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.

FORM 3.4
ONSITE SERIOUS ADVERSE EVENT REPORT

FOR NCMH-REC USE
Received by:

Name (REC Secretariat)	Signature	Date

Reviewer's Comments/ Recommendations

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

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

NCMH-REC Decision:

☐ No further action; documents for filing

☐ Request information

☐ Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks

☐ Recommend implementation of additional procedures for protecting/ safeguarding participants

☐ Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)

☐ Recommend suspension of the entire study

☐ Others:

Signature above printed name of Primary Reviewer	Date
Signature above printed name of NCMH-REC Chairperson	Date