**DEVIATION/ NON-COMPLIANCE/ VIOLATION REPORT (Form 3.5)**

**TO THE PRINCIPAL INVESTIGATOR:** *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION. IF A POINT IS NOT APPLICABLE, PLEASE WRITE “N/A” OR “NONE” AS APPROPRIATE.*

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| --- | --- | --- | --- |
| **Date of Submission (MMM/DD/YYYY)** |  | **IRB Protocol Number** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Sponsor** |  | **Sponsor’s Protocol Number** |  |

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| --- | --- | --- | --- |
| **Principal Investigator** |  | **Co-investigator(s)**  **(if any)** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator’s Signature** |  | **Principal Investigator’s Contact Number** |  |

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

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| **Reported by** |  | **Contact Number** |  |

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| **Description of Deviation/ Violation:** |
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| --- | --- | --- | --- |
| **Action(s) Taken** |  | **Date (MMM/DD/YYYY)** |  |

|  |  |
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| **Nature of the Protocol Deviation/ Violation:** | |
| Principal Investigator Deviation from the protocol  Participant Non-Compliance  Others: Beyond the situations | Major  Minor |

**TO THE PRIMARY REVIEWER:***PUT AN (X) MARK ON THE APPROPRIATE TICK BOX. PRINT NAME, SIGN AND DATE THIS FORM.*

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| **IRB DECISION** |  | Continue study and monitor compliance |  | Amend Informed Consent Form |
|  | Request for further information: |  | Suspend the study |
|  | For site visit |  | Terminate approval of current study |
|  | Amend Protocol |  | |

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| **Primary Reviewer’s Name** | **Signature** | **Date (MMM/DD/YYYY)** |
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| **Date of IRB meeting the report was presented**  **(MMM/DD/YYYY)** |  |