affected subject ☐ ☐ Adjusted dosage

☐ Interrupted temporarily ☐ Discontinued/terminated study

For all subjects/ Study design:

SECTION G- SIGNATURE
Report by

Name	Signature	Date