Delegation of Responsibilities Log

Protocol #		**Sponsor Name:**	
Principal Investigator:		**Site #:**	
Site Name			

Name	**Signature**	**Initials**	**Study Role**	**Key Study Tasks** (choose from list below)	**Start** (DD/MMM/YYYY)	**End** (DD/MMM/YYYY) (complete only if prior to end of study)	**PI Initials & Date** (DD/MMM/YYYY)

Comments:

Delegation of Responsibilities Log

Protocol #		**Sponsor Name:**	
Principal Investigator:		**Site #:**	
Site Name			

Name	**Signature**	**Initials**	**Study Role**	**Key Study Tasks** (choose from list below)	**Start** (DD/MMM/YYYY)	**End** (DD/MMM/YYYY) (complete only if prior to end of study)	**PI Initials & Date** (DD/MMM/YYYY)

Electronic Signature Declaration for Principal Investigator and Site Staff

My electronic signature as it applies to entering electronic data or signing records in sponsor-owned or sponsor-outsourced computer systems is the legally binding equivalent of my handwritten signature.

I will not share password(s) assigned to me for this study with any other persons.

Delegation of Responsibilities Log

Principal Investigator's End of Study Declaration

I hereby confirm that the above information is accurate and complete and that I authorized the delegation of study-related tasks to each individual as listed above.

Principal Investigator's Signature: _____ Date: _____

Delegation of Responsibilities Log

Protocol #		**Sponsor Name:**	
Principal Investigator:		**Site #:**	
Site Name			

Task Key: These task may only be performed by qualified individuals as permitted by local law, medical or standard of care practices or applicable training as per job description or designation

1. Obtain informed consent
2. Subject selection/ recruitment
3. Confirm eligibility (review inclusion/ exclusion criteria)
4. Obtain medical history (source documents)
5. Perform physical examination
6. Conduct study visit procedures as outlined in the protocol
7. Make study-related medical decisions
8. Assess AEs/ SAEs
9. Perform study-related assessments as per protocol
10. Evaluated study-related test results
11. Sign-off (e)CRF
12. Sample collection
13. Sample processing and/ or shipment
14. Make entries/ corrections on (e)CRF
15. Maintain essential documents
16. Complete AEs/SAE forms and submit to Sponsor/ Regulatory Authorities
17. Use IWRS/IVRS
18. Dispense study drug
19. Perform drug accountability
20. Study drug storage and temperature monitoring
21. Complete company-specific logs (if applicable)
22. Other (specify)_____
23. Other (specify)_____