**DELEGATION OF RESPONSIBILITIES OF STUDY TEAM**

Study title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- |
| **Name**  | **Role**  | **No.**  |
|  | Principal Investigator  | 1  |
|  | Co-Investigator  | 2  |
|  | Co-Investigator  | 3  |
|  | Co-investigator  | 4  |
|  | Co-Investigator  | 5  |
|  | Co-investigator  | 6  |
|  | Study co-ordinator \*  | 7  |
|  | Study co-ordinator \*  | 7  |
|  | Laboratory Technician  | 8  |
|  |  | 9  |
|  |  | 10  |

\* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor)

(Please place tick marks against assigned duties for each member in the following table)

|  |  |  |  |
| --- | --- | --- | --- |
| **Code**  | **TASKS**  |  | **Role Played by Each Study Team Member**  |
| **1**  | **2**  | **3**  | **4**  | **5**  | **6**  | **7**  | **8**  | **9**  | **10**  |
| A  | All relevant documents pertaining to protect blinding  |  |  |  |  |  |  |  |  |  |  |
| B  | Research participants selection/ Screening  |  |  |  |  |  |  |  |  |  |  |
| C  | Obtain informed consent  |  |  |  |  |  |  |  |  |  |  |
| D  | Evaluate inclusion/ exclusion criteria  |  |  |  |  |  |  |  |  |  |  |
| E | Conduct the visit assessments  |  |  |  |  |  |  |  |  |  |  |
| F  | Physical examination  |  |  |  |  |  |  |  |  |  |  |
| G  | Complete the source documents  |  |  |  |  |  |  |  |  |  |  |
| H  | Complete Case Record Form  |  |  |  |  |  |  |  |  |  |  |
| I  | Final review and sign Case Record Form  |  |  |  |  |  |  |  |  |  |  |
| J  | Collect laboratory safety test samples  |  |  |  |  |  |  |  |  |  |  |
| K  | Processing of blood samples  |  |  |  |  |  |  |  |  |  |  |
| L  | Preparing aliquots & keeping a track of the samples sent  |  |  |  |  |  |  |  |  |  |  |
| M  | Review & sign of the lab reports  |  |  |  |  |  |  |  |  |  |  |
| N  | Receive the study drug**, ,** document drug dispensing, storage & accountability  |  |  |  |  |  |  |  |  |  |  |
| O  | Person to whom research participants should contact in case of adverse event  |  |  |  |  |  |  |  |  |  |  |
| P  | Report all serious adverse events  |  |  |  |  |  |  |  |  |  |  |
| Q  | Follow up of Serious Adverse Event  |  |  |  |  |  |  |  |  |  |  |
| R  | Maintaining study site master file  |  |  |  |  |  |  |  |  |  |  |
| S  | In-charge of inventory & supplies  |  |  |  |  |  |  |  |  |  |  |
| T  | Archiving of study documents  |  |  |  |  |  |  |  |  |  |  |
| U  | Resolution of queries  |  |  |  |  |  |  |  |  |  |  |
| V  | Overall coordination and supervision  |  |  |  |  |  |  |  |  |  |  |