## **APPENDIX 1: STUDY DELEGATION LOG**

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| **Protocol Title/Name:**  | **Protocol No:** |
| **Principal Investigator:**  | **Site/Site no:** |

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| Name | Job Description | Signature | Responsibilities**\***(Please list responsibilities by number separated by a comma – as per GCP requirements) | Date started work on Trial | Date finished on Trial | Authorised by PI to perform the delegated responsibilities listed (PI signature) | Date of PI Authorisation |
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\* **Key:**

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| 1 – Overall responsibility for study at site2 – Ethics3 – Screening of patients4 – Randomisation5 – Obtaining Informed Consent6 – Patient’s assessments & medical care | 7 – Prescriptions8 – Administration of investigational product9 – Reporting of Adverse Events & Serious Adverse Events10 – eCRF/CRF completion & data queries11 – Maintain essential documents & study site file12 – Drug receipt, dispensing & accountability | 13 – Maintain Pharmacy File14 – Storage of investigational product15 – Monitoring visit support16 – Archiving17 – Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |