Protocol Number:	
Site Name and Branch Name:	

1. **Guidance on completing the Log -** In case of questions, consult 2A F01-203-S01 Clinical Site Delegation of Authority Log FAQs.
   - This Log is to be completed and signed **digitally**.
   - Enter the protocol number and 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.
     - Note: Include all Staff listed on Form FDA-1572 on this Log. Staff duties/tasks must remain within the scope of their professional licensure. Study-specific tasks may be added to the list of numbered task codes as needed.
     - Note: Staff duties/tasks delegated by the PI may not be performed if the Staff member's training documentation is not available for the following:

1. Protocol	Also, as applicable: • Dangerous Goods Handling or International Air Transport Association (IATA) • Other specialized procedures, e.g., study product preparation • Non-NIH PI and site Staff electronic data capture (EDC) system Users must provide a record of training on the protocol-specific use of the EDC system. Required before site activation.
2. Human Subjects Protection (HSP)	
3. Good Clinical Practice (GCP)	

   - 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.
   - Provide the End Date when the individual no longer performs a delegated duty/task or participates in the study. If blank, this indicates that the duties/tasks were conducted until the completion of the study (Date of PI End-of-Study declaration).
   - An entry for named Staff is not complete without the PI´s **digital signature and date**. This indicates that the PI confirms that the Staff member is authorized, trained appropriately for the role, and qualified to perform the duties/tasks assigned. PI retains the overall responsibility for the conduct of the clinical trial, including delegated duties/tasks.
   - Retain the current Log and all previous original Log versions in the site study file. Update the Log as personnel, roles, and/or study tasks change.

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2. Completion instructions at the end-of-study

- Fill and sign digitally: If blank rows remain, enter NA or N/A in each unused Name, Role, and Task Codes cell.
- After reviewing all entries for accuracy at the end of the study, the PI will sign and date the Log in the designated area for the End-of-Study declaration.

***Task Code Key**

1. Obtain hand-written Informed Consent 2. Obtain electronic 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	11. Assess AEs and SAEs 12. Assess concomitant medications 13. SAE form preparation – delegated to qualified personnel at PI discretion 14. SAE form approval – delegated to a physician licensed to diagnose listed on the 1572 15. Confirm response criteria met 16. Evaluate test results, including labs, for clinical significance 17. Enter eCRF data 18. Review/confirm eCRF data	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. Complete and sign the OSRO SROS Source Location Record Form
26. Other: _____ 27. Other: _____ 28. Other: _____ 29. Other: _____	30. Other: _____ 31. Other: _____ 32. Other: _____ 33. Other: _____	34. Other: _____ 35. Other: _____ 36. Other: _____ 37. Other: _____

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Name	**Role**	**Task Codes** (per Key)	**Staff Signature** (Digital with Date)	**Start Date**	**PI Signature** (Digital with Date)	**End Date**	**PI Signature** (Digital with Date)
	Principal Investigator						

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Name	**Role**	**Task Codes** (per Key)	**Staff Signature** (Digital with Date)	**Start Date**	**PI Signature** (Digital with Date)	**End Date**	**PI Signature** (Digital with Date)

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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: _____