**This tool is provided as a template for those that need one. Modify as necessary for your study.**

NIH defines key personnel as the Program Director (PD) or Principal Investigator (PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel.

OHRP considers the following conditions as NOT engaged in research: 1) the services performed do not merit professional recognition or publication privileges; 2) the services performed are typically performed by those personnel for non-research purposes; 3) the institution’s employees or agents do not administer any study intervention being tested or evaluated under the protocol.

Use the following information to facilitate the completion of the Delegation of Authority and Staff Signature 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 Tasks**

This section should identify the tasks and 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.

**CWRU Continuing Research Education Credits Program (CREC) Certification Expiration Date**

All staff listed on the study personnel table must be CREC certified. This date should be updated with each new expiration date.

**Start Date**

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 date 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 End Date corresponds with the end of the protocol then 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.

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

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

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| |  |  |  |  | | --- | --- | --- | --- | | **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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |