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| **FORM 3.5 DEVIATION / NON-COMPLIANCE / VIOLATION REPORT**  |

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| --- | --- | --- | --- | --- |
| URERC Protocol Number |  | Sponsor Protocol Number |  | Date of Submission |
|  |  |  |  |  |

|  |  |
| --- | --- |
| Title |  |

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| Principal Investigator/ Researcher |  | Contact Number |  |

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|  |  | PI Deviation from Protocol | Date of Incident : |  |  |
|  |  |  |  |  | Date PI/Site notified or made aware of PD: |  |  |
|  |  |  | Major  |  | Minor |  |  | Date of Corrective/Preventive Action :  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | Participant Non-Compliance |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

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| Description |  |

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| Actions Taken by PI/Researcher |  |

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|  | URERC Recommendation | Type of Review: |  |
|  |  |  |  |  |  |
|  |  | Acknowledged. No further information or action required |  | Expedited |  |
|  |  |  |  |  |  |  |
|  |  | Additional information required |  | Full Review  |  |
|  |  |  |  |  |  |  |
|  |  | Corrective action required |  | Date of Full Board Meeting |  |
|  |  |  |  |  |  |  |
|  |  | Site Visit Needed |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  | Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |
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| URERC Decision |  |

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| Reported By/Date |  | Noted By (Secretariat)/Date |
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