

WORK INSTRUCTION

Title: Completing Signature and Delegation Logs at Melbourne Children's

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1. PURPOSE

This Work Instruction (WI) supports the Principal Investigator (PI) and site team members to meet their documentation of delegation requirements in accordance with [MCTC194a SOP Trial-Specific Qualification, Education, and Training - Clinical Trial Team Members](#).

2. BACKGROUND

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 a) demonstrate which tasks have been delegated and to whom and b) capture the signature and initials of the PI and all staff involved with the study. The log must be updated regularly to document changes in staff responsibilities throughout the duration of the study.

3. SCOPE

This WI applies to all staff conducting clinical trials at Melbourne Children's at the Site level: the PI, sub-investigator(s), research coordinators and all other staff delegated research-related activities by the PI.

This WI (and associated template [MCTC025b Template | Signature and Delegation Log](#)) has been designed for use in clinical trials. However, it may also be used for other types of research projects at the discretion of the PI/study Sponsor.

The scope of this WI includes the process for completing hardcopy (paper) and electronic Signature and Delegation Logs using [MCTC025b Template | Signature and Delegation Log](#). This includes the log templates in Florence.

4. RESPONSIBILITY

The PI is responsible for ensuring the site Signature and Delegation Log is maintained and current and that delegation of tasks is documented in accordance with this WI.

Site trial team members are responsible for ensuring their delegation is recorded and signed off before they commence these activities in accordance with this WI.



5. RELATED DOCUMENTS

[MCTC017a Work Instruction | Completing Training Logs at Melbourne Children's](#)

[MCTC017b Template | Trial-Specific Training Log](#)

[MCTC025b Template | Signature and Delegation Logs](#)

[MCTC098 Template | Wet-Ink Signature Log](#)

[MCTC099 Form | Wet Ink Signature Page](#)

[MCTC194a SOP | Trial-Specific Qualification, Education, and Training – Clinical Trials Team Members, v1.1](#)

[MCTC214 Work Instruction | Change of Investigator for Commercially Sponsored Trials \(CSTs\)](#)

[MCTC221 Form | Change of Investigator Acknowledgement form](#)

6. INSTRUCTIONS

6.1. 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 delegation log. This includes the PI, who has delegated tasks to themselves.
- All tasks that could impact significantly on participant safety, protocol compliance, quality and the integrity of the study data must be delegated.
- A selection of study tasks have been pre-listed on the template log ([MCTC025b Template | Signature and Delegation Log](#)), however studies may require additional tasks not listed. It is important to work with the study Sponsor/ PI to identify these additional study specific tasks.
- When adding new study-specific tasks to the log, add a new number to the study task key, use the "Other" designation, and specify the task.
- Log lines must be filled out by a member of the study team.
- Use the study task key to assign delegated tasks. 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 delegated tasks are aligned with the roles, expertise and training of the delegated individual.
- If extra space is required for any fields, use the next line below.
- Information entered in all sections of the log should be legible and correct.
- The start date of each team members delegation is the date of PI signature in the “Authorised by the PI” column. Team members must not commence any delegated tasks until after the PI has signed them on.
- The end date needs to reflect the team member’s last day of work on the trial. Therefore, we require both the actual end date and the PI confirmation of the end date. These dates may be different.
- The delegation log must be updated in a timely manner as team members join or depart the team and/or study roles and responsibilities change. Changes must be authorised by the PI (as indicated by their signature and date) before they commence any of their delegated duties.
- If any team member needs to document or clarify anything that is not possible to document on the log, a file note should be used.
- At the conclusion of the study/once archiving has been completed, all staff should be signed off (all log lines completed and fully signed), and the log signed and dated in the designated area by the PI after reviewing all entries for accuracy¹.
- The original log/s should be retained at the site. The Sponsor may take copy/ies for their records. These do not need to be certified copies as they are not replacing the original document.

6.2. Hard copy vs Digital Logs

- Logs may be kept as either a hard paper copy or in an ICH GCP compliant electronic system (eg. Florence, SiteDocs).
- An individual log cannot use a combination of hard copy and digital methods. Logs must be filled out and signed either in wet ink (hard copy) or using digital signatures (eLogs).
For example, an eLog cannot be printed and filled in/signed with a wet ink signature and then uploaded into an electronic system for subsequent signing with digital signatures.

¹ In Florence, this is done by “finalising” the log. In hard copy, this is done by completing the end date and signing off the log



- If both hard copy and digital logs are required for a study, due to unavoidable circumstances, then that study will have to have two separate logs – one hard copy with wet ink signatures and one digital with digital signatures.

6.3. Signatures

- Study team members signing the delegation log must sign their own line.
- Study team members signing the delegation log must sign with or before the PI.
- If signing electronically, delegation logs must be signed using Validated Digital Signatures. For more information, see [MCTC178 Factsheet | eSignatures and Digital Signatures](#).
- If there is a delay between the study team member and PI signing, for example a pharmacist signing a hard copy log, the study team member cannot commence their delegated duties or tasks until the PI has signed.
- Given this potential for delays, it is best practice to send an email to the newly delegated team member once all signatures have been received, confirming they can now start work on the study.
- It is essential that there is a record of the handwritten initials and signatures of the study team in the ISF (and/or the TMF, as applicable). This is to allow validation of signatures/initials used for study related documentation e.g. consent form, source documents, CRF entry, logs, etc.
 - For hard copy (wet ink) logs, the signature and delegation log functions as this record.
 - For digital (e)Logs, this record should be kept separately.
 - If eLogs are being kept in Florence, [MCTC099 Form | Wet Ink Signature Page](#) is used for this, and is “shortcutted” from the Florence Central Files to the trial-specific ISF.
 - If eLogs are NOT being kept in Florence, [MCTC098 Template | Wet-Ink Signature Log](#) is used for this. This document should be kept in the trial-specific ISF.
- The PI and delegated team members should use the same signature and initials, as documented on the signature and delegation log (or elsewhere, in the case of eLogs), when signing and initialling participant records and any study-related documents.
- All Florence signatures are automatically time & date stamped. Therefore, in Florence eLogs there is no need for start & end dates. Start and End dates of delegation are captured in the PI authorisation of start date & PI confirmation of end date columns.



6.4. Role, Key Study Tasks, or Name Change:

- If there are changes to study tasks for an individual, a new line should be started with the updated delegated study tasks. In this case, the individual will have two active lines on the Delegation Log. The PI should sign both lines as relevant, when tasks are commenced/ceased.
- If the role of a study staff member changes during the study, the current delegation line should be updated with an end date. A new line is then started with the updated role, if there is one. The PI should sign both lines as relevant, when tasks are commenced/ceased.
- In the event of a name change (e.g., marriage), sign the staff member off the log under their old name, and start a new line with their new name.

6.5. Permanent Change of Principal Investigator, hard copy/wet ink logs:

If this is a permanent change (as defined in [MCTC214 Work Instruction | Change of Investigator for Commercially Sponsored Trials \(CSTs\)](#)), follow these steps, in this order, after all relevant approvals have been received:

- The original PI signs themselves off the log.
- Both the outgoing and the incoming PIs sign [MCTC 221 Change of PI Acknowledgement form](#). This form documents that the incoming PI has reviewed all previously delegated tasks and agrees with the delegations by the outgoing PI.
- This form is then filed in the same folder as the Delegation Log
- The new PI begins a new Signature and Delegation of Duties Log. This new log contains only the incoming PI and any staff delegated after the change of PI.
- Staff delegated before the change of PI do not have to sign the new log, so the study has two active Delegation logs.
- Both logs are held by the site in the ISF.

6.6. Permanent Change of Principal Investigator, digital/eLogs:

If this is a permanent change (as defined in [MCTC214 Work Instruction | Change of Investigator for Commercially Sponsored Trials \(CSTs\)](#)), follow these steps, in this order, after all relevant approvals have been received:

- The original PI signs themselves off the log.
- Both the outgoing and the incoming PIs sign [MCTC 221 Change of PI Acknowledgement form](#). This form documents that the incoming PI has reviewed



all previously delegated tasks and agrees with the delegations by the outgoing PI².

- This form is then filed in the same folder as the Delegation Log.
- The New PI signs themselves onto the log, in their new role as PI.
- The new PI changes the name of the PI in the “Log Details” section to be their name, which is time and date stamped and saved in the Delegation log.

6.7. Temporary Change of PI (hard copy/wet ink and digital/eLogs)

If this is a temporary change (as defined in [MCTC214 Work Instruction | Change of Investigator for Commercially Sponsored Trials \(CSTs\)](#)), follow these steps, in this order, after all relevant approvals have been received:

- The original PI delegates the temporary PI to the role of PI.
- The original PI signs themselves off the log.
- When the original Principal Investigator returns, they sign themselves back onto the Delegation Log prior to undertaking any study-related activity.
- Simultaneously, the original PI ends the temporary PI in their role as the PI and reassigns them as appropriate.

7. DISSEMINATION AND TRAINING

This WI and associated templates and forms will be made available via METIS.

All staff with duties and responsibilities covered by this WI should ensure they take time to read and understand the content of this WI.

DOCUMENT END

²If your digital/eLog software allows it, for example like Florence, you can upload this document and sign it using this software (for example, using the “stamp” signature in Florence).

