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| **FORM 3.3 FINAL REPORT** |

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| URERC Protocol Number |  | Date of Approval |  |

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| Title |  |

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| --- | --- | --- | --- |
| Principal Investigator/ Researcher |  | Sponsor |  |

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| Study Site(s) |  |

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| --- | --- | --- | --- | --- |
| 1. Study Arms | | | |  |
| 1. Summary of Participants | | | |  |
|  | Total Screened |  |  |  |
|  | Total Screened Failures |  |  |  |
|  | Total Rescreened |  |  |  |
|  | Total Randomized |  |  |  |
|  | Total Completed |  |  |  |
|  | Total Early Termination |  |  |  |
|  |  |  |  |  |
| 3. | Amendments to the original protocol | | |  |
| 4. | Summary of Onsite SAE’s reported | | |  |
| 5. | Summary of Participant’s Complaints or Grievances documented | | |  |
| 6. | Summary of Benefits to Participants | | |  |
| 7. | Summary of Indemnifications of Study Related Injury (If applicable) | | |  |
| 8. | Reasons for Early Terminations | | |  |
| 9. | Progress Reports Submitted | | |  |
| 10. | Duration of Study | | |  |
| 11. | Informed Consent Versions Used (Indicate Version and Date) | | |  |
| 12. | Study Objectives | | |  |
| 13. | Summary of Results | | |  |

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| Name and Signature  (PI/Researcher) |  | Date |  |

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|  | URERC Recommendation | |
|  |  | |
|  |  | Acknowledged. No further information or action required |
|  |  |  |
|  |  | Additional information required |
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|  |  | Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| Name of Reviewer |  | Signature |  | Date |
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