**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. |