**CONTINUING REVIEW APPLICATION/PROGRESS REPORT FORM**

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| **SECTION 1** (*To be filled up by PI*) |

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| **MCU-FDTMF PROTOCOL CODE** |  | **Submission Date** |  |
| **Sponsor Protocol Number** |  | **Approval Date** |  |

|  |  |
| --- | --- |
| **Protocol Title** |  |

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| **NAME** | | **Email** | **Mobile / Phone / Fax Number** |
| **Principal Investigator(s)** |  |  |  |
| **Sponsor** |  |  |  |

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| **ACTION REQUESTED** | □ | Renewal: New participant accrual to continue |
|  | |
| □ | Renewal: Enrolled participant follow-up only |

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| 1. Any amendment since the last review? (Describe brieftly) | □ | Yes | □ | No |
| 1. Any change in participant population, recruitment, or selection criteria since the last review? (Explain the changes) | □ | Yes | □ | No |
| 1. Any change in the Informed Consent process or documentation since the last review? Please explain) | □ | Yes | □ | No |
| 1. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in this study? (Discuss and attach a narrative) | □ | Yes | □ | No |
| 1. Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative) | □ | Yes | □ | No |
| 1. Did any participant withdraw from this study since the last approval? (Reasons for withdrawal) | □ | Yes | □ | No |
| 1. Any new investigator that has been added or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators) | □ | Yes | □ | No |
| 1. Were there protocol deviation/violation reports? (Summarize) | □ | Yes | □ | No |
| 1. 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 | □ | Yes | □ | No |

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| **Summary of protocol participants: (Number)** |  | | | | |
|  |  | New participants accrued since last review | | |
|  |  |  | | |
|  |  | Total participants accrued since protocol began | | |
|  |  | | | |
|  |  | Male |  | Female |
|  |  | | | |
| **Accrual Exclusions (Number)** |  |  |  |  |  |
|  |  | Male |  | None |
|  |  |  |  |  |
|  |  | Female | Reason/s for exclusion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
|  |  |  |  |  |
| **Impaired participants (Number)** |  |  |  |  |  |
|  |  | None |  | Cognitively |
|  |  |  |  |  |
|  |  | Physically |  | Both |
|  |  |  |  |  |

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| **Principal Investigator’s Signature** |  | **Date** |  |

Please take note of the following to be submitted on or before the expiration date of the approval:

* Ten (10) copies of the completed and signed original copy of the Investigator’s Progress Report (Use Form )
* Ten (10) copies of the recently approved consent/assent if applicable, with changes underlined and bold-faced to highlight changes.
* Ten (10) copies of the recently approved amendments/revision since their last renewal and copy of each previously submitted Progress Report

**SECTION 2** *(To be filled up by the MCU-FDTMF IRB)*

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| **Received by**  **(***Signature over Printed Name***)** |  | **Date Received** |  |

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| **Assessment by the Primary Reviewer** | **Yes** | | | **No** | | | **Comments** | |
| 1. Do the risks to the study participants remain reasonable in relation to anticipated benefits? |  |  |  | |  |  |  |  |
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| 1. 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? |  |  |  | |  |  |  |  |
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| 1. Is there a need to revise the ICF? |  |  |  | |  |  |  |  |
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| 1. Is there a need to reconsent subjects enrolled in the study? |  |  |  | |  |  |  |  |
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| 1. 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? |  |  |  | |  |  |  |  |
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| 1. Are there concerns about participants safety inability to comply with the protocol, high dropout rate that affect study implementation? |  |  |  | |  |  |  |  |
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**NOTE: Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/violation) submitted by the PI.**

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| **Recommendations** |  |  |  |  |
|  |  |  | Approve (indicate frequency of Progress Reporting) |
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|  |  |  | Request information |
|  |  |  |  |
|  |  |  | Suspend |
|  |  |  |  |
|  |  |  | Terminate |
|  |  |  |  |

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| **Primary Reviewer/s** | **Signature** | **Date** |
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| **MCU-FDTMF IRB Final Decision** |  | Type of Review  □ Expedited review  □ Full board review | |
| Date of Meeting |  |

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| **MCU-FDTMF IRB Chair** | **Signature** | **Date** |
|  |  |  |