**PROTOCOL AMENDMENT APPLICATION**

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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** |  | **Initial Approval Date**  |  |

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

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

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| **List of Amendments (Include Version and Version Date)** | **Reason/s** |
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| **Principal Investigator’s Signature** |  | **Date** |  |

Please take note of the following:

* Approval should be obtained from MCU-FDTMF IRB prior to implementation of an amendment.
* Amendment should be integrated into a revised RESEARCH PROTOCOL/PACKAGE.
* Submit this form, MCU-FDTMF IRB Form 3.2 – 2020: Protocol Amendment Application Form, and related documents in two (2) printed copies and (1) electronic copy.
* SUMMARIZE the amendment in a cover letter indicating in which page of the revised research protocol the respective revisions may be found, attached to every submission package.
* Modified part should be **underlined and bold-faced**; and
* Include a footer (in all pages) that indicates both the DATE and VERSION NUMBER of the resubmitted research protocol.

**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 Primary Reviewer** | Type of Amendment: | **□** Minor | **□** Major |
| Does the amendment increase the risk to participants? | **□** Yes | **□** No |
| Does the amendment increase the benefits to the participants | **□** Yes | **□** No |
| Is there favorable benefit/risk balance? | **□** Yes | **□** No |
| Comments: |
| **Recommendations** | **□** Approve□ Request further information/Modification□ Disapprove |

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| **Primary Reviewer/s** | **Signature** | **Date** |
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| MCU-FDTMF IRB Decision / Action Taken | □ Approve□ Minor Modification□ Major Modification□ Disapprove | Type of Review□ Expedited review□ Full board review |
| Date of Meeting |  |

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