This tool is provided as a template for those that don’t have one. You should modify it so that it is appropriate for your study.

NIH defines key personnel as individuals who are involved in the design and conduct of NIH-funded human subjects’ clinical research. This includes all individuals named on the Form FDA 1572 or Investigator Agreement and any clinical research site personnel who have more than minimal involvement with the conduct of the research (performing study evaluations or procedures or providing intervention) or more than minimal study conduct-related contact with study subjects or confidential study data, records, or specimens.

Use the following information to facilitate the completion of the Staff Signature and Delegation of Responsibility Log.

**Principal Investigator, Protocol Title, and IRB Number**

The Principal Investigator’s name, the Protocol Title and IRB Number should be added into the header of the document

**Print Name, Signature, and Initials**

All staff who have been delegated any task related to the protocol should be listed on this log. This includes PI, Sub-Investigators, Research Nurses and Coordinators, Research Fellows and Residents, Regulatory Coordinators, students (medical, dental, nursing, undergraduate, etc.) and any other individual who is considered key study personnel must be listed in this log. Changes must be approved by the PI before they are implemented.

**Study Role**

Indicate the role for this study. Some examples are provided in the key on the form.

**Study Specific Responsibilities**

This section should identify the responsibilities as listed in the table found at the bottom of the document. The key is provided as an example and may be changed to more accurately reflect your protocol if desired.

**Start Date**

The Start Date refers to the date that the individual has been delegated the task by the PI. The individual must be added to the protocol and approved by the IRB and they must receive training for the task to which they have been delegated and this should be documented in a training log.

**End Date**

The End Date is when the individual is no longer delegated the tasks or at the end of the study. The individual must be removed from the protocol and with the IRB if the study has not ended. The IRB application can be updated at the next Continuing Review. If the end date corresponds to the end of the protocol then just close the study with the IRB when appropriate.

**PI Initials**

The PI initials indicate that the individual has been delegated the tasks as noted on the log.

**Principal Investigator Signature**

At the end of the study, when the protocol and log are complete, the log must be signed by the PI. This may occur at the time the study is closed with the IRB.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Print Name** | **Study Role** | **Study Specific Tasks** | **Signature** | **Initials** | **Dates of Responsibilities** | | **PI Approval ( PI initials and Date)** |
| **Start Date** | **End date** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

End of Study

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  | | --- | --- | --- | --- | | **Role**  Principal Investigator  Sub- investigator | Research Coordinator  Research Nurse | Pharmacist  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_ | Other:\_\_\_\_\_\_\_\_\_\_\_\_  Other:\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | | | | | |
| **Study Specific Tasks**  1. Obtain informed consent | 9. Dispense study drug | 17. Sign- off on (e)CRFs |
| 2. Subject selection/recruitment | 10. Perform drug accountability | 18. Maintain essential documents |
| 3. Confirm eligibility (review inclusion/exclusion criteria) | 11. Study drug storage and temperature monitoring | 19. Perform study-related assessments as per protocol |
| 4. Obtain medical history (source documents) | 12. Sample collection | 20. Regulatory submissions |
| 5. Perform physical exam | 13. Sample processing and/or shipment | 21. Billing/Finance |
| 6. Conduct study visit procedure as outlined in the protocol | 14. Evaluate study-related test results | 22. Project Management |
| 7. Make study-related medical decisions | 15. Use IWRS/IVRS | 23. Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 8. Assess AEs/SAEs | 16. Make entries/corrections on (e)CRFs | 24. Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |