FORM 3.2
PRGRESS REPORT

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		
Principal Investigator		Contact Information	Tel. No.: Mobile No.:	
Co-PI (if any)			Email:	
Sponsor			Sponsor Contact No.:	
Institution				
Signature of PI				
Date signed	<dd/mm/yyyy>			

Any amendment since the last review? (Describe briefly) ➢	☐ No	☐ Yes
Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes) ➢	☐ No	☐ Yes
Any change in the Informed Consent process or documentation since the last review? (Please explain) ➢	☐ No	☐ Yes
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Summarize) ➢	☐ No	☐ Yes
Any unexpected complication or side effect noted since the last review? (Summarize) ➢	☐ No	☐ Yes

Were there protocol deviation/ violation reports? (Summarize) What corrective actions were taken? ➢	☐ No	☐ Yes

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion. ➢	☐ No	☐ Yes
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.) ➢	☐ No	☐ Yes

Summary of recruitment:

<number>	Accrual ceiling set by REC
<number>	New participants accrued since last review
<number>	Total participants accrued since protocol began
<number>	No. of participants who are lost to follow up
<number>	No. of participants withdrawn from the study
<number>	No. of participants who experienced SAEs/ SUSARs

Received by: <REC Staff>	Date Received:

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ASSESSMENT BY THE PRIMARY REVIEWER	COMMENTS	RECOMMENDATION
Do the risks to the study participants remain reasonable in relation to anticipated benefits? ☐ Yes ☐ No		
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent? ☐ Yes ☐ No		
Is there need to revise the ICF? ☐ Yes ☐ No		
Is there need to reconsent subjects enrolled in the study? ☐ Yes ☐ No		
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety? ☐ Yes ☐ No		
Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation? ☐ Yes ☐ No		

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the Principal Investigator

Recommended Action:

- ☐ Approve
- ☐ Request further information, specify
- ☐ Recommend further action, specify
- ☐ (e.g. Require protocol / ICF amendment, re-consent) to address concerns about patient safety)
- ☐ Others

Primary Reviewer:	Signature:	Date:

NCMH-REC Chair	Signature:	Date: