**Study Delegation Log**

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| Study Title:  |  |
| Principal Investigator at site:  |  | EudraCT ref:  |  |
| Site Name: |  | Sponsor/JRCO Ref |  |

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| **Print Full Name & Title** | **Signature** | **Initials** | \*Study Role | **\*\*Key Delegated Study Task(s)**See Examples Listed Below | **Duration** | Principal Investigator Signature | **Date** PI’s signature  |
|  |  |  |  |  | **From:** | **To:** |  |  |
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\*Identification of study role includes but is not limited to sub-investigators, study nurses, pharmacist (when appropriate) and data recorders. List individuals delegated significant study-related tasks (ICH GCP 4.1.5). Signatures/Initials required for all persons authorised to make entries and/or corrections to Case Report Forms (ICH GCP 8.3.24)

\*\* Identify key study tasks when delegated by the investigator. Examples of key delegated study tasks could include:

1 Obtain Informed Consent 6 Investigational Product Accountability 11 Taking blood samples 16 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2 Obtain Medical History 7 CRF Completion /data entry 12 Medical care of trial subjects 17 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3 Perform Physical Exams 8 CRF Sign off 13 Archiving 18 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4 Inclusion/Exclusion Assessment 9 Source document entry (ie. Medical notes) 14 Maintaining investigator site file \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 19 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5 Drug Dispensing 10 Reviewing & reporting adverse events/SAEs 15 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_