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| --- | --- |
| **Date of this report:** |  |

|  |  |
| --- | --- |
| **Principal Investigator Name & Title:** |  |
| **Company Name:** |  |
| **Company Address, City, State, Zip:** |  |
| **Primary Contact Name:** |  |
| **Contact Phone # & Fax #:** |  |
| **Contact e-mail address:** |  |

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| --- | --- |
| **Protocol Title:** |  |
| **Protocol #:** |  |
| **Sponsor:** |  | **File #:** |  |

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| Patient Initials (ID): | Site # and Patient #: | Male / Female:  |

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| --- | --- | --- | --- |
| **Date of Deviation/Violation:** |  | **Sponsor provided an exemption?** | [ ]  Yes [ ]  No |
| **Date Site Aware:** |  | **Date IRB Notified:** |  |
| **Date Sponsor Notified:** |  |  |  |

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| **Consent Process Deviation/Violation:**[ ]  **Consented after screening procedures**[ ]  **Unapproved/wrong version consent used**[ ]  **Not re-consented w/consent form revision**[ ]  **Other**  | **Protocol/Procedure Deviation/Violation:**[ ]  **Inclusion/Exclusion criteria**[ ]  **Medication error**[ ]  **Lab Test error**[ ]  **Other** |

|  |  |  |
| --- | --- | --- |
| **Does this protocol deviation/violation increase risk to subject/others?** | [ ]  **Yes** | [ ]  **No** |

|  |
| --- |
| **Description of violation/deviation:**  |
| **Corrective action taken (or written justification for why none is provided):**  |
| **Preventive measures to prevent similar occurrences:**  |

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|  |  |  |
| **Form Prepared by** (Typed Name) | **Form Prepared by** (Signature) | **Date** |

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| *“I have reviewed the deviation/violation and find no basis for modifying or ceasing this study protocol. I certify that the information provided in this* ***entire report*** *is true and accurate to the best of my knowledge.”* |
|  |  |
| **Principal Investigator Signature** | **Date** |

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| --- | --- | --- |
| ***Please attach a copy of the current protocol (requirement). Attached?******Protocol Version and date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** | [ ]  **Yes** | [ ]  **No** |