NATIONAL CENTER FOR MENTAL HEALTH
RESEARCH ETHICS COMMITTEE

FORM 2.9
APPLICATION FOR CONTINUING REVIEW

General Information				
Title of Study				
APPROVAL DATE: <dd/mm/yyyy>		EXPIRY OF ETHICAL CLEARANCE: <dd/mm/yyyy>		
NCMH-REC Code (to be provided by REC)		Study Site		
Name of Researcher		Contact Information	Tel. No.: Mobile No.:	
Co-Researcher (if any)			Fax No.: Email:	
Sponsor			Sponsor Contact No.:	
Institution				
Address of Institution				

1. START DATE:
1.1. ☐ Date of research site initialization: <dd/mm/yyyy>
1.2. ☐ Explanation, if not yet initialized as of date of this application: <reason/s>

2. ACTION REQUESTED:
2.1. ☐ Renewal: New participant accrual to continue
2.2. ☐ Renewal: Enrolled participant follow up only
2.3. ☐ Renewal: Data analysis only
2.4. ☐ Other (specify):

3. HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL?
3.1. ☐ No
3.2. ☐ Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s)

4. HAVE THERE BEEN ANY DEVIATION/NONCOMPLIANCE REPORTS SINCE THE LAST REVIEW/APPROVAL?

4.1. ☐ No

4.2. ☐ Yes (Describe briefly and indicate date/s of Study Protocol Deviation Submission/s)

5. SUMMARY OF STUDY PROTOCOL PARTICIPANTS:

<number>	5.1. Accrual ceiling set by the Panel
<number>	5.2. New participants accrued since last review/approval
<number>	5.3. Total participants accrued since study protocol began

6. ACCRUAL EXCLUSIONS

6.1. ☐ None

6.2. ☐ Male

6.3. ☐ Female

6.4. ☐ Other (specify):

7. IMPAIRED PARTICIPANTS

7.1. ☐ None

7.2. ☐ Physically

7.3. ☐ Cognitively

7.4. ☐ Both

8. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTIONCRITERIA SINCE THE LAST REVIEW/APPROVAL?

8.1. ☐ No

8.2. ☐ Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

9. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach latest version of participant information sheet and informed consent form/document

9.1. ☐ No

9.2. ☐ Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

10. HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE PANEL'S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?

10.1. ☐ No

10.2. ☐ Yes (Describe briefly and provide copy of literature cited, including the Investigator's Brochure if applicable)

11. HAVE THERE BEEN ANY UPDATES OR MEASURES IN THE PROTOCOL TO GUARANTEE PROTECTION OF PRIVACY AND CONFIDENTIALITY OF PARTICIPANT INFORMATION IN COMPLIANCE WITH LOCAL REGULATIONS (e.g. DATA PRIVACY ACT OF 2012)?

11.1. ☐ No

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11.2. ☐ Yes (Describe briefly these provisions)

12. IS A BIOBANK BEING MAINTAINED FOR THIS STUDY?

12.1. ☐ No

12.2. ☐ Yes (Describe governance and custodianship, access to data and transfer of materials, and measures protecting privacy and confidentiality)

13. HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?

13.1. ☐ No

13.2. ☐ Yes (Summarize and indicate date/s of SUSAR report submission/s)

14. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW/APPROVAL?

14.1. ☐ No

14.2. ☐ Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)

15. HAVE THERE BEEN NEW/ADDITIONAL INVESTIGATIONAL NEW DRUG/DEVICE REGISTRATIONS ASSOCIATED WITH THIS STUDY SINCE THE LAST REVIEW/APPROVAL? (Indicate registration information)

15.1 ☐ None	FDA Registration No.
15.2 ☐ IND	Product Name:
15.3 ☐ IDE	Sponsor:
	Holder:

16. HAVE THERE BEEN ANY NEW INTERVENTION(S) OR METHODS IN THE CONDUCT OF STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL

16.1. ☐ No

16.2. ☐ Yes (Describe use and indicate date/s of Study Protocol Deviation/Non Compliance/Violation Report Submission/s)

17. HAVE ANY INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW/ APPROVAL?

17.1. ☐ No

17.2. ☐ Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the UPMREB Review Panel)

18. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW/ APPROVAL?

18.1. ☐ No

18.2. ☐ Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)

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19. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL? 19.1. ☐ No 19.2. ☐ Yes (Append a statement of disclosure)
20. HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL? 20.1. ☐ NONE 20.2. ☐ DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s) 20.3. ☐ ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)
21. HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis. 21.1. ☐ No 21.2. ☐ Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
22. HAS THE STUDY SITE BEEN VISITED BY NCMH REC OR ANOTHER ETHICS COMMITTEE, AUDITED BY SPONSOR, OR INSPECTED BY ANY REGULATORY AGENCY? 22.1. ☐ No 22.2. ☐ Yes (Provide details regarding the visit/audit/inspection (when, where, etc), findings and recommendations, and corrective action of the site, if any)
23. PROGRESS STATUS (List the different components or activities in approved study protocol, provide a short description and indicate completion status, e.g., 50% complete, 75% complete) 23.1. ☐ <Component 1> <Provide description as needed> 23.2. ☐ <Add components as necessary>
SIGNATURE OF PRINCIPAL INVESTIGATOR:
DATE SIGNED: <dd/mm/yyyy>
Received by: <REC Staff> Date:

RECOMMENDATIONS (for NCMH-REC use only)

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Comments of Primary Reviewer

RECOMMENDED ACTION:

☐ APPROVE

☐ REQUEST INFORMATION: (INDICATE INFORMATION)

☐ RECOMMEND FURTHER ACTION: (INDICATE ACTION)

☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER	Signature	DATE
NCMH-REC CHAIR		