**Notes for Completion of the Delegation log**

* All personnel who perform study related activities (including staff from other departments) must have delegations clearly documented in the delegation log, prior to involvement with the study.
* Each staff member **MUST** complete his/her own entry, including all initials, signatures and dates. Entries will be used to verify handwriting on research documents.
* By signing the log, the PI is approving the delegation of duties and confirms that the member of staff has received study specific training and is appropriately qualified to perform the delegated task.
* This document must be completed clearly in black ink; corrections made with a single strike through, date and initials.
* Delegations can be added and/or deleted depending on study need.
* Signature date must be completed where indicated.

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| 1. Overall Responsibility (PI only) | 11. Drug Return / Destruction |
| 2. Informed Consent Process | 12. CRF completion |
| 3. Eligibility Criteria Review | 13. CRF sign off |
| 4. Physical Examination | 14. Query resolution |
| 5. Study Procedures | 15. Data Management |
| 6. Clinical Assessment | 16. Statistical Analysis |
| 7. AE/SAE review (Physician, and/or PI only) | 17. IRB Submissions |
| 8. Study Prescription | 18. Samples shipment / receipt |
| 9. Randomization | 19. Samples preparation / analysis |
| 10. Drug Accountability / Inventory | 20. Other (please specify) |

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| PI – Principal Investigator |
| SI – Sub-Investigator |
| RN – Research Nurse |
| RM – Research Manager |
| DM – Data Manager |
| SC – Study Coordinator |

***\*\* A copy of the delegation log MUST be submitted to IRB prior to study start\*\****

***\*\*Final PI attestation should be signed at study closure only\*\****

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|  | **PRINT YOUR NAME**  **& TITLE** | **STUDY ROLE**  *(YOURS)* | **DELEGATED TASK**  *(YOURS)* | **INITIAL**  *(YOURS)* | **SIGNATURE & DATE**  *(YOURS)* | **DURATION DATES** | | | **PI SIGNATURE & DATE** |
| **FROM** | **PI INITIAL** | **TO** |
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| **1.** Overall responsibility (PI) | **2.** Obtain informed consent | **3.** Eligibility criteria review | **4.** Physical examination |
| **5.** Study procedure | **6.** Clinical assessment | **7.** AE/SAE review | **8.** Study prescription |
| **9.** Randomization | **10.** Drug accountability | **11.** Drug return | **12.** CRF completion |
| **13.** CRF sign off | **14.** Query resolution | **15.** Data management | **16.** Statistical analysis |
| 17**.** IRB submissions | **18.** Sample shipment | **19.** Samples preparation | **20.** Others |