

Protocol Number:	
Site Name and Branch Name:	

- List the names of all Site Staff, their respective roles (e.g., Principal Investigator (PI), Sub-Investigator, Pharmacist, Study Coordinator, Data Manager, Regulatory Coordinator, Research Nurse, Research Laboratory Technician), and the significant study-related duties/tasks delegated by the PI using the Task Codes.
- All Staff listed on the Log must provide an electronic ‘certified’ digital signature, i.e., PIV card, to indicate an understanding of the responsibilities assigned.
- Provide the Start Date for delegated study duties/tasks. If a Site Staff member’s duties/tasks change, enter the End Date, then add a new line with their updated duties/tasks and Start Date.

<ol style="list-style-type: none"> 1. Obtain <u>hand-written</u> Informed Consent 2. Obtain <u>electronic</u> Informed Consent (e.g., iMed) 3. Obtain and document medical history 4. Obtain inclusion/exclusion assessment 5. Confirm eligibility criteria met 6. Perform study product management, dispensing, accountability 7. Perform study product dose administration 8. Perform physical exam 9. Perform significant study-specific assessments 10. Make study-related medical decisions 	<ol style="list-style-type: none"> 11. Assess AEs and SAEs 12. Assess concomitant medications 13. Expedited event (e.g. RNI) form preparation 14. Expedited event (e.g. RNI) form review and approval 15. Confirm response criteria 16. Evaluate procedures and test results, including labs, for clinical significance 17. Enter eCRF data 18. Review/confirm eCRF data 	<ol style="list-style-type: none"> 19. Address eCRF data queries 20. Sign-off on eCRFs 21. Coordinate IRB communications, submissions 22. Maintain site essential regulatory document file 23. Process and/or ship laboratory specimens 24. Conduct quality assurance/quality control procedures 25. Assume PI responsibilities when PI is unavailable
<ol style="list-style-type: none"> 26. Other: _____ 27. Other: _____ 28. Other: _____ 29. Other: _____ 	<ol style="list-style-type: none"> 30. Other: _____ 31. Other: _____ 32. Other: _____ 33. Other: _____ 	<ol style="list-style-type: none"> 34. Other: _____ 35. Other: _____ 36. Other: _____ 37. Other: _____

Protocol Number:	
Site Name and Branch Name:	

Principal Investigator END-OF-STUDY Declaration:

By signing below, I declare that the information documented on this Log is correct and that the study has ended.

PI Name: _____ Date: _____

Signature of Principal Investigator: _____