**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 |  |  |  |  |  |  |  |  |  |  |