SIGNATURE LOG AND DELEGATION OF DUTIES: GUIDANCE & TEMPLATE

Purpose

The responsibilities of the site Principal Investigator (PI) are outlined in Section 4 of the Integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) (herein referred to as ICH GCP). Usually the PI will delegate many of these responsibilities to members of the study team. In accordance with **ICH GCP E6 Guideline Sections 4.1.5,** and **8.3.24** a Signature and Delegation of Duties log must be maintained at the site to demonstrate which tasks have been delegated and to whom and capture the signature and initials of the PI and all staff. The log must be updated regularly to document changes in staff responsibilities throughout the study. This log may also be kept as either a hard paper copy or in an ICH GCP compliant electronic system.

Instructions for completing and maintaining the (e)Signature and (e)Delegation of Duties Log

- All persons who have been delegated significant study related duties or tasks, must be listed on the log.
- All duties/tasks that could impact significantly on subject safety, protocol compliance, quality and the integrity of the study data must be delegated. A selection of study tasks have been listed on the template log, however protocols may have additional tasks not listed. It is important to work with the study Sponsor/site PI to identify 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 initialling 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 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. Evidence of relevant training and qualifications must be maintained in the site Investigator File and study-specific training documented in the study-specific training log.
- 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 Signature and Delegation of Duties Log), as the final date they were on the study. The new Principal Investigator should complete a new Signature and Delegation of Duties 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. Both the original and the new log will be held by the site.

- 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.
- 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.
- If extra space is required for any fields, use the next line below.
- The original log should be retained at the site and kept up to date. The Sponsor may take a photocopy for their records. This does not need to be a certified copy as it is not replacing the original document.
- Investigators may like to include a **COMMENTS** section in the template. 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. The Sponsor may take a photocopy for their records. This does not need to be a certified copy as it is not replacing the original document.

For additional information/guidance, please refer to http://www.transceleratebiopharmainc.com/wp-content/uploads/2015/04/TransCelerate-Site-Signature-DOR-Guidance-JUNE.pdf murdoch children's research institute

SIGNATURE AND DELEGATION OF DUTIES

Protocol Name/No:	
Study Sponsor:	**Site Name:**

Name of Principal Investigator	Principal Investigator's Signature	Principal Investigator's Initials	Start (dd/mmm/yyyy)	End (dd/mmm/yyyy)

Staff with delegated duties/tasks

Print Name	Signature	Initials	Study Role (e.g. study nurse, pharmacist)	Task(s) Delegated	Authorised/Confirmed by the Principal Investigator	
					Start Date (dd/mmm/yyyy)/ Initials	End Date (dd/mmm/yyyy)/ Initials

1. Coordinates HREC communications
2. Screens/recruits study participants
3. Obtains Informed Consent (inc. sign off)
4. Confirms eligibility (inclusion/exclusion
5. Obtains medical history
6. Performs physical examination
7. Maintains essential documents
8. Activities related to regulatory submissions
9. Conducts study visit procedures
10. Makes study related medical decisions
11. Evaluates study related test results
12. Performs study related assessments
13. Assesses AEs / SAEs
14. Reports SAEs
15. Prepares/dispenses study drug/device (investigational product)
16. Activities related to code break
17. Stores study drug and monitors temperature
18. Collects Samples
19. Makes entries / corrects e/CRFs
20. Processes biologic sample and ships sample
21. Signs off e/CRFs
22. Resolves data queries
23. Manages study drug/device accountability
24. Randomisation (e.g. IVRS)
25. *
26.
27.

*Cells left blank for possible additional categories, eg: Follow-up phone calls, provision of discharge instructions, study specific procedures (specify these)