IRB Protocol No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Site: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reported By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| Principal Investigator must submit completely filled out Form 3.5 Noncompliance Report **7 to 14 days of Violation** occurrence or **attached the said form on the next progress/continuing review/ final report for deviations** | | |
| *To be filled out by the Principal Investigator:* | | |
| **TYPE OF NONCOMPLIANCE**  VIOLATION  Affect safety and welfare of study participants  Affect integrity of data  DEVIATION (*Deviations that don’t affect* *safety and welfare* *of study participants and integrity of data)* | Date of Deviation Occurrence | *DD-MMM-YYYY* |
| Date Sponsor was Informed | *DD-MMM-YYYY* |
| Date PELI-IRB was informed | *DD-MMM-YYYY* |
| **Is this a first initial report of this type of noncompliance for this study?**  Yes  No. Pls. indicate how many numbers of Initial reports submitted for this study:\_\_\_\_\_\_\_\_ | | |
| **DESCRIPTION OF DEVIATION OCCURRENCE:** | | |
| **REASON WHY DEVIATION OCCURRED:** | | |
| **CORRECTIVE ACTION** DONE TO TAKE  *Pls. Describe corrective action done or to do to prevent the same deviation to occur* | | |

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| *To be filled-out by PELI-IRB:* |
| Name of Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_ |
| **REVIEWERS ASSESSMENT:** |
| **REVIEWERS RECOMMENDATION:** |

|  |  |
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| **Recommended Action:**  \_\_\_\_Request an amendment to the protocol  \_\_\_\_Request an amendment to the informed form  \_\_\_\_Request further information  \_\_\_\_Suspend or terminate the study  \_\_\_\_Take note and no further action is needed.  \_\_\_\_Others:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Type of review:  \_\_\_\_\_ Expedite Review  \_\_\_\_\_\_Full board Review  Date of Meeting: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

IRB CHAIR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name over Signature