

Information and Guidance Document for the Completion of the Site Signature and Delegation of Responsibilities (DOR) Log

The purpose of the Site Signature and Delegation of Responsibilities Log is:

To describe how to complete the Site Signature and Delegation of Responsibilities Log form to fulfill the requirements stated in ICH GCP E6 R2:

- **Section 4.1.5 “the Investigator should maintain a list of appropriately qualified and trained persons to whom the Investigator has delegated significant study –related duties”**
- **Section 8.3.24 “signature sheet”** to document signatures and initials of all persons authorized to make entries and/or corrections on CRFs.

IMPORTANT NOTES

The Site Signature and Delegation of Responsibilities Log must be completed with accuracy and clearly indicate the delegation of tasks throughout the study.

Principal Investigator

- The Principal Investigator (PI) is responsible for the conduct of all tasks and therefore the PI does not delegate tasks to himself/herself in the task section of the log
- The Principal Investigator is responsible for assigning study tasks to medically qualified/licensed staff in accordance with country specific regulations.
 - The evaluation of whether study staff is performing functions within the scope of their professional licensure depends not only on the scope of their licensure, but also on local regulations.
 - Thus, the professional licensing authority in the State(s), Province(s) or Country (ies) in which the study is taking place makes the final determination.
 - Each Principal Investigator must be aware of their local regulations.
- All personnel who have been delegated **significant** study related duties or tasks, which the Principal Investigator would otherwise do, must be listed on the log.

Completing the Log

- Information entered in all sections of the log should be legible and accurate.
- The Principal Investigator and site staff that have been delegated duties/tasks should use the same signature and initials, as provided on the site signature and delegation of responsibility log, when signing and initialing patient records and any study related documents.
- The signature and initial columns need to be handwritten to allow validation of signatures/initials used for study related documentation e.g. consent form, source documents, CRF entry, drug logs, etc.
- The log must be updated in a timely manner as personnel are added or removed and/or study roles and responsibilities change. Changes must be approved by Principal Investigator (PI) before they are implemented (as indicated by PI initials and date).
- All staff delegated to significant study related duties must show evidence of education and training appropriate to the role to confirm that they are qualified to perform the delegated task.

- If extra space is required for any fields, use the next line below.
- If extra rows are needed in the completion of this log then, duplicate the last page of the Site Signature and Delegation of Responsibilities Log.
- If satellite sites are involved in the study, please discuss with your Sponsor how best to complete this log.
- Principal Investigator Initials and Date: The Principal Investigator records his/her initials and date prior to delegation and at any time there are changes/updates to the log.
- The end of study declaration (page 1) is signed by the PI at the conclusion of the study (COV) to attest that the PI acknowledges the delegation and training of staff throughout the trial.
- Pages 1 and 2 are mandatory for use in all instances. Page 3 is a repeating page to be used as needed to capture all delegated staff.

** NOTE – TransCelerate periodically reviews and updates this log, if an issued version of the log changes during a study, no action is required unless requested by the Sponsor.*

COMPLETION OF THE LOG

Study Sponsor:	Enter name of the sponsor company	Principal Investigator:	Enter the name of the Principal Investigator
Protocol Study Number:	Enter the Protocol Study number designated on the protocol	Study site Number:	Enter the study site number. This number is specific for the site.
Country:	Enter the Country in which the study site resides		

Name of Principal Investigator	Principal Investigator's Signature	Principal Investigator's Initials	Date
Enter the legal name of the Principal Investigator	The Principal Investigator signs here.	The Principal Investigator enters his/her initials.	Date is the date the PI initialed and signed the form at the start of the study

Name	Signature <i>My signature below indicates that I accept the study task.</i>	Initials	Study Role	Study Task(s) (Select from key)	PI initials and Date (dd/mmm/yyyy)	End of task (dd/mmm/yyyy) <i>Complete when staff exit during the study</i>	PI initials and Date (dd/mmm/yyyy) <i>Complete when staff exit during the study</i>
Printed Name of person who will have duties/tasks delegated to them.	Signature of the person who has accepted delegated duties/tasks. <i>(Handwritten)</i>	Initials of the person who has accepted delegated duties/tasks. <i>(Handwritten)</i>	The role of the person who as accepted delegated duties/tasks.	A study tasks are listed on the log.	Initial and date by the Principal Investigator to confirm agreement with the start of delegation. <i>(Handwritten)</i>	Date when the duty or task ended during the study <i>(Handwritten)</i>	Initial and date by the Principal Investigator to confirm agreement with the end of delegation during the study

Name

Print or write legibly the full legal names of the site staff members who will be assigned key study tasks related to the clinical study/study. Always record only one name per line.

Signature

Each individual signs the log as the signature will appear on any study related documentation.

Please note, in some regions there may be more than one signature in addition to the English signature; in this case, both signatures should be captured on the log.

Initials

Each individual enters her/his initials as they will appear on any study related documentation.

Initials are generally defined as the first letter of the person's first (given) name and last (family) name. If another way of recording initials is used as a common practice then this can be accepted.

Study Role

Enter the site staff's study-specific role next to his/her name on each line.

Examples of study roles may include but are not limited to:

- Sub Investigator
- Study Coordinator
- Pharmacist
- Study Nurse

Study Tasks

Use the study task key to assign the tasks delegated.

- Record the numbers corresponding to the tasks.
- Numbers recorded can be consecutive numbers, or range, e.g. 1,3,5,6,7 or 1,3,5-7.
- Ensure that tasks are aligned with the roles, expertise and training of the individuals.
- The study tasks identified to completed by Medically Qualified / Trained/Licensed staff are **assessments** of the study data and results.
- The task code 'perform study activities' is intended for staff members who complete routine study tasks and activities.
- SI = Study Intervention [formally Investigational Product (IP)]. This new term aligns with the Common Protocol Template.

“Other” task codes

- May be utilized by the Principal Investigator to specify additional tasks beyond those listed on the log.
- ‘Other’ can be used for significant site activities not included in the task list on the log template.
- May be utilized by the Sponsor when there are significant study related tasks

Changes/corrections to tasks should be made to the log as described below, this includes the correction of any tasks delegated to staff in error

End of task

End date is completed during the course of the study when the individual is:

- No longer working on the trial
- When delegated tasks have changed or ended

For each site staff individual, this may be a different date depending on when his/her involvement in the study has concluded.

Once a staff member is ended; the particular person will not conduct the delegated tasks and any passwords/accesses for study related systems must be terminated.

This column is left blank for staff active at the conclusion of the study.

Principal Investigator initials and date

The Principal Investigator records his/her initials and date at the time of adding to or making changes to the log to acknowledge that the delegations to the staff are correct and to authorize the staff member to start activities.

By initialing the Principal Investigator confirms the staff member is authorized, trained appropriate to the role and qualified to perform the tasks assigned to him/her.

Tasks may not be performed by the staff member without or prior to the Principal Investigator's initials and date.

Investigator Site Comments

- Included for the Principal Investigator and/or site staff to explain or comment on the delegation log during the course of the study.

CHANGES THAT OCCUR DURING THE COURSE OF THE STUDY

Change of Principal Investigator:

If during the study, there is a change in the Principal Investigator (PI) the following documentation must be made.

OPTION 1 (start a new log)

- Outgoing PI will sign and date the PI signature line on the bottom of page 1.
- Enter a statement in the comment section of the form to indicate there was a change in PI.
- The new PI will start a new DOR form by signing and dating a new page 1.
- Delegation by the new PI for all site staff is documented on the new form. Date = Date new PI signed new form.

OPTION 2 (keep existing delegations and start a new log)

- Enter a statement in the comment section of the form to indicate there was a change in PI.
- The new PI will start a new DOR form by signing and dating the top section of a new page 1
- The new PI will enter a statement in the comments section of the original DOR form agreeing with the existing delegations.
- Changes or new additions to the DOR that occur after a new PI begins will be made on the new DOR log.

Role or key Study Tasks change

- If there are any changes to the role and/or study tasks for an individual, the current delegation line should be updated with an end date. A new line is then started with the updated delegated study tasks. The new line must be initialed and dated by the PI.
- Task(s) newly added to previously authorized staff member may be added in another line, initialed and dated by the PI to reflect the new authorization

Name changes during the study

- Staff will sign and initial a new line on the log to reflect the signature and initials used in the study records
- A comment should be added to the 'Investigator Site Comments' box to explain the change and the start date of the change