WORK INSTRUCTION

Title: **Completing Trial-Specific Training Logs by trial site teams at Melbourne Children's**

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Document History

Revision	Modified by	Effective Date [DD/MMM/YYYY]	Description of Change
1.0	Sarah Rathjen	14/OCT/2025	New Issue

Contents

1. PURPOSE

This Work Instruction supports the members of the clinical trials workforce at Melbourne Children's to meet their documentation of training requirements, in accordance with MCTC194a SOP Trial-Specific Qualification, Education and Training - Clinical Trial Team Members.

2. BACKGROUND

In accordance with ICH GCP E6 (R2) Guideline Sections 4.2.4 – 6 and ICH GCP E6 (R3) Guideline Sections 2.3.2 and C.3.3, a Training log must be maintained at the site as documented evidence that the Principal Investigator and all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties. The log must be updated regularly to document changes in staff training throughout the duration of the study.

3. SCOPE

This WI applies to all staff in MCRI/RCH site trial teams. See Table 1 for a listing of typical site trial team members.

Key personnel in the **MCRI/RCH SITE TRIAL TEAM**
1. Site Principal Investigator (PI)
2. All Associate/Sub-Investigators
3. Clinical Trial Pharmacist
4. Trial/Study Coordinators and Research Nurses
5. Clinical Trial Assistants (if applicable)
6. Data Manager/s (if applicable)
7. Ancillary staff

Table 1 – Key personnel in MCRI/RCH Site Trial Teams

This WI (and associated MCTC017b Template | Trial-Specific Training Log template) 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.

4. RESPONSIBILITY

In the case of a clinical trials team, ultimately, this process is the responsibility of the Principal Investigator.

However, all staff covered by this document are directly responsible for ensuring they are

qualified and capable to undertake their delegated tasks, and that their training is recorded and signed off before they commence these activities.

The responsible investigator[1] is responsible for ensuring their trial team members are documenting their trial-specific training in trial-specific training logs that are maintained in the Investigator Site File.

5. RELATED DOCUMENTS

MCTC194a SOP Trial-Specific Qualification, Education and Training - Clinical Trial Team Members

MCTC017b Template | Trial-Specific Training Log

6. INSTRUCTIONS

MCTC017b Template | Trial-Specific Training Log is a log for documenting trial-specific training.

Complete this log to document the "trial-specific training" described in MCTC194a SOP Trial-Specific Qualification, Education and Training - Clinical Trial Team Members.

Maintain one log per study to record trainings received by clinical trial team members

6.1 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.
- 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.

6.2 Completing clinical trial-specific training logs

- Log lines should be filled out by a member of the clinical trials team.

[1] PI/SI/etc.

- Clinical trials team members signing the training log MUST sign their own line.
- Additional rows/pages should be added as required for the study needs.

6.3 Use of Sponsor Portals

Some external Sponsors may require the site team to document their trial-specific training in the Sponsor's portal.

If a Sponsor portal can provide current training records that meet the minimum requirements of a training log (as listed below), which can be downloaded and filed in the ISF, then it DOES meet our minimum standards. In this case, trial team members should follow the Sponsor's process for documenting training in the portal, as well as the processes described in this document (sections 6.2, 6.3).

If a Sponsor portal does NOT meet our minimum standards for documentation of training, then one of the templates named in this document must be used (section 6.1).

In order to meet our minimum standards, a training log or portal must have all of the following fields:

- Who provided the training
- Who attended the training
- What documents were used in the training OR what topic was the training on (including version numbers and dates
- Date the training was provided
- How the training delivered (e.g. in person, self-directed online, match template examples)

7. REGULATORY CONSIDERATIONS USING TRAINING LOGS

Date of training is included in the Training Log templates because it allows for better cross-matching of dates between the Training Log and the Delegation Log (in clinical trials), allowing for direct confirmation that study team members are trained in the tasks they have been delegated, before or at the same time as they were delegated.

The training provider column is used to document who provided the training. GCP and the other relevant regulations and guidelines do not require the name of the individual presenting the training, nor their signature. They simply require identification of the body delivering the training.

For commercially sponsored clinical trials, the training provider is usually the Global/Local Sponsor or Local CRO. For investigator-initiated studies, this may be the Sponsor-Investigator or may be one of the education bodies on Campus (CRDO, Data Office, CEBU, etc).

If the name of the training provider is not sufficient, external bodies (monitors, auditors, inspectors, etc) can ask the study team for alternate documentation.

There is no requirement to have an individual column for PI signature on a training log in any of the relevant national and international guidelines and standards.

8. 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