Site Qualification and Training (SQT)

INFORMATION AND GUIDANCE SHEET FOR SITE SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

TransCelerate BIOPHARMA INC.
ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

INFORMATION AND GUIDANCE SHEET FOR THE COMPLETION OF THE SITE SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG

The purpose of the Site Signature and Delegation of Responsibilities Log

To fulfill the requirements stated in **ICH GCP E6 Guideline 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"** and to document study-specific roles and responsibilities assigned to all staff on the study team by the Investigator.

To fulfil the requirement in **Section 8 of ICH GCP 8.3.24 "signature sheet"** to document signatures and initials of all persons authorized to make entries and/or corrections on CRFs.

Important notes

- 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. The intention of the log is not to capture every task that an individual may perform, but to list the study personnel and the key study duties/tasks that they have been delegated. This would be any duty/task that could impact significantly on subject safety, protocol compliance, quality and the integrity of the study data. A selection of study tasks have been listed on the log, however protocols may have additional tasks not listed. It is important to work with the sponsor to define additional study specific tasks and add them to the 'Other' section on the log.
- Information entered in all sections of the log should be legible and correct. The Principal Investigator and site staff who 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 before they are implemented (as indicated by his/her initials).
- 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. 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 investigational site should be aware of their local regulations as to what the scope of practice is.
- **Change of Principal Investigator.** If during the course of the study there is a change in the Principal Investigator the current Principal Investigator should complete the end date,(END column in the table), as the final date on the study. The new Principal Investigator should complete a new log. The new Principal Investigator may specify in the comments section that he/she has reviewed all previously delegated tasks and is in agreement with the delegations or to clarify any changes in delegated tasks for site staff members.
- **Role or Key Study Tasks Change.** The Principal Investigator is required to initial and date changes to confirm and acknowledge any additional or deleted tasks. If the role of a staff member changes during the course of the study, an end date should be entered at the time the role is no longer being completed by the individual. If there are any changes to 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. It is important to ensure that it is clear on the log what tasks the individual has been delegated to perform.
- 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 third page of the Site Signature and Delegation of Responsibilities Log and number pages accordingly (3a,3b,etc).
- If satellite sites are involved in the study please discuss with your Sponsor how best to complete this log.
- The original log should be retained at the site and kept up to date. Determine with the Sponsor what their requirements are.

The 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:	Country in which the study site resides		

Name of Principal Investigator	Principal Investigator's Signature*	Principal Investigators Initials	Start *(dd/mmm/yy)*	End *(dd/mmm/yy)*
Enter the legal name of the Principal Investigator.	The Principal Investigator signs here.	The Principal Investigator enters his/her initials.	This date records the commencement of any study related activities.	This date records the cessation of all Principal Investigator study related activities due to the study ending or a change in Principal Investigator.

In the event that the Principal Investigator changes, the end date will be recorded and a new log will be completed by the new Principal Investigator prior to them commencing any study activities. Both the original and the new log will be held by the site.

Name	Signature *(my signature below indicates that I accept the study task.)*	Initials	Study Role	Study Task *(Select from key)*
Name of person who will have duties/tasks delegated to them.	Signature of the person who has accepted delegated duties/ tasks.	Initials of the person who has accepted delegated duties/ tasks.	Identity the role of the person who as accepted delegat- ed duties/tasks.	A selection of study tasks is listed on the log and in this guidance.

Start of task *(dd/mmm/yy)*	PI Initials	End of task *(dd/mmm/yy)*	PI Initials
Date of when the duty or task was delegated.	Initials by the Principal Investigator to confirm this delegation.	Date when the duty or task ended or when the study was completed.	Initials by the Principal Investiga- tor to confirm that the duty or task has ended.

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 assigned a task must sign in the column next to their name. This signature will be used to compare entries made later on study related documentation by the individual. **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 their 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, or 1-4; 8-11. Ensure that tasks are aligned with the roles, expertise and training of the individuals. If there are additional study-specific tasks that are not included on the log, use the "Other" designation and specify the task. Consult the Sponsor on what these tasks may be.

1. *Coordinates IRB/ EC communications*
2. *Screens/recruits study subjects*
3. *Obtains Informed Consent*
4. *Confirms eligibility (Inclusion/ Exclusion)*
5. *Obtains medical history*
6. *Performs physical examination*
7. *Conducts study visit procedures*
8. *Makes study related medical decisions*
9. *Evaluates study related test results*
10. *Performs study-related assessments*
11. *Assesses AEs/SAEs*
12. *Reports SAEs*
13. *Stores study drug and monitors temperature*
14. *Collects samples*
15. *Processes biologic sample and ships sample*
16. *Uses IWRS/IVRS*
17. *Makes entries/ corrects e/CRFs*
18. *Signs-off e/CRFs*
19. *Resolves data queries*
20. *Maintains essential documents*
21. *Prepares/dispenses study drug/device*
22. *Manages study drug/device accountability*
23. *Activities related to Regulatory submissions*
24. *Activities related to code break*
25. *Other (*)*
26. *Other (*)*
27. *Other (*)*
28. *Other (*)*

Start of task *(format: dd/mmm/yy)*

"Start" indicates the start date when the individual has been delegated study tasks (not necessarily when the Principal Investigator has added the staff to the study team). Note: All study training appropriate to the role should be completed prior to the delegation of the task. No study related tasks can be performed prior to training.

End of task *(format: dd/mmm/yy)*

"End" indicates the date when the individual is no longer participating on the study. For each site staff individual, this may be a different date depending on when their involvement in the study has concluded. The "End Date" should be left blank unless the individual's involvement concluded prior to the end of the study, at which point, an end date should be entered. If no entry is made in this column, it is assumed that the tasks were conducted until the completion of the study (the date of the close-out visit). After "End Date", the particular person will not undertake any delegated tasks and all passwords/accesses for study related systems must be terminated.

Principal Investigator Initials

The Principal Investigator records his/her initials at the time of adding to or making changes to the log to acknowledge that the delegations to the staff are correct. By initialing the start, the Principal Investigator confirms the particular staff member is authorized, trained appropriate to the role and qualified to perform the tasks assigned to him/her. This information about the staff member is not complete without the Principal Investigator's initials. Once the particular staff member is no longer delegated to the task the Principal Investigator must initial to verify this fact.

Comments

The Principal Investigator may use this space to clarify any changes that were not possible to document on the log. An example can be acknowledgement by the new Principal Investigator that he/she has reviewed and is in agreement with tasks delegated by the previous Principal Investigator.

At the conclusion of the study, the log should be signed and dated in the designated area by the Principal Investigator after reviewing all entries for accuracy. The completed log should remain at the site in accordance with Sponsor requirements.