|  |  |  |
| --- | --- | --- |
| **PROTOCOL TITLE:** | | |
| **PROTOCOL NO.:** | **PRINCIPAL INVESTIGATOR:** | **SITE NAME:** |

**LIST OF STUDY RESPONSIBILITIES\***

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Trial participant Screening | 6. Reviewing ECG Results | 11. Obtaining Vital Signs and Demographics | 16. Managing study supplies |
| 1. Obtaining Informed Consent | 7. Signing Case Report Forms | 12. Making data entries and corrections into CRFs | 17. Randomization |
| 1. Confirming Trial participant Eligibility | 8. Signing off Data Queries | 13. Investigational Product Management | 18. Others: |
| 1. Performing Physical Examination | 9. Safety Reporting | 14. Handling Biological Samples | 19. Others: |
| 1. Reviewing Laboratory Results | 10. Communicating with IRB and HSA | 15. Maintaining Investigator Site Files | 20. Others: |

*\*Responsibilities 1-9 should be delegated to a locally registered medical doctor or dentist, whilst the remaining responsibilities may be delegated to other study staff.*

To be signed by Principal Investigator at Site Closing Visit:

I confirm that the individuals listed are authorised and qualified by education, training and experience to conduct the study responsibilities assigned. The overall assurance for the quality and accuracy of all study data is my responsibility as the Principal Investigator.

|  |  |  |
| --- | --- | --- |
| Name of Principal Investigator | Signature | Date |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PROTOCOL TITLE:** | | | | | | | | |
| **PROTOCOL NO.:** | | **PRINCIPAL INVESTIGATOR:** | | | | **SITE NAME:** | | |
| **Name of**  **Study Staff** | **Study Role#** | **Delegated Study Responsibilities** | **Start Date** | **End Date** | **Initials of Study Staff** | **Signature of Study Staff** | **Authorization by Principal Investigator**  **(Signature and Date)** | **CV collected**  **(Tick)** |
|  | Principal Investigator |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

|  |
| --- |
| *# For e.g.: Principal Investigator (PI), Sub-Investigator (SI), Clinical Research Coordinator (CRC), Study Pharmacist (PH), Unblinded Study Staff (UB) etc.* |