STUDY PERSONNEL SIGNATURE/RESPONSIBILITY LIST

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| PRINTED NAME and E-MAIL ADDRESS | TITLE | STUDYTASKS | SIGNATURE | INITIALS | START DATE | PI Initials (delegated) | END DATE | PI or SC (initials, *verified end date*) |
|  | Principal Investigator |  |  |  |  |  |  |  |
|  | Sub-investigator |  |  |  |  |  |  |  |
|  | Pharmacist |  |  |  |  |  |  |  |
|  | Lab Tech |  |  |  |  |  |  |  |
|  | Lead Study Coordinator |  |  |  |  |  |  |  |
|  | Regulatory Coordinator |  |  |  |  |  |  |  |
|  | QM Manager |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| * List individuals delegated study related tasks (ICH GCP 4.1.5).
* All personnel listed on Form FDA 1572 must be listed on this form.
* Signature/initials required for all personnel.
* Update as personnel, roles and/or study tasks change.
* PI or SC who verify the end date should initial
* Copy of completed form to be collected by Monitor at study closeout.
 | KEY - DELEGATED STUDY TASK CODES: |
| Medically Qualified/Trained/Licensed Staff (*individual with the training and authority to make a medical diagnosis and listed on the Form FDA 1572 as an investigator*)1. Perform physical exams2. Determine subject’s eligibility 3. Make study-related medical decisions4. Evaluate study related test results5. Assess AE/SAE severity, seriousness, and relatedness/alternative etiology6. Assess Safety Reports from Sponsor7. Sign off on (e)CRF visit data8. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_9. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Qualified/Trained Staff10. Obtain Informed Consent11. Inclusion/Exclusion Assessment/ Screening 12. Obtain vital signs/height/weight13. Obtain medical history14. Record information verbatim by subject or records (e.g. Con Meds, vaccinations, travel, health history,)15. Assess solicited adverse events (severity)16. Dispense/Prepare Test Article17. Verify Test Article18. Administer Test Article | 19. Test Article Accountability, Monitor Temperature 20. Make CRF/Clinical Database Entry, Corrections, Query Resolution21. Collect biological specimens22. Perform CLIA-waiver tests: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_23. Process/Manage storage for Biological Specimens 24. Make Lab Database Entry, Corrections, Query Resolution25. Update/Manage Essential Documents26. Report SAE to Sponsor/IRB27. Ship Biological Samples 28. Conduct Quality Assurance/QM Management29. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Principal Investigator Signature (Initial Delegation):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature (Close Out):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_