Version no. 7 June 19, 2023 Page 1 of 2	**NATIONAL CENTER FOR MENTAL HEALTH** **RESEARCH ETHICS COMMITTEE**

FORM 3.4
ONSITE SERIOUS ADVERSE EVENT REPORT

Whenever there is any SAE event in any research approved by the National Center for Mental Health – Research Ethics Committee (NCMH-REC), it has to be reported by the Principal Investigator (PI) to the NCMH-REC.

SECTION 1

Principal Investigator:	
Study Title:	Protocol No.:
Name of the study medicine / device:	Report Date: ☐ Initial ☐ Follow-up Onset Date:
Sponsor:	Date of first use:
Title of the Report	Date of the report

Subject's initial / number: _____ Age: _____ ☐ Male ☐ Female

Subject's history:	Laboratory findings:
SAE:	Treatment: Outcome: ☐ Resolved ☐ On-going

Seriousness:

☐ Death ☐ Life Threatening

☐ Hospitalization:

☐ Initial ☐ Prolonged

☐ Disability/Incapacity

☐ Congenital Anomaly

☐ Others

Relation to

☐ Drug ☐ Device ☐ Study

☐ Not related

☐ Possibly

☐ Probably

☐ Definitely related

☐ Unknown

Note: PI should attach standard SAE report form (CIOM) to this NCMH-REC form.

NATIONAL CENTER FOR MENTAL HEALTH
RESEARCH ETHICS COMMITTEE

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ONSITE SERIOUS ADVERSE EVENT REPORT

FOR NCMH-REC USE

Received by:

Name (REC Secretariat)	Signature	Date

Reviewer's Comments/ Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended? ☐ No ☐ Yes
Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

Recommendation

Name of Reviewer	Signature	Date

To be filled up by the Secretariat

REC Final Action:

- ☐ Request an amendment to the protocol or the consent form
- ☐ Request further information
- ☐ Suspend enrolment of new research participants
- ☐ Suspend all trial-related procedures
- ☐ Termination of the Study
- ☐ Take note and continue monitoring
- ☐ Conduct Study Site Visit
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting

_____