



**NATIONAL CENTER FOR MENTAL HEALTH  
RESEARCH ETHICS COMMITTEE**

**FORM 3.5  
PROTOCOL VIOLATION/DEVIATION  
REPORT**

Version no. 7

June 19, 2023

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REC Protocol No.

Sponsor Protocol No.

Date of Submission

Study Title

Investigator

Contact No.:

Sponsor

Contact No.:

Reported by

Contact No.:

Description:

For NCMH-REC

Primary Reviewer Assessment

PI Deviation from the Protocol

\_\_\_\_\_ Major

\_\_\_\_\_ Minor

Participant Non-Compliance

Study Staff

Recommendation :

Noted (no further action needed)

Corrective action required

Site visit needed

Date of Full Board meeting

REC Decision:

Required corrective  
action

Recorded by REC Secretariat

Name/ Signature

Received by Principal Investigator

Name/ Signature

Date:

Date: