**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. PUT A (√) MARK ON THE APPROPRIATE TICK BOX. PRINT, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

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| **Date of Submission (MMM/DD/YYYY)** | Click here to enter text. | **IRB Protocol Number** | Click here to enter text. |

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| **Sponsor** | Click here to enter text. | **Sponsor’s Protocol Number** | Click here to enter text. |

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| **Principal Investigator** | Click here to enter text. | **Co-investigator(s)** **(if any)** | Click here to enter text. |

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| **Principal Investigator’s Signature** | Click here to enter text. | **Principal Investigator’s Contact Number** | Click here to enter text. |

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| **Protocol Title**  | Click here to enter text. |

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| **Reported by** | Click here to enter text. | **Contact Number** | Click here to enter text. |

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| **Description of Deviation/ Violation:** |
| Click here to enter text. |

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| **Action(s) Taken** | Click here to enter text. | **Date (MMM/DD/YYYY)** | Click here to enter text. |

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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 A (√) MARK ON THE APPROPRIATE TICK BOX. PRINT NAME, SIGN AND DATE THIS FORM.*

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| **IRB DECISION** | * Continue study and monitor compliance
* Request for further information
* For site visit
* Amend Protocol
 | * Amend Informed Consent Form
* Suspend the study
* Terminate approval of current study
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| **Primary Reviewer’s Name** | **Signature** | **Date (MMM/DD/YYYY)** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

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| **Date of IRB meeting the report was presented****(MMM/DD/YYYY)** | Click here to enter text. |