DOCUMENTATION OF TRIAL PERSONNEL RESPONSIBILITIES, QUALIFICATIONS & TRAINING – MELBOURNE CHILDRENS

Who does this apply to?

PART 1 – MCRI/RCH SITE TEAM

Key personnel in the MCRI/RCH Site Team include:

1. Site Principal Investigator
2. All 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.

Other personnel may include:

- Ethics/RGO Submissions Officers
- Laboratory Staff
- Research Managers
- Administration Staff

PART 2 - CENTRAL TRIAL COORDINATING TEAM (MCRI IITs ONLY)

Key personnel in the Central Trial Coordinating Team include:

1. Sponsor-Investigator/Coordinating Principal Investigator
2. All other Investigators and Sub-Investigators listed on the protocol
3. Clinical Trial Manager/Coordinator (Lead/Back-Up, if applicable)
4. Statistician
5. Data Manager/s (if applicable)
6. Members of Trial Executive Committee/ Management Group

Note: *Only one part of this fact sheet applies,* ***unless*** *the Melbourne Children's campus is both the Trial Sponsor and a Participating Site (i.e., is sponsoring AND enrolling participants into the trial). In this case,* ***both*** *part 1 and part 2 apply.*

Resources

- MCTC040 Template | Investigator Short CV
- MCTC017 Template | Study Staff Training Logs
- MCTC025 Guidance | Signature and Delegation Logs

Why does this process exist?

This factsheet guides MCRI triallists in ensuring that they appropriately document the qualifications, experience, training, and delegated tasks of trial personnel, in line with ICH-GCP requirements.

There are additional requirements if MCRI is sponsoring the trial (i.e., MCRI-led IITs). These include trial personnel meeting the ICH-GCP requirements for Sponsors.

The CRDO templates are recommended for use when documenting this, as they contain all required fields.

What are the documentation requirements?

PART 1 – MCRI/RCH SITE TEAM:

Documentation of Delegation of Duties (Delegation Log):
The site team keeps up to date a log of all key site staff involved in a trial. At a minimum, this includes the site team (*Part 1, left),* and anybody collecting data from a trial participant, or accessing/entering participant data into a trial database, their roles, and delegated responsibilities.

Documentation of qualifications and experience:
CVs, GCP certificates, & medical licenses for all key site staff should be filed in the Investigator Site File. They must be current* and include training, qualifications, and current/ previous positions.

Documentation of training (Training Log):
Up-to-date training records are required for any staff listed on the Site Team's Delegation of Duties Log.

PART 2 – CENTRAL TRIAL COORDINATING TEAM (MCRI IITs ONLY):

Documentation of Delegation of Duties (Delegation Log):
The central team keeps up to date a log of all key central team staff involved in a trial. At a minimum, this includes the central team (*Part 2, left*), and anybody accessing/ entering participant data into a trial database, their roles, and delegated responsibilities.

Documentation of qualifications and experience:
CVs, GCP certificates, and medical licenses for all key central team staff should be filed in the Trial Master File. They must be current*, and include training, qualifications, and current/previous positions.

Documentation of training (Training Log):
Up-to-date training records are required for any staff listed on the Central Team's Delegation of Duties Log.

**CVs are current for 2 years, GCP certificates are current for 3 years*

Find Out More:
CRDO Launching Pad, ICH GCP Sections 4.1 + 4.2 , ICH GCP Section 5 and National Statement 1.1 (e)
Please contact CRDO at crdo.info@mcri.edu.au if you have any questions.