**EARLY STUDY TERMINATION APPLICATION FORM**

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| **Section 1** (To be filled-up by PI) | **Submission Date** |  |

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| **MCU-FDTMF PROTOCOL CODE** |  | **Sponsor Protocol Number** |  |

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **IRB Approval Date** |  | **Date of Last Report** |  |
| **Starting Date** |  | **Termination Date** |  |
| **Number of Participants** |  | **Number of Enrolled Participants** |  |

|  |  |
| --- | --- |
| **Reason for Early Termination** |  |
| **Summary of Results** |  |
| **Data Accrual** | |
| 1. How many completed the study? |  |
| 1. How many are still active? |  |
| 1. What are the plans for follow up of still active participants? |  |

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

**Section 2** (for MCU-FDTMF IRB Use Only)

**Assessment by the Primary Reviewer**

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| --- | --- |
| **Comments on issues related to participants’ safety:** |  |

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| --- | --- | --- | --- | --- |
| **Recommendations** |  |  |  |  |
|  |  |  | Approval / No further action |
|  |  |  |  |
|  |  |  | Further action required, indicate action \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |
|  |  |  | Further information / clarification form PI required, specify \_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |

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| **Primary Reviewer/s** | **Signature** | **Date** |
|  |  |  |

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| **MCU-FDTMF IRB Decision** |  |
| **Full Board Meeting Date** |  |

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