**Study Personnel Signatures/Responsibility Log**

**Site PI:**

**Institution:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Study #/Study Title: \_\_\_\_**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Printed Name**  | **Title**  | **Study Responsibilities (see Legend below)**  | **Signature** | **Initials** | **Phone # & Email**  | **Date began \***  | **Date ended \***  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

|  |
| --- |
| \*These dates reflect the beginning and end of individual personnel responsibilities for this protocol. \*\*Requires annual training |
|  | **Legend**  |  |
| 1. Obtain and Administer Informed Consent  | 6. Complete Source Documents \*\* | 11. Assess SAE/AE  | 16. Adverse Event Assessment |
| 2. Perform Study Drug Accountability  | 7. Perform Physical Examinations  | 12. Instruct Patient on Study Procedures  | 17. PBMC collection and process\*\*  |
| 3. Determine Patient Eligibility  | 8. Maintain IRB/Regulatory Documents\*\* | 13. Complete & Correct eCRFs \*\* | 18. PK collection & process\*\* |
| 4. Recruit and Screen Patients  | 9. Obtain Medical History  | 14. Arrange & conducts study visits  | 19. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 5. Obtain and Process Lab Samples  | 10. Dispense Study Medication  | 15. Adverse Event Reporting | 20. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Signed by Principal Investigator upon **study closure:** Date: