

# Standard Operating Procedure

**Title:** Clinical Trial Staff Qualifications and Trial-Specific Training and Documentation Requirements – Good Clinical Practice and Trial-Specific

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## Document History

Revision	Modified by	Effective Date	Description of Change
1.0	Sarah Rathjen	16/08/2024	New Issue
1.1	Sarah Rathjen	22/11/2024	Minor change to accept non-CRDO endorsed GCP courses. Transclerate recognition now required in these cases.
2.0	Sarah Rathjen	13/10/2025	<ul style="list-style-type: none"><li>• Addition of requirements for ancillary staff</li><li>• Link to MCTC017a and MCTC017b (Work Instruction and template related to Training Logs)</li><li>• Link to MCTC025a and MCTC025b (previously one document MCTC025 but now separated into separate Work Instruction and Template for trial delegations)</li></ul>



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## 1. PURPOSE

All staff involved in clinical trials must be appropriately trained for the role they are carrying out, and document that training in a way that demonstrates to external reviewers that their training and experience are adequate for their role. The purpose of this Standard Operating Procedure (SOP) is to:

- a) Define the necessary qualifications and training required of members of multidisciplinary Clinical Trials Team members involved in developing, conducting, and providing services to clinical trials across the Melbourne Children's Campus (MCC).
- b) Ensure that there is documentary evidence that team members have the required qualifications and training to successfully perform in their role as a member of the Clinical Trials Team
- c) Ensure there is a process for Clinical Trials Team members to maintain currency of qualifications, and training.

### 1.1. Quality Improvement

Clinical trials rely on a highly trained and skilled workforce. Staff working in clinical trials routinely undergo additional training and education, which is regularly refreshed to ensure currency of skills and knowledge in line with current procedures, policies, and principles relevant to both individual trials and national/international guidelines.

This SOP provides clear instructions to the clinical trials workforce regarding their training requirements, thereby supporting the conduct of quality research.

### 1.2. Participant Safety

The processes described in this SOP are designed to support clinical trials staff working as part of a Clinical Trial Team to be appropriately qualified for their role.

Key areas where this will be most impactful for participant safety include, but are not limited to, better understanding of:

- Principles of informed consent, including autonomy and understanding of risks and benefits.
- Better understanding of the difference between standard of care and above standard of care procedures, and the burdens that participation in a trial may place on participants
- Monitoring and reporting safety events related to trial participants and trial staff.
- Risk-based approaches to managing participant safety, including controls/mitigation strategies

Improved staff skills, knowledge and accountability lead to high-quality and safe participant care, and the responsible conduct of research.



## 2. BACKGROUND

The responsible Investigator<sup>1</sup> is responsible for their team members and for the conduct of the trial, in accordance with applicable regulatory and local requirements:

- The ICH Good Clinical Practice (GCP) standard, and the TGA's Integrated Addendum to it
- the [National Statement on Ethical Conduct in Human Research](#)
- the National Clinical Trials Governance Framework (NCTGF)
- National SOP 03
- conditions of Ethics approval
- policies of the Research Ethics and Governance (REG) Office
- this SOP

This includes ensuring that they, and their entire Clinical Trials Team, are qualified by education, training, and experience commensurate with their roles and responsibilities, and that their delegation practices meet regulatory, NCTGF, and MCC requirements.

## 3. SCOPE

### 3.1. Who does this document apply to?

This SOP applies to staff involved in the conduct of clinical trials across the MCC including those developing, conducting, and providing services to clinical trials, and those interacting with participants and/or their samples/data across MCRI-sponsored, investigator initiated, and externally sponsored clinical trials.

Examples of these roles could include, but are not limited to:

- Clinical trials staff across the MCC conducting and providing services to externally sponsored clinical trials.
- Clinical trials staff across MCC developing, conducting and providing services to MCRI-sponsored investigator-initiated trials.
- Third-party service providers, contractors, or consultants for clinical trials.

This SOP does not apply to the following people:

- Clinical Staff who do not interact with clinical trial participants, and are not involved in clinical trial tasks.
- HREC members/REG Office Staff<sup>2</sup>
- Consumers, Consumer Representatives, and Lay People who may be involved as

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<sup>1</sup> PI/SI, etc.

<sup>2</sup> At time of writing



- representatives in clinical trial steering committees, or in other capacities
- External Participating Sites

In this document, the term “Clinical Trials Team” covers both the Site Trial Team and the Central Trial Coordinating Team. This SOP applies equally to all members of the Clinical Trials Team. All references to the Clinical Trials Team as a group here include the responsible Investigator<sup>3</sup>, unless otherwise specified.

Examples of the roles that make up Clinical Trials Teams can be found in Table 1 below.

Key personnel in the <b>MCRI/RCH SITE TRIAL TEAM</b>	Key personnel in the <b>CENTRAL TRIAL COORDINATING TEAM (MCRI-sponsored trials ONLY)</b>
<ol style="list-style-type: none"> <li>1. Site Principal Investigator (PI)</li> <li>2. All Associate/Sub-Investigators</li> <li>3. Clinical Trial Pharmacist</li> <li>4. Trial/Study Coordinators and Research Nurses</li> <li>5. Clinical Trial Assistants (if applicable)</li> <li>6. Data Manager/s (if applicable)</li> <li>7. Ancillary staff</li> </ol>	<ol style="list-style-type: none"> <li>1. Sponsor-Investigator (SI)</li> <li>2. All other Investigators listed on the protocol</li> <li>3. Clinical Trial Manager/Coordinator (Lead/Back-Up, if applicable)</li> <li>4. Clinical Trial Assistants (if applicable)</li> <li>5. Statistician/Biostatistician</li> <li>6. Data Manager/s (if applicable)</li> <li>7. Database Manager/Programmer (if applicable)</li> <li>8. Trial and-Medical Monitors</li> </ol>

Table 1 -MCRI/RCH Site Trial Team vs Central Trial Coordinating Team

### 3.2. What tasks does this SOP cover?

This SOP applies to tasks involved in the conduct of individual clinical trials across the MCC. This includes trial-specific qualifications, training, and delegations, and the mandatory training required of clinical trials staff (ICH GCP certification).

While members of the clinical trial workforce often require additional training and qualifications to work in their role effectively (e.g., CAAA IATA Safe Transport of Infectious Substances by Air, Responsible Data Usage), this additional training applies equally across all trials. This SOP only covers GCP, and the qualifications/training required to work on specific, individual trials (“trial-specific training”).

This additional “role-specific” training (e.g., Melbourne Children’s SOPs, CAAA IATA Safe Transport of Infectious Substances by Air, Responsible Data Usage) will be covered in MCTC194b SOP (in development)..

<sup>3</sup> PI/SI, etc.



## 4. RESPONSIBILITY

Ultimately, this process is the responsibility of the Investigator. However, all staff covered by this SOP are directly responsible for implementing the procedures set out in this SOP, ensuring they are qualified and capable to undertake their assigned role, and maintaining their training records and documentation of delegated tasks as appropriate.

The responsible Investigator depends on the situation:

- In the case of the Central Trial Coordinating Team on an MCRI-Sponsored trial, the **responsible** Investigator is the **Sponsor-Investigator**
- In the case of the Site Trial Team, the **responsible** Investigator is the **Principal Investigator**

It is recognised that staff join and leave teams as part of normal practice, and that new staff members joining teams must be trained in all relevant trial systems and procedures, so that they can meet the requirements of the research. Depending on the structure of the unit, this training may be the responsibility of the responsible Investigator or their Manager.

## 5. PROCEDURE

All trial-related training within the scope of this SOP must meet the minimum standards defined in this SOP.

### 5.1. Evidence of Training

The evidence required to demonstrate adequate staff qualifications and training include, but are not limited to:

- Qualifications and evidence of an appropriate level of experience (e.g., CV, registrations, licenses, etc)
- Evidence of training course completion, e.g. GCP certificate
- Trial-specific training logs, other trial-specific training documentation

These documents will be referenced and/or linked to throughout this SOP where appropriate.

### 5.2. Workflow

See [Appendix 1: Summary of Roles and Responsibilities](#)

See [Appendix 2: GCP Training Options Flowchart](#)

### 5.3. Good Clinical Practice (GCP) Training



### 5.3.1. What is GCP?

The ICH GCP standard is an internationally accepted framework that can be used for conducting ethical and high-quality human participant research.

GCP training (training to the ICH GCP standard) is a mandatory requirement for all members of a Clinical Trials Team as per *RCH Investigators Responsibility in Research Procedure* (available on PROMPT, excerpted below). It must be completed every three years, at a minimum.

*“If the research is a clinical trial, the PI must ensure that the investigative team have successfully completed Good Clinical Practice (GCP) training within the last three years using a Transclerate-accredited course; this includes all Investigators, study coordinator, research nurse, pharmacist, and anyone undertaking a trial-specific procedure that is additional to standard of care. It is strongly recommended that all investigators for other clinical research also complete GCP training.”*

GCP training is highly recommended for all staff working in Human Participant Research.

The ICH GCP standard is updated infrequently. However, when updates do occur and are ratified by the TGA, all Clinical Trials Team staff must undergo training in the updated standard as soon as practicable, regardless of where they are at in their 3-year timeline.<sup>4</sup>

### 5.3.2. GCP Training for the Site Trial Team

Site Trial Team members have the following options to complete GCP training at MCC:

- [CRDO Good Clinical Practice = Good Research Practice](#) Workshops (in-person)
- [A-CTEC Good Clinical Practice = Good Research Practice](#) Online Course (virtual)

The in-person CRDO workshops are preferred over the A-CTEC online course for GCP certification.

However, if a team member requires GCP certification immediately, or there will be a material impact on their trial, the A-CTEC online course can be completed instead.

GCP courses not on the above list are not recommended.

Site Trial Team members who attend the CRDO in-person workshops and complete the quiz after will automatically have their certificate saved in Florence and their certification expiry date set by CRDO. An email will be sent prior to the expiry date of their

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<sup>4</sup> In this circumstance, CRDO will advise all members of the clinical trials team exactly what they must do, when, and how, to update their GCP certification.



certification, with a reminder to rebook into a GCP training session.

Site Trial Team members who complete the A-CTEC online course, and pass the quiz, have two options to save their certification:

1. If they have access to Florence, upload the certificate to their Central Personnel File and set the expiry date as two (2) months prior to their certificate's expiry date themselves
2. Send their certificate to the Florence Inbox (florence@mcri.edu.au) with the subject line GCP CERTIFICATE FOR FILING, so it can be recorded and filed in Florence.

Following either of the above steps will ensure that completion of this training is recorded and a reminder email is sent prior to the expiry date of their certification.

If you have done a GCP course not on the above list, please upload/send (as above) both the GCP certificate and proof of [Transcelerate recognition](#). Contact CRDO (crdo.info@mcri.edu.au) to discuss further.

If any department or personnel have concerns about using Florence for this purpose, contact the Florence Administrator at florence@mcri.edu.au. For storage in a central location outside of Florence, see [Section 5.4.3](#).

### 5.3.3. GCP Training for the Central Trial Coordinating Team

There are additional GCP requirements for Sponsors. As representatives of the Sponsor, these additional requirements apply to the members of the Central Trial Coordinating Team.

Depending on the nature of the Clinical trial, members of the Central Trial Coordinating Team may need to complete a full<sup>5</sup> GCP course instead of the A-CTEC or CRDO courses discussed above to fulfil both their Site and Sponsor requirements. This will be determined by as part of the Sponsorship approval process.

[The NIDA GCP course](#) is the recommended full GCP course. Other courses are not recommended and may not be accepted (assessed on a case-by-case basis). Contact CRDO (crdo.info@mcri.edu.au) to discuss further.

Members of the Central Trial Coordinating Team have the same two options to save their certification as the Site Trial Team members:

1. If they have access to Florence, upload the certificate to their Central Personnel File and set the expiry date as two (2) months prior to their certificate's expiry date

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<sup>5</sup> A "full" GCP course covers the whole of the ICH GCP standard and includes both Site and Sponsor responsibilities.



themselves

2. Send the certificate to the Florence Inbox (florence@mcri.edu.au) with the subject line GCP CERTIFICATE FOR FILING so it can be recorded and filed in Florence.

Following either of the above steps will ensure that completion of this training is recorded and a reminder email is sent prior to the expiry date of their certification.

If any department or personnel have concerns about using Florence for this purpose, contact the Florence Administrator at florence@mcri.edu.au. For storage in a central location outside of Florence, see [Section 5.4.3](#).

## 5.4. Trial-Specific Requirements

Each clinical trial comes with its own specific training and qualification requirements in addition to GCP training.

Clinical trials staff often work across multiple trials. While storing multiple copies of the same document in multiple places may seem inefficient, for every trial there must be a copy of the training records and qualifications for each team member within that trial's file, or a file note stating where they are located.

### 5.4.1. Qualifications

The PI is responsible for ensuring all members of the Site Trial Team are appropriately qualified by education, training, and experience, and have the necessary skills and abilities, to carry out any trial-related responsibilities and tasks they are delegated while working on a trial.

All Site Trial Team members are responsible for keeping records of their qualifications up to date. These are stored in the Investigator Site File (ISF) and should include a signed and dated<sup>6</sup> CV updated within the last 3 years, GCP certificates, registration and licenses, etc.

Copies of them should be available for review (upon request) for the duration of the trial.

The requirements for documenting and filing qualifications are the same for the Site Trial Team and the Central Trial Coordinating Team, except that the Sponsor-Investigator is responsible for the qualifications of the Central Trial Coordinating Team (not the Site PI).

For more information on the qualifications required from a Sponsor-Investigator/Central Trial Coordinating Team perspective, refer to [MCTC182 SOP | Sponsor-Investigator Responsibilities in MCRI-Sponsored IITs](#).

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<sup>6</sup> Signed and dated either by hand or electronically



#### 5.4.2. Training

All Clinical Trials Team members must complete training on, and receive information about, the trial they are working on, as relevant to their role in the study. This commonly includes:

- Trial protocol (clinical background, study hypothesis and endpoints, study aims and objectives, etc)
- Trial intervention, known risks, and safety profile (i.e., expected AEs/SAEs etc)
- Eligibility criteria, Screening, Enrolment and Randomisation procedures
- Informed consent procedures
- Trial assessments/procedures required
- Trial-related documentation as applicable e.g., Laboratory, Pharmacy, Imaging manuals, Manual of Procedures/Manual of Operations
- Trial-specific systems e.g. the trial database, e-CRF software, etc.

Completed training must be documented in a trial-specific training log (e.g., [MCTC017b Template | Trial-Specific Training Log](#)). This log must list the format of the training, the documents and resources used in delivering the training, who delivered the training, date the training was delivered, and trainee signature to acknowledge training completion.

In some cases, a Sponsor Portal (or similar system) is used to document training, instead of a trial-specific training log. If a given portal can provide regularly updated training records that meet the minimum requirements of a training log (as listed above), and these training records can be regularly downloaded and filed in the ISF, then it meets the minimum standards of this SOP.

For more guidance on training logs and the use of Sponsor portals, see [MCTC017a Work Instruction | Completing Training Logs at Melbourne Children's](#).

##### 5.4.2.1. Site Trial Team

The Site PI is responsible for ensuring all trial-specific training is completed and documented by all Site Trial Team members. All Site Trial Team members are responsible for ensuring their individual trial-specific training is current and their training log entries are up to date.

This log should be filed in the ISF, and should be available for review (upon request) for the duration of the trial.

Site Trial Team members can refer to [MCTC011 Guidance | Investigator Site File - Table of Contents Document Filing for the Investigator Site File](#) template filing structure used for MCRI research.

##### 5.4.2.2. Central Trial Coordinating Team



The Sponsor/Sponsor-Investigator is responsible for both the development and delivery of trial-specific training to all members of the Clinical Trials Team. They are also responsible for informing Clinical Trials Team members of their individual training requirements – both initial and ongoing (as a result of any amendments). The Sponsor/Sponsor-Investigator is also responsible for ensuring all Sponsor-level trial-specific training is completed and documented by all Central Trial Coordinating Team members. All Central Trial Coordinating Team members are responsible for ensuring their individual trial specific training is current and their training log entries are up to date.

This log is to be filed in the Trial Master File (TMF), and should be available for review (upon request) for the duration of the trial.

Central Trial Coordinating Team members can refer to the [MCTC012 Guidance | Trial Master File \(TMF\) Table of Contents Document Filing for the Trial Master File](#) Template Filing Structure used for MCRI-sponsored Clinical trials

For more information on training from a Sponsor-Investigator perspective, refer to [MCTC182 SOP | Sponsor-Investigator Responsibilities in MCRI-Sponsored IITs](#).

#### 5.4.3. Central Storage of Records

Where a Site Trial Team member is working on multiple trials, and/or for trials utilising the Florence eBinders™ platform, it is acceptable to store training records and qualifications in a central location and link out to them from each ISF.

For trials using Florence eBinders™, the 'shortcut' method can be used to add a shortcut from the Central Files Binder (containing copies of training records and qualifications) to the corresponding ISF.

For trials not using Florence eBinders™, a file note must be placed in the relevant section of the trial's ISF linking out to the relevant training records and qualifications, so that they can be easily located upon review/request.

#### 5.4.4. Delegations

The responsible Investigator (whether PI or SI) is not able to perform all trial tasks, assessments and procedures for all participants. Therefore, they must delegate to other members of their team. All tasks that could impact significantly on participant safety, protocol compliance, quality, and the integrity of the study data must be delegated to named trial team members carrying out those tasks.

Records of delegation must be documented in a trial-specific delegation log (e.g., [MCTC025b Template | Signature and Delegation Logs](#)) in the trial's ISF (for the Site Trial Team) or TMF (for the Central Trial Coordinating Team).



Delegation practices and requirements are functionally the same for the Site Trial Team and the Central Trial Coordinating Team, except that the Sponsor-Investigator is the responsible Investigator (not the Site PI). Maintaining an up-to-date Site Trial Team/Central Trial Coordinating Team Delegation Log throughout the trial is the responsibility of the PI or SI, respectively. Delegation Logs must be available for review (upon request) for the duration of the trial.

When delegating, the PI/SI must ensure the following occurs:

- Record the trial tasks and responsibilities delegated to each trial team member
- Record the start date of all delegations
- Record any changes to delegations, for example end dates, adding or changing delegated responsibilities, etc.

Delegation log entries must be co-signed by both the PI/SI and trial team members as an acknowledgement of the tasks and responsibilities assigned to them. This must be done contemporaneously, and before any trial activities are undertaken by the delegated party.

To ensure delegations are documented in accordance with the requirements of this SOP and GCP, follow the steps outlined in [MCTC025a Work Instruction | Completing Signature and Delegation Logs at Melbourne Children's](#). For more information on delegation from a Sponsor-Investigator perspective, refer to [MCTC183 SOP | Delegation of Sponsor Responsibilities in MCRI-Sponsored IITs](#).

## 5.5. Ancillary Staff

In addition to the core Site Trial Team, ancillary staff are often involved in conducting trial-related assessments and/or procedures or involved in the care of trial participants. Ancillary staff include (but are not limited to) those in Supporting Departments, chemotherapy nurses whose only role is to administer investigational products, and ward staff.

In general, these staff are not required to undertake trial-specific training or GCP training because they

- a) are performing tasks within their usual duties
- b) are suitably qualified to undertake the trial by virtue of their prior education, training and experience, and
- c) work to quality systems outlined in their professional codes of practice.

Ancillary staff are only required to undertake additional training and delegation for a trial if they are conducting trial-related assessments and/or procedures outside of their usual duties or handling/dispensing/administering novel/non-routine interventions. A trial risk assessment can be used to inform and justify the level of training in these situations.

See [MCTC035 Template | Risk Assessment and Risk Management Tool for Clinical Trials](#) for



more on this.

The following minimum requirements apply:

- The PI must delegate the activity to a Named Person who will supervise all staff carrying out the activity.
- The Named Person will require trial-specific training and may require GCP training. Training should be proportionate to:
  - Type of intervention (novel/non-routine/standard of care)
  - Type of trial activity
  - Individual's role
  - Risks that threaten the safety of trial participants and reliability or interpretability of the study results

This training may be in an abbreviated format. For example, short training sessions covering relevant requirements such as:

- Recording adverse events
- Documenting activities in the source record
- Notifying reportable events (e.g. protocol deviations, serious breaches and adverse events) to the site trial team
- GCP Principles
- Other relevant trial/GCP requirements related to staff role

## 5.6. Third Parties

In some cases, a Sponsor or Site will delegate some of the trial responsibilities to a third party, e.g. a third-party nursing agency conducting home visits.

If this is the case, the responsible party (either Sponsor or Site Principal Investigator) for overseeing third party training, qualification, delegation of activities and documentation should be in accordance with the Clinical Trial Research Agreement (CTRA) and/or Services Agreement.

## 6. CORRECTIVE ACTIONS

The Site PI/Sponsor-Investigator is responsible for ensuring any deviation from this SOP resulting in a member(s) of the Site Trial Team/Central Trial Coordinating Team not having the relevant qualifications/education/training for their role in the trial is investigated as per [MCTC061 SOP Continuous improvement: A corrective and preventive action \(CAPA\) plan](#).



## 7. GLOSSARY

Refer to [MCTC218 Glossary](#) for an updated list of glossary terms.

## 8. REFERENCES

- [ICH Harmonised Guideline for Good Clinical Practice \(GCP\) E6\(R2\) \(2017\) and Integrated Addendum to E6\(R1\)](#)
- [National Statement on Ethical Conduct in Human Research \(2023\)](#)
- [National Clinical Trials Governance Framework \(2022\)](#)
- [National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia \(2023\)](#)
- CR-P-004 Research Site Staff Qualifications and Training v1.1 12May23

## 9. COLLABORATORS

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- Jaclyn Dorland, Clinical Nurse Consultant for Research & Clinical Trials, RCH
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- Dianne Tucker, NCTGF Project Lead, RCH
- Kate Lee, Group Leader / Snr Princ Research Fellow, CEBU
- Suzette Sheppard, Research Coordinator Anaesthetics, MCRI
- Carmel Delzoppo, Data, Quality, Audit, & Research Team Leader, PICU Clinical Sciences, MCRI



## 10. APPENDICES

### 10.1. Appendix 1: Summary of Roles and Responsibilities

	Team Member (Site OR Central)	Site Principal Investigator	Sponsor-Investigator
<b>Oversight</b>		Is appropriately qualified to assume the role of Site Principal Investigator and is ultimately responsible for the study at their site	Is appropriately qualified to assume the role of Sponsor-Investigator and is ultimately responsible for the study at all sites
<b>Study conduct</b>		Responsible for the conduct of the study, and for any study-related duty or function performed and any data generated at their site	Responsible for the conduct of the study, and for any study-related duty or function performed and any data generated during the study
<b>Staffing</b>		Responsible and accountable for selecting an adequate number of qualified, trained staff to form the Site Trials Team	Responsible and accountable for selecting an adequate number of qualified, trained staff to form the Central Trial Coordinating Team
<b>Evidence of training and qualifications</b>	Provide documentary evidence of their education, training, and experience	Ensure Site Trial Team members <sup>7</sup> , external service providers, etc, involved in the trial are qualified by education, training, and experience,	Ensure Central Trial Coordinating Team members, external service providers, etc, involved in the trial are qualified by education, training,

<sup>7</sup> This includes research staff at both Primary and Satellite sites, in the case of Teletrials or other decentralized trials.

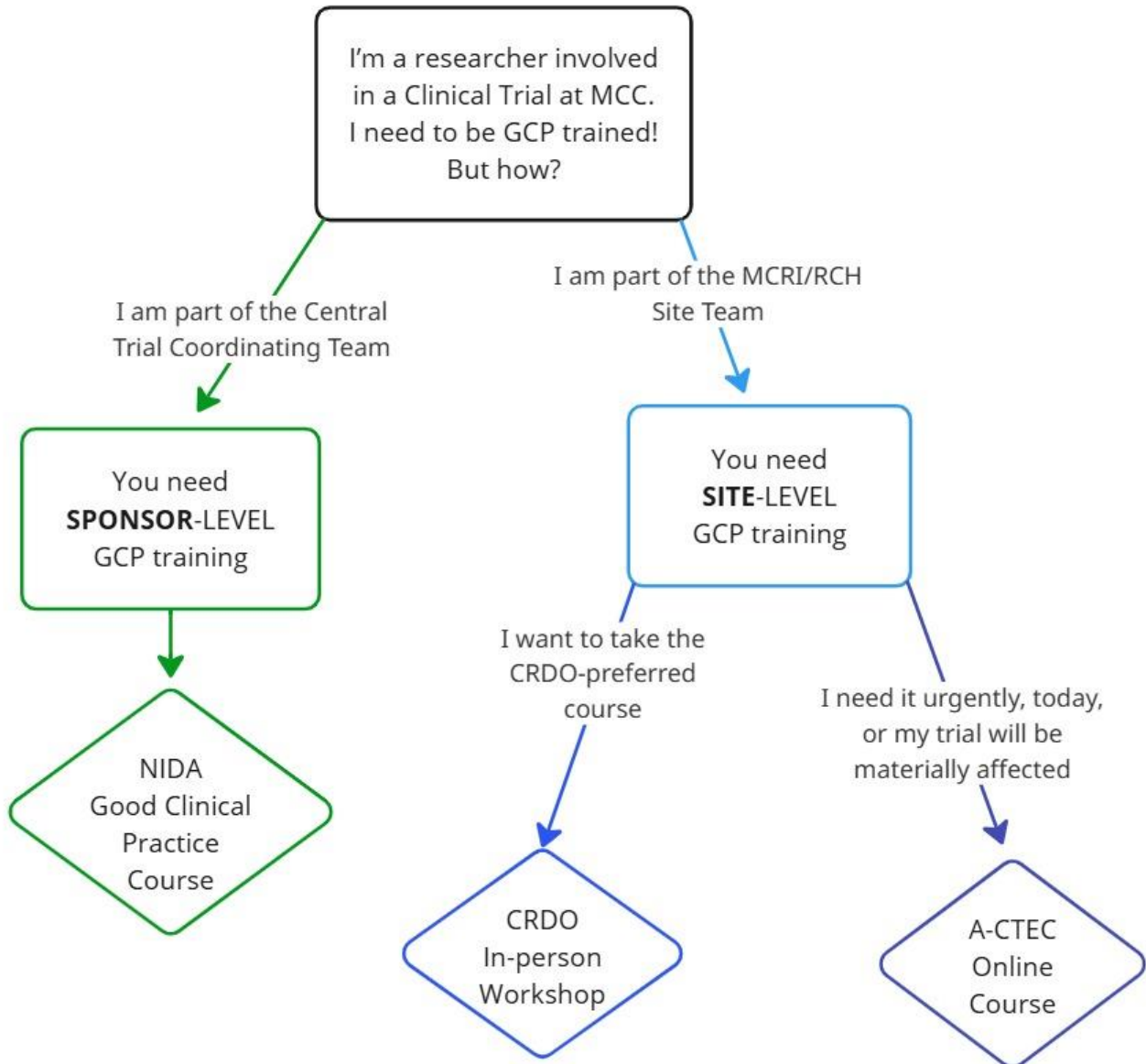


		and must review their qualifications before delegating any study-related duties/tasks	and experience, and must review their qualifications before delegating any study-related duties/tasks
<b>Providing training</b>	Undertake the necessary trial-specific training and/or receive the necessary trial-specific information	Ensure Site Trial team members, external service providers involved in the trial receive trial-specific information and training <sup>8</sup>	Design and deliver trial-specific information and training
<b>Tasks</b>	Perform only the trial-related tasks and responsibilities delegated to them, as per the Delegation Log	Delegate trial-related tasks and responsibilities to appropriately qualified members of the Site Trial Team, and document this in the Delegation Log	Delegate trial-related tasks and responsibilities to appropriately qualified members of the Central Trial Coordinating team, and document this in the Delegation Log

<sup>8</sup> This could include, but is not limited to, Protocol training, Investigational product or intervention training, training on study-specific duties, tasks and responsibilities, systems training, etc.



10.2. Appendix 2: GCP Training Options Flowchart



Key personnel in the MCRI/RCH SITE TRIAL TEAM	Key personnel in the CENTRAL TRIAL COORDINATING TEAM (MCRI-sponsored trials ONLY)
<ol style="list-style-type: none"> <li>1. Site Principal Investigator (PI)</li> <li>2. All Associate/Sub-Investigators</li> <li>3. Clinical Trial Pharmacist</li> <li>4. Trial/Study Coordinators &amp; Research Nurses</li> <li>5. Clinical Trial Assistants (if applicable)</li> <li>6. Data Manager/s (if applicable)</li> <li>7. Ancillary staff</li> </ol>	<ol style="list-style-type: none"> <li>1. Sponsor-Investigator</li> <li>2. All other Investigators listed on the protocol</li> <li>3. Clinical Trial Manager/Coordinator (Lead/Back-Up, if applicable)</li> <li>4. Clinical Trial Assistants (if applicable)</li> <li>5. Statistician/Biostatistician</li> <li>6. Data Manager/s (if applicable)</li> <li>7. Database Manager/Programmer (if applicable)</li> <li>8. Trial and Medical Monitors</li> </ol>



## 11. RELATED DOCUMENTS

[MCTC011 Guidance | Investigator Site File - Table of Contents Document Filing](#)

[MCTC012 Guidance | Trial Master File \(TMF\) Table of Contents Document Filing](#)

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

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

[MCTC025a Work Instruction | Completing Signature and Delegation Logs at Melbourne Children's](#)

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

[MCTC061 SOP | Continuous improvement: A corrective and preventive action \(CAPA\) plan](#)

[MCTC182 SOP | Sponsor-Investigator Responsibilities in MCRI-Sponsored IITs](#)

[MCTC183 SOP | Delegation of Sponsor Responsibilities in MCRI-Sponsored IITs.](#)

[RCH0498 Investigators Responsibilities in Research](#)

DOCUMENT END

