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| INSTRUCTION:  This form is required for to report the activities done in a previously approved protocol. This form should be submitted together with any Post-Approval Assessment Form and copy of approval letter. ***Incomplete submissions will NOT BE ACCEPTED.*** |

*------------------------------- Section A (for the primary investigator) ------------------------------------*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SPUP REC Code: |  | | | |
| Protocol Title: |  | | | |
| Principal Investigator: |  | Contact Number: | |  |
| Institution: |  | Email Address: | |  |
| Adviser/s: |  | | | |
| Date of Initial Submission: |  |
| Date of Approval: |  | Date of last Submission of Progress Report: | |  |
| Initial Primary Reviewer:  (*for SPUP REC)* |  | Type of Initial Review | | |
|  | Expedited | |
|  | Full Review | |
|

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Any amendments since the last review? |  | Yes |  | No |
| Explain Briefly: | | | | |
| Any change in participant population, recruitment, or selection criteria since the last review? |  | Yes |  | No |
| Explain the Changes: | | | | |
| Any change in the Informed Consent process or documentation since the last review? |  | Yes |  | No |
| Explain Briefly: | | | | |
| Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? |  | Yes |  | No |
| Discuss: | | | | |
| Did any participant withdraw from this study since the last approval? |  | Yes |  | No |
| Reasons for withdrawal | | | | |
| Any new investigator that has been added to or removed from the research team since the last review? |  | Yes |  | No |
| Identify and submit their CV: | | | | |
| Were there protocol deviation/violation reports? |  | Yes |  | No |
| Summarize | | | | |
| Are there any new collaborating sites that have been added or deleted since the last review? |  | Yes |  | No |
| Identify New sites/note addition or deletion: | | | | |

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| --- | --- | --- | --- | --- | --- |
| Summary of protocol participants: (Number) |  | expected number of participants | | | |
|  | new participants since last review | | | |
|  | total participants since protocol began | | | |
|  | Male |  | | Female |
|  | | | | | |
| Excluded Participants (Number) |  | Male |  | | None |
|  | Female | Reason/s for exclusion: | | |
|  | | |
|  | | |  | | |
| Impaired Participants (Number) |  | None | |  | Cognitively |
|  | Physically | |  | Both |
|  |  |  | | | |
| No. of participants who are lost to follow-up |  | No. of participants who experienced RNEs | | |  |
|  |  |

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| Principal Investigator  (Printed Name and Signature) |  | Date Submitted |  |

*------------------------------- Section B (for the primary Reviewer) ------------------------------------*

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| **Assessment by the Primary Reviewer** | **Yes** | **No** | **Comments** |
| Do the risks to the study participants remain reasonable in relation to anticipated benefits? |  |  |  |
| Are there new findings in the literature that need to be included in the informed consent? |  |  |  |
| Is there a need to revise the ICF? |  |  |  |
| Is there a need to re-consent subjects enrolled in the study? |  |  |  |
| Are there concerns about conduct of the research team or institutional commitment that may affect participants safety? |  |  |  |
| Are there concerns about participants safety, inability to comply with the protocol, high dropout participant rate that affect study implementation? |  |  |  |

*Note: Check the protocol file to ensure consistency of the progress report with actual reports (RNEs, protocol violation/deviation, etc.) submitted by the PI.*

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| Recommendations |  | Approve |
|  | Requests an amendment to the protocol or the consent form |
|  | Request additional information |
|  | Suspend or terminate the study |

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| Primary Reviewer  (Printed Name and Signature) |  | Date |  |