

 **MERITUS MEDICAL CENTER**

 **DEVIATION REPORT FORM**

Please complete and send an electronic copy to Christine.fornwalt@meritushealth.com and one hard copy to IRB RW Suite 229, Room 2224.

**STUDY INFORMATION**

|  |  |
| --- | --- |
| MMC IRB # Click here to enter text.  | Principal Investigator Click here to enter text. |
| Study Title Click here to enter text. |  |
| Date of Report Click here to enter a date. | Sponsor Click here to enter text. |

**DEVIATION INFORMATION**

|  |  |
| --- | --- |
| Participant ID Click here to enter text. | Date of Deviation Click here to enter text. |
| How was the deviation found and by whom Click here to enter text. |  |
| Reported to Sponsor [ ]  Yes [ ]  No | Date Reported Click here to enter a date. |
| Participant enrolled [ ]  Yes [ ]  No | Participant randomized [ ]  Yes [ ]  No |
| Has this type of deviation occurred before? [ ]  Yes [ ]  No If yes, explain Click here to enter text. |  |

**CHECK ALL THAT APPLY**

|  |
| --- |
| [ ] Yes [ ]  No Deviation resulted in an increased risk to participants or others |
| [ ] Yes [ ]  No Deviation affected the rights, safety, or welfare of the participants |
| [ ] Yes [ ]  No Deviation affected the integrity of the study |
| [ ]  None of the above. Explain: Click here to enter text. |

**TYPE OF DEVIATION**

|  |  |
| --- | --- |
| [ ] Failure to consent or re-consent appropriately | [ ] Drug dispensing/dosing error |
| [ ] Failure to complete all screening procedures (required labs) prior to enrollment/randomization | [ ] Failure to control the study product (i.e. temperature monitoring, secure storage) |
| [ ] Use of an unapproved consent form | [ ] Inclusion/ exclusion criteria deviation |
| [ ] Performing a study procedure not outlined in the IRB approved protocol | [ ] Omitting study procedure(s) required by the IRB approved protocol |
| [ ] Failure to promptly report serious adverse events(s) | [ ] Participant non-compliance |
| [ ] Study visits or procedures outside of window | [ ] Other (please describe)Click here to enter text. |

**DESCRIPTION OF DEVIATION**

|  |
| --- |
| Click here to enter text. |

**EXPLAIN REASON FOR DEVIATION**

|  |
| --- |
| Click here to enter text. |

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**DESCRIBE CORRECTIVE ACTION IMPLEMENTED TO PREVENT RECURRENCE**

|  |
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| Click here to enter text. |

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| Printed/typed name of reporter Click here to enter text. | Date Click here to enter a date. |
| Signature (Principal Investigator or Authorized Designee) | Date |

|  |
| --- |
| Reviewer’s Comments: Click or tap here to enter text. |
| Reviewer’s Signature: Date:  |

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