STUDY PERSONNEL SIGNATURE/RESPONSIBILITY LIST

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| PRINTED NAME and  E-MAIL ADDRESS | TITLE | | STUDY  TASKS | 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 exams  2. Determine subject’s eligibility  3. Make study-related medical decisions  4. Evaluate study related test results  5. Assess AE/SAE severity, seriousness, and relatedness/alternative etiology  6. Assess Safety Reports from Sponsor  7. Sign off on (e)CRF visit data  8. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  9. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | Qualified/Trained Staff  10. Obtain Informed Consent  11. Inclusion/Exclusion Assessment/ Screening  12. Obtain vital signs/height/weight  13. Obtain medical history  14. 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 Article  17. Verify Test Article  18. Administer Test Article | | | 19. Test Article Accountability, Monitor Temperature  20. Make CRF/Clinical Database Entry, Corrections, Query Resolution  21. Collect biological specimens  22. Perform CLIA-waiver tests: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  23. Process/Manage storage for Biological Specimens  24. Make Lab Database Entry, Corrections, Query Resolution  25. Update/Manage Essential Documents  26. Report SAE to Sponsor/IRB  27. Ship Biological Samples  28. Conduct Quality Assurance/QM Management  29. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |

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

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