**APPENDIX I**

**Delegation of Tasks Log (DTL) Study Tasks List**

| **Task ID** | **Task Name** | **Task Description** | **RCR**  **Registration**  **Required** | **Allowed Registration Types to Perform Task** |
| --- | --- | --- | --- | --- |
| NA | Principal Investigator (PI) | Lead investigator with overall responsibility for study conduct at the Lead Academic organization (LAO) or accruing Affiliate Organization (AO); responsible for signing the Delegation of Tasks Log (DTL) for a given protocol. | Yes | IVR, NPIVR |
| 1 | DTL and RCR Administrator | Person assigned by the PI to manage the DTL and RCR registration. | Yes | IVR, NPIVR, AP |
| 2 | Primary Study/Site Contact | The point of contact for the study. | Yes | IVR, NPIVR, AP |
| 3 | Person Authorized to Obtain Consent | Responsible for the consenting process. | Yes | IVR, NPIVR, AP |
| 4 | Data Management/EDC | At the LAO level: Responsible for management of the Data Management System, creating manuals, reviewing data entered by the sites into the Electronic Data Capture system (EDC). At the AO level: Responsible for entry of data into the EDC, and possibly some data quality control and query management functions. | Yes | IVR, NPIVR, AP |
| 5 | Eligibility Assessments | Responsible for verification of eligibility. *Eligibility assessments for screening may be performed by IVR, NPIVR or AP; eligibility assessment for randomization must be performed by an IVR.* | Yes | IVR*,* NPIVR, AP |
| 6 | Endpoint Assessment | Responsible for assessing study endpoints and response assessments. | Yes | IVR, NPIVR |
| 7 | AE/SAE and Toxicity Assessments | Responsible for Adverse and Serious Adverse events assessment/attribution and reporting of SAEs. | Yes | IVR |
| 8 | History and Physical (H&P) Assessments | Responsible for conducting physical exams and assessments. | Yes | IVR |
| *9* | IND Agent Prescribing | Responsible for writing an order for a participant who is receiving an IND agent. | Yes | IVR |
| 10 | Non-IND Agent Prescribing | Responsible for writing an order for a participant who is receiving a non-IND agent. Must be a licensed prescriber, per local laws, and delegated to perform this task by the clinical investigator. *For international studies, this must be an RCR-registered investigator (IVR) if prescribing an NCI DCP supplied agent, including locally sourced agents that are reimbursed using NCI DCP funding.* | Yes | IVR |
| 11 | Investigational Product Accountability | Responsible for tracking of distribution/receipt/dispensation and return of investigational product. | Yes | IVR, NPIVR, AP |
| 12 | Study-Related Interventions | Responsible for coordinating and/or administering study-related interventions and procedures. | Yes | IVR, NPIVR, AP |
| 13 | Patient Screening/Recruiting | Responsible for screening and recruiting of participants. | Yes | IVR, NPIVR, AP |
| 14 | Source Documentation Completion | Responsible for collecting data on study-related assessments. | Yes | IVR, NPIVR, AP |
| 15 | Regulatory Contact | Responsible for regulatory submissions and maintaining essential documents. | Yes | IVR, NPIVR, AP |
| 16 | Specimen Tracking System | Responsible for entering specimen data into a Specimen Tracking System.  Of note, LAOs are most likely only to view the Specimen Tracking System. | Yes | IVR, NPIVR, AP |
| 17 | Specimen Processing and Shipping | Responsible for protocol-specific specimen processing/shipping. | Yes | IVR, NPIVR, AP |
| 18 | Pathology Lab Support | Responsible for pathology lab support, such as obtaining and preparing lab samples. | Yes | IVR, NPIVR, AP |
| 19 -20 | Other | Responsible for tasks identified/added by the site. | Yes | Task-dependent |

Of note, LAOs will most likely only have the following tasks assigned: 1, 2, 4, 15, 16, 17, and possibly 18.