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| 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> | | | |

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| Any amendment since the last review? (Describe briefly) |  | No |  | Yes |
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| Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes) |  | No |  | Yes |
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| Any change in the Informed Consent process or documentation since the last review? (Please explain) |  | No |  | Yes |
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| 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 |
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| Any unexpected complication or side effect noted since the last review? (Summarize) |  | No |  | Yes |
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| Were there protocol deviation/ violation reports?  (Summarize)  What corrective actions were taken? |  | No |  | Yes |
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| 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 |
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| 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 |
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| 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 | No. of participants withdrawn from the study |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 |
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| 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

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| Primary Reviewer: |  | Signature: |  | Date: |
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|  |  |  |  |  |
| NCMH-REC Chair |  | Signature: |  | Date: |
|  |  |  |  |  |