**Signature and Delegation of Responsibilities Log - INSTRUCTIONS**

This log records all study related delegated study tasks to study personnel.

Only those study team members delegated tasks are required to provide their CV, medical licenses (if applicable), study training, ICH-GCP and Division 5 (if applicable) training.

A Principal Investigator holds all responsibility of a trial. He/She can delegate specific responsibilities to qualified members of the study team. Both the study team member and the PI sign the row to indicate this transfer/acceptance of responsibility. Start dates for each study team member should be included, and end dates should only be documented when the study team member has left the study team (not pre-emptively).

Delegation of Responsibility Log Helpful Tips:

* PIs initial and date only the right-hand column. The signature line at the bottom is only to be completed at the end of the study.
* If subsequent pages are needed, ensure to complete footer “Page \_\_ of \_\_”
* Training date column should correspond with the Study Personnel Training Log.
* If someone is a co-Investigator on the protocol but does not have any study tasks (even in the case of a backup etc), then they should not be included on the Study Delegation Log (and therefore their CV, medical license and documentation of ICH-GCP and Division 5 training are not required).
* Delegated tasks specified in this template can be added, removed or altered as need to fit your particular study

**SIGNATURE AND DELEGATION OF RESPOSIBILITIES LOG**

|  |  |  |
| --- | --- | --- |
| **Study Title:** | **REB #:** Pro | **PI Name:**  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Study Role** | **Delegated Tasks (see key)** | **Initials** | **Signature** | **Training Date****(dd/mmm/yy)** | **Study Involvement Dates** | **PI Initials & Date** |
| **From****(dd/mmm/yy)** | **To****(dd/mmm/yy)** |
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**Delegated Tasks:**

|  |  |  |  |
| --- | --- | --- | --- |
| A. Make eligibility/termination decisions | E. Evaluate adverse events (cause/severity) | I. Complete data entry and corrections on case report forms | M.  |
| B. Obtain Informed Consent | F. Complete history and physical exam | J. Phlebotomy | N.  |
| C. Label and dispense study drug | G. Maintain drug accountability records | K. Maintain regulatory documents  |  |
| D. Administer study drug | H. Schedule study visits | L. Complete electronic data entry |  |

I confirm that this list accurately reflects the signatures, training and delegation of responsibilities during this research study.

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**Principal Investigator Signature\* Date**

 *(\*complete at close-out)*