**STUDY PROTOCOL NON-COMPLIANCE REPORT FORM**

**(VIOLATION/DEVIATION)**

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

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

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

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  | |  |  | |
|  |  | PI Deviation from protocol | | | | | | |  | Participant Non-compliance | |  |
|  |  |  |  |  |  |  |  |  | |  |  | |
|  |  |  |  | Major | |  | Minor |  | |  |  | |
|  |  |  |  |  |  |  |  |  | |  |  | |

|  |  |
| --- | --- |
| **Description** |  |
| **Action/s Taken** |  |

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

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

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **MCU-FDTMFIRB Decision** |  |  |  |  | **Type of review** | | |
|  |  | No further action |  |  |  |  |
|  | | |  |  | Expedited |  |
|  |  | Require additional information |  |  |  |  |
|  |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  | Full board |  |
|  | | |  |  |  |  |
|  |  | Site Visit |  |  |  |  |
|  | | |  |  | **Date of Meeting** | |
|  |  | Terminate |  |  |  |  |
|  |  |  |  |  |  |  |

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