Standard Operating Procedure

Title: Clinical Trial Staff Qualifications, Training Records, and Capability

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Author

NAME and TITLE: Sarah Rathjen – Project Officer, Education and Training Coordinator

The author is signing to confirm the technical content of this document

Signature: Signed Electronically by:
Sarah Rathjen - sarah.rathjen@mcri.edu.au
22-Nov-2024 @ 09:41 AM AEDT
Reason: Authorship

Institution/Department name: Melbourne Children's

Reviewed and Approval

These signatures confirm the reviewers agree with the technical content of the document and that this document is approved for implementation at the Melbourne Children's.

NAME and TITLE: Kate Scarff, Clinical Research Development Office Lead

Signature: Signed Electronically by:
Kate Scarff - kate.scarff@mcri.edu.au
22-Nov-2024 @ 03:41 PM AEDT
Reason: Approval

Document History

Revision	Modified by	Date of Release	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. Transcelerate recognition now required in these cases.

CONTENTS

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, education, and training required of members of multidisciplinary Clinical Trials Teams 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, education, and training to successfully perform in their role as a member of the Clinical Trials Teams
c) Ensure there is a process for Clinical Trials Team members to maintain currency of qualifications, education, 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[1] 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 includes ensuring that they, and their entire Clinical Trials Team, are qualified by education, training, and experience commensurate with their roles and responsibilities.

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, investigator-initiated and/or externally sponsored clinical trials.
- Clinical trials staff across MCC developing, conducting, and providing services to MCRI-sponsored clinical 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
- Clinical Staff who are not responsible for, or providing services to, clinical trials

[1] PI/CPI/SI, etc.

beyond their routine scope of practice (e.g. Supporting Departments)2
- HREC members/REG Office Staff3
- Consumers, Consumer Representatives, and Lay People who may be involved as representatives in clinical trial steering committees, or in other capacities2
- 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[4], unless otherwise specified.

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

Key personnel in the **MCRI/RCH SITE TRIAL TEAM**	Key personnel in the **CENTRAL TRIAL COORDINATING TEAM (MCRI-sponsored trials ONLY)**
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. Those undertaking a trial-specific procedure that is additional to standard of care.	1. Sponsor-Investigator/Coordinating Principal Investigator (SI/CPI)[5] 2. All other Investigators listed on the protocol 3. Clinical Trial Manager/Coordinator (Lead/Back-Up, if applicable) 4. Clinical Trial Assistants (if applicable) 5. Statistician/Biostatistician 6. Data Manager/s (if applicable) 7. Database Manager/Programmer (if applicable) 8. Trial and Medical Monitors

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

[2] Trials involving routine treatments or procedures often involve large numbers of healthcare professionals that are suitably qualified to undertake the trial by virtue of the prior education, training and experience, and work to quality systems outlined in their professional codes of practice. Knowledge of GCP should be provided in a way that is proportionate to the individual's role and level of trial activity.
[3] At time of writing
[4] PI/CPI/SI, etc.
[5] The Sponsor-Investigator is the Coordinating Principal Investigator on an MCRI-Sponsored trial. See the glossary entry for "Investigator" for more on this.

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 future versions of this document, or in related documents.

4. RESPONSIBILITY

Ultimately, this process is the responsibility of the Investigator (see Section 5.4.3). 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 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, eg 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

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 (RCH0498)*. 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 EvetGood Clinical Practice (GCP) training within the last three years using a Transcelerate-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." *(RCH 0498)*

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.[6]

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

[6] 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.

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 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 CERTIFCATE 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 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[7] 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

[7] A "full" GCP course covers the whole of the ICH GCP standard and includes both Site and Sponsor responsibilities.

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 themselves
2. Send the certificate to the Florence Inbox (florence@mcri.edu.au) with the subject line GCP CERTIFCATE 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[8] 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.

[8] Signed and dated either by hand or electronically

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.

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, MOP/MOO
- 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., MCTC017 Template | Study Staff Training Logs). 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.

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. Storage in a Central Location

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.

Records of delegation must be documented in a trial-specific delegation log (e.g., MCTC025 Guidance | 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 add stop dates, add or change 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.

For more information on delegation from a Site PI perspective, refer to MCTC025 Guidance | Signature and Delegation Logs. For more information on delegation from a Sponsor-Investigator perspective, refer to MCTC183 SOP | Delegation of Sponsor Responsibilities in MCRI-Sponsored IITs.

5.5. 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 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

Australian Clinical Trials Education Centre (A-CTEC)

A-CTEC is a not for profit, Australia wide, member-based education platform, hosting a suite of evidence- based, interactive clinical trials education opportunities suitable for a range of learning needs.

A-CTEC designs courses for all staff involved in clinical trials in health service settings across Australia, regardless of role or site.

Civil Aviation Academy/International Air Transport Authority (IATA)

The current government legislation requires that all those who pack, mark, label or complete the paperwork associated with the shipping of dangerous goods must be trained (classified as a Group F Employee). Therefore, for example, anyone who places a sample of the above in packaging, uses dry ice (or liquid nitrogen) as a refrigerant for any shipment (regardless of the content) or a flammable liquid must be approved by successfully completing this training.

Central Trial Coordinating Team

A group of MCRI researchers (at the Sponsor-level) organised to coordinate the planning, development, operations and conduct of an MCRI-sponsored, Investigator-Initiated, clinical trial.

Clinical Research Coordinator

A research worker who works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted under Good Clinical Practice guidelines. May also be called a Research Coordinator, Study Coordinator or (for clinical trials research) a Clinical Trial Coordinator.

Clinical Research Development Office (CRDO)

CRDO provides education and training to facilitate and increase capacity for clinical and public health research across the Melbourne Children's campus. This includes the development and implementation of Standard Operating Procedures and templates to enable researchers to conduct high quality research.

Clinical Trial

The World Health Organization (WHO) definition for a clinical trial is 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

Clinical Trial Team

This includes anyone involved in overseeing or conducting the clinical trial. In this document, the term "Clinical Trials Team" covers both the Site Trial Team and the Central Trial Coordinating Team.

Collaborative Research Group

An academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing, and coordinating a research study/trial.

Corrective and Preventive Action Plan

A Corrective and Preventive Action (CAPA) plan is a quality system plan and incorporates:

1. Identifying issues, including scope and impact
2. Identifying the root cause of the issue – how/why it occurred
3. Identifying actions to prevent recurrence of the issue (corrective action) or, identify actions to prevent an issue from occurring (preventive action)
4. Documenting that the corrective actions/preventive actions were completed
5. Documenting that the corrective/preventive action has resolved the problem

Essential Documents

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. Filing essential documents at the Sponsor site and participating trial sites also assists with the successful management of the trial.

File Note

A Note to File (NTF), also known as a File Note, is written to document a discrepancy or other issue in the conduct of a research study. The NTF also provides a forum for you to document the action taken to correct this.

The NTF can apply to a single participant, multiple participants or to the study/trial as a whole. Reasons for using an NTF could include:

- documenting a missing data item
- clarifying/adding information regarding source documentation
- clarifying/adding information regarding site-specific regulatory file requirements
- documenting/addressing issues that are protocol and/or site specific.

A NTF should be printed on institution letterhead and should be initiated and authored by the individual or organisation responsible for its content.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible

and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

International Conference on Harmonisation (ICH)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

Investigator

A person responsible for the conduct of the clinical trial at a trial site. There are four types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below.

Associate Investigator

Any individual member of the clinical trial team designated and supervised by the Principal investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). May also be referred to as sub-investigator.

Coordinating Principal Investigator (CPI)

If a study is conducted at more than one study site, the Principal Investigator taking the additional responsibility for coordination of the study across all sites in a region is known as the Coordinating Principal Investigator (CPI). This role applies to externally sponsored studies where the Sponsor may be a collaborative research group, commercial Sponsor or an institution. The Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

Sponsor-Investigator

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (eg, it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Principal Investigator (PI)

The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice and, is

responsible for adequately supervising his or her clinical trial team.

The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol.

Investigator-Initiated Trials (IITs)

A clinical trial which is initiated and organised by an Investigator i.e. an individual rather than a collaborative group, company, or organisation. In these cases, the Investigator will take on the role of the trial sponsor and will then be responsible for the extensive GCP and regulatory requirements associated with both the management and conduct of the trial.

Investigator Site File (ISF)

Filing repository controlled by the site Principal Investigator. It is held at the trial site and contains all the essential documents necessary for the site trial team to conduct the trial as well as the essential documents that individually and collectively permit evaluation of the conduct of the trial at the site and the quality of the data produced.

Investigator's Brochure (IB)

The document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product that are relevant to the study of the product in humans.

Manual of Procedures (MOP)

A handbook which supplements the protocol to guide a study's conduct and facilitate consistency in protocol implementation and data collection across participants and clinical sites. Also commonly known as Manual of Operations (MOO).

Melbourne Children's

The campus encompassing all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

Melbourne Children's Trials Centre (MCTC)

Melbourne Children's Trials Centre (MCTC) is a collaboration between the Royal Children's Hospital, The Murdoch Children's Research Institute, The Royal Children's Hospital Foundation and The University of Melbourne. This Centre brings together expertise in research, clinical practice, and education and incorporates anyone who initiates or carries out research under one or more of these institutional affiliations.

Murdoch Children's Research Institute (MCRI)

An Australian paediatric medical research institute located in Melbourne, Victoria, affiliated with the Royal Children's Hospital and the University of Melbourne. The institute has six research themes: cellular biology, clinical sciences, genetics, infection and immunity, population health,

and data science.

National Clinical Trials Governance Framework (NCTGF)

The National Clinical Trial Governance Framework (NCTGF) outlines the necessary actions to achieve integrated corporate and clinical governance systems for clinical trial service delivery by health service organisations. This framework supports the integration of clinical trial service provision into routine hospital care for improved patient outcomes.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.

Research Ethics and Governance Office (REG)

REG supports the HREC and institutional research governance processes at MCRI.

Research Governance Office (RGO)

The Office or coordinated function within Melbourne Children's which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the CEO / delegate as to whether a research project should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance).

The Royal Children's Hospital (RCH)

The Royal Children's Hospital is major specialist paediatric hospital in Victoria, the Royal Children's Hospital provides a full range of clinical services, tertiary care, as well as health promotion and prevention programs for children and young people. Its campus partners are the Murdoch Children's Research Institute and The University of Melbourne Department of Paediatrics, which are based on site at the hospital.

Sponsor

An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.

For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term **Sponsor-Investigator** to reflect the dual role of the CPI in investigator-initiated trials.

Standard Operating Procedure (SOP)

Detailed, written instructions to achieve uniformity of the performance of a specific function.

Study Team

Refers to the extended group of people involved in a research study at the site. This includes the

investigator team and any additional members of staff who are involved in the set-up or conduct of the study e.g. research nurse, research assistants.

Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods.

Clinical Trial Manager/Clinical Trial Coordinator

A Trial Coordinator has a significant role in the management of the clinical trial at the Sponsor level and provides leadership in clinical trial activities to ensure that the trial is completed within budget, on time and of the highest quality. A Trial Coordinator is responsible for managing the planning, implementation, and tracking of the clinical monitoring process, administration, and start-up of the clinical trial at the participating site and maintaining an overview of the conduct of the trial at sites. Some common roles and responsibilities performed by the Trial Coordinator include:

- Participate in protocol development, CRF design and clinical study report writing
- Guide in the creation and development of important study documents and manuals
- Conduct feasibility assessments
- Develop study budgets
- Oversee participant recruitment
- Oversee overall trial conduct
- Ensure compliance of site-staff with the trials Standard Operating Procedures
- Ensures compliance to all regulatory requirements both at a local and international level
- Ensures compliance to all data protection requirements both at a local and international level
- Ensures compliance to all safety reporting requirements both at a local and international level
- Conduct team meetings and site-staff training programs
- Overall responsibility of the trial
- Supervise in-house clinical trial staff

Trial Master File (TMF)

Filing repository controlled by the Sponsor/Sponsor-Investigator. It is the collection of essential documents that allows the Sponsor responsibilities for the conduct of the clinical trial, the integrity of the trial data and the compliance of the trial with Good Clinical Practice (GCP) to be evaluated.

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.pdf

9. COLLABORATORS

- Kate Scarff, CRDO Lead, CRDO
- Kylie Crompton, Research Officer Neurodisability and Rehabilitation, MCRI
- Carolyn Stewart, Business and Operations Manager, MCTC
- Jade Sheppard, Research Nurse Manager, MCTC
- Jaclyn Dorland, Clinical Nurse Consultant for Research & Clinical Trials, RCH
- Richard Hall, Senior Data Manager, MCTC
- Laura Galletta, Senior Study Coordinator, MCTC
- 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

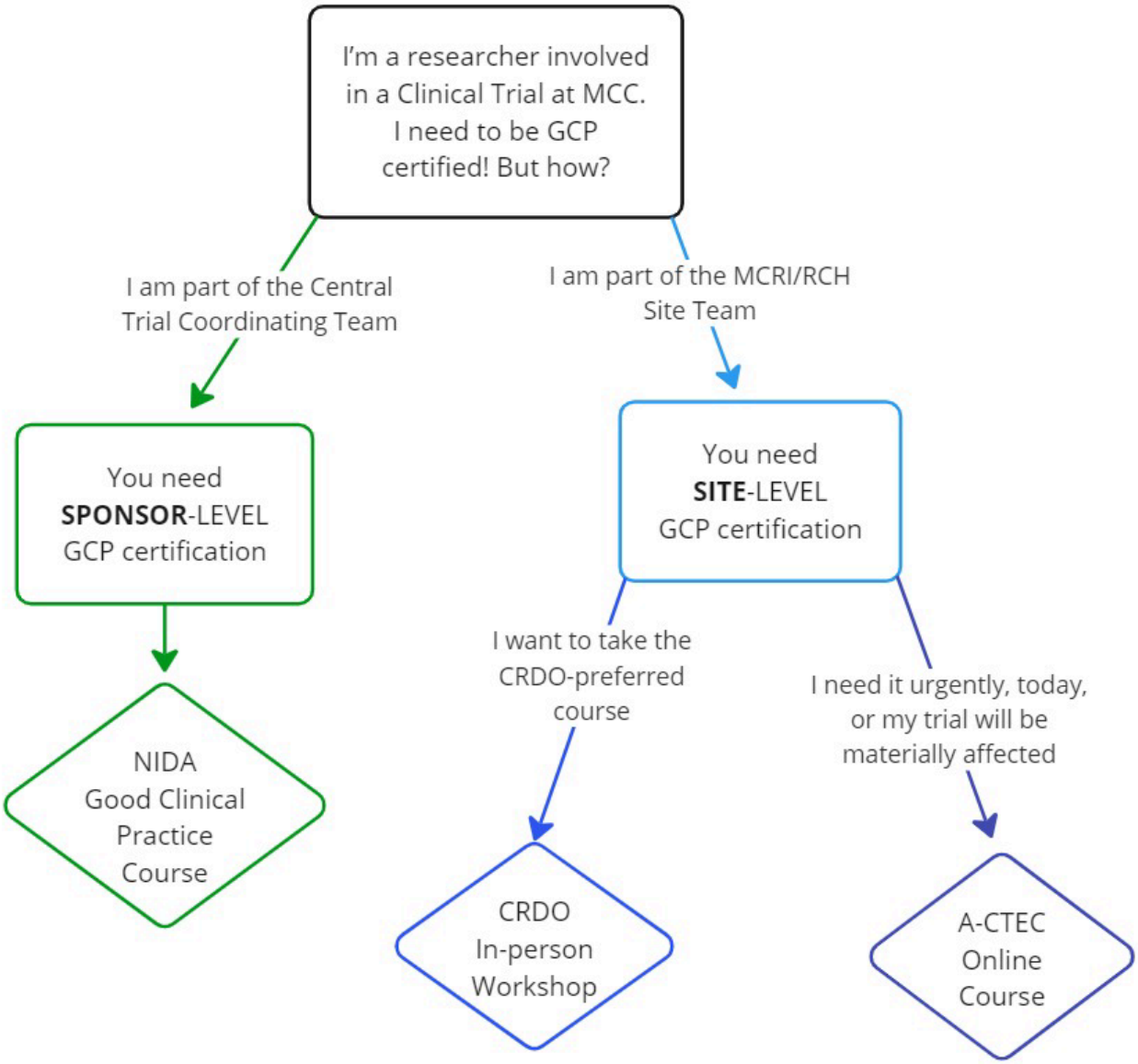
	Team Member (Site OR Central)	Site Principal Investigator	Sponsor-Investigator
Oversight		Is appropriately qualified to assume the role of Site Principal Investigator and is ultimately responsible for the study at their site	Is appropriately qualified to assume the role of Sponsor-Investigator and is ultimately responsible for the study at all sites
Study conduct		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
Staffing		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
Evidence of training and qualifications	Provide documentary evidence of their education, training, and experience	Ensure Site Trial Team members[9], 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,

[9] 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
Providing training	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[10]	Design and deliver trial-specific information and training
Tasks	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

[10] 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)
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. Those undertaking a trial-specific procedure that is additional to standard of care.	1. Sponsor-Investigator/Coordinating Principal Investigator (SI/CPI) 2. All other Investigators listed on the protocol 3. Clinical Trial Manager/Coordinator (Lead/Back-Up, if applicable) 4. Clinical Trial Assistants (if applicable) 5. Statistician/Biostatistician 6. Data Manager/s (if applicable) 7. Database Manager/Programmer (if applicable) 8. Trial and Medical Monitors

11. RELATED DOCUMENTS

MCTC061 SOP Continuous improvement: A corrective and preventive action (CAPA) plan.

MCTC183 SOP | Delegation of Sponsor Responsibilities in MCRI-Sponsored IITs.

MCTC025 Guidance | Signature and Delegation Logs

MCTC012 Guidance | Trial Master File (TMF) Table of Contents Document Filing

MCTC182 SOP | Sponsor-Investigator Responsibilities in MCRI-Sponsored IITs

MCTC011 Guidance | Investigator Site File - Table of Contents Document Filing

MCTC017 Template | Study Staff Training Logs

RCH0498 Investigators Responsibilities in Research

FOR THIS TEMPLATE:

MCTC076 | Guidance: Electronic File Naming Conventions V1.0
MCTC121 | SOP: Document Management and Version Control V1.0

DOCUMENT END