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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** |

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

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| **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** |

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