|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator:** |  | **Protocol Study Number:** | ULACNet-XXX |
| **Lead Academic Organization Name:** |  | **Affiliate Organization Name:** |  |
| **CTEP Site ID:** |  | **Laboratory Name:** |  |
| **IRB Name:**  |  | **IRB Number:** |  |

Please refer to Appendix I Delegation of Tasks Log (DTL) Study Tasks List for task descriptions and NCI Registration and Credential Repository (RCR) registration types needed to perform each delegated task.

The Lead Academic Organization (LAO) Principal Investigator (PI) is the protocol lead investigator responsible for the oversight of the accruing Affiliate Organizations (AOs) conducting the clinical trial. The LAO PI will complete this form to assign personnel at the LAO specific responsibilities for the oversight and/or conduct of study-related tasks at the LAO. The LAO PI can take the role of AO PI when the study is conducted at the LAO.

The AO Principal Investigator (PI) is the AO protocol-specific lead investigator responsible for the oversight and conduct of the clinical trial at the AO. The PI will complete this form to assign personnel at the AO who have been delegated significant study-related tasks specific responsibilities.

The Principal Investigator must ensure that personnel do not start their delegated study-related tasks until (1) this form has been completed and is up to date, (2) the Principal Investigator has documented delegation on this form through his/her initials and date, and (3) the Principal Investigator has ensured documentation that personnel have completed study related training appropriate to the role(s) and task(s), if applicable.

**PRINCIPAL INVESTIGATOR: (Of note, the PI should fill out only this table and not the table on the subsequent page(s))**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Principal Investigator** | **Principal Investigator’s Signature\*** | **Principal Investigator’s Initials** | **Start Date**(MM/DD/YYYY) | **End Date**(MM/DD/YYYY) |
|       |  |  |       |       |

\*My signature confirms/acknowledges that the information contained here is accurate and that:

* I will remain responsible for the overall study conduct and reported data.
* I will ensure study oversight.
* I will authorize the delegation of study-related tasks to each individual as listed.
* The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
* I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.
* I will ensure that site staff receives, in a timely manner, the appropriate information and training for delegated tasks.
* I will ensure that all changes in staff or delegated study-related task will be recorded in a timely manner.

In the event of a change in the Principal Investigator, a new DTL must be completed and submitted to ULACNet@mail.nih.gov.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name | Signature My signature below indicates that I accept the study task(s) | Initials | Study Role / RCR Registration ID (select from list below) | Delegated Study Tasks (select from list below) | PI Initials & Date (a)(MM/DD/YYYY) | Tasks Start Date (b)(MM/DD/YYYY) | Tasks End Date(MM/DD/YYYY) | PI Initials & Date (c)(MM/DD/YYYY) |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |
|   |   |   |   |   |  |  |   |   |

(*a*) PI Initials & Date indicates the date when delegation is authorized by PI.

(*b*) Tasks Start Date indicates the date when personnel begin performing their tasks. For tasks that require study-specific training, training must be completed prior to this date.

(*c*) PI Initials & Date indicates the date when delegation of tasks ends due to task reassignment or study closure. Field may be left blank until task reassignment or study closure.

(*d*) Other tasks may include those that are site-specific and/or are local regulatory requirements. If adding more than 2, document the tasks in the Comments box (number consecutively).

\* Of note, personnel at the LAOs are most likely to be assigned study tasks 1, 2, 4, 15, 16, 17, and possibly 18.

## RCR-Registration Types:

**Investigator** (**IVR)** *MD, DO, or international equivalent*

**Non-Physician Investigator** (**NPIVR)** *advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD)*

**Associate Plus (AP)** *clinical site staff (e.g., RN or CRA) with data entry access*

## Study Tasks List:

1. DTL and RCR Administrator (IVR, NPIVR, AP)

2. Primary Study/Site Contact (IVR, NPIVR, AP)

3. Person Authorized to Obtain Consent (IVR, NPIVR, AP)

4. Data Management/EDC (IVR, NPIVR, AP)

5. Eligibility Assessments (IVR, NPIVR, AP) **\*\***

6. Endpoint Assessments (IVR, NPIVR)

7. AE/SAE and Toxicity Assessments (IVR)

8. H&P Assessments (IVR)

9. IND Agent Prescribing (IVR)

10. Non-IND Agent Prescribing (IVR)

11. Investigational Product Accountability (IVR, NPIVR, AP)
12. Study-Related Interventions (IVR, NPIVR, AP)

13. Patient Screening/Recruiting (IVR, NPIVR, AP)

14. Source Documentation Completion (IVR, NPIVR, AP)

15. Regulatory Contact (IVR, NPIVR, AP)

16. Specimen Tracking System (IVR, NPIVR, AP)

17. Specimen Processing/Shipping (IVR, IVR, AP)

18. Pathology Lab Support (IVR, NPIVR, AP)

19. Other*(d)*:

20. Other*(d)*:

*\*\*Eligibility Assessments:*

Screening (IVR, NPIVR, AP)

Randomization (IVR)

**Comments**: Enter comments as appropriate; date and initial all comments.

|  |
| --- |
|  |

Please check box at the end of the study if there are no comments [ ]

**To be completed by the PI at the end of the study, once the study is closed with the IRB or ethics committee and all trial data reporting is complete:**I confirm that the information contained in this document is accurate and complete.

**Principal Investigator Signature** **Date** (MM/DD/YYYY)