MCTC RECOMMENDATIONS FOR DOCUMENTATION OF TRIAL PERSONNEL RESPONSIBILITIES, QUALIFICATIONS AND TRAINING FOR INVESTIGATOR-INITIATED TRIALS (IITs)

Listed below are some preliminary recommendations to guide MCRI triallists towards ensuring that MCRI (as the Sponsor of MCRI-led IITs) meets the ICH-GCP requirements for Sponsors to ensure that trial personnel are adequately qualified and experienced to undertake their trial-assigned roles. Key methods for documenting this include logs of delegated (assigned) responsibilities, evidence of qualifications and experience (CVs) and training records (trial-specific and general) for all key personnel.

* Personnel at Participating Sites also need to comply with their own national and local requirements.

PART 1 - CENTRAL TRIAL COORDINATING TEAM (MCRI)

Key research personnel from the Central Trial Coordinating Team include:

1. Sponsor-Investigator
2. All Sub-Investigators listed on the protocol
3. Translational Research Sub-Investigator, if applicable
4. Trial Coordinator – Lead and Back-Up, if applicable
5. Statistician
6. Lead Data Manager, if applicable
7. Members of Trial Executive Committee/Management Group

Documentation of personnel

The central team should maintain a log for assigned personnel responsibilities; this can be a standard Delegation and Signature Log (the CRDO template on the CRDO website is recommended) or an alternative log listing study team members, their role and responsibilities. The log should list all key research team personnel from the Central Trial Coordinating Team involved with the trial – i.e. the Sponsor-Investigator, all Sub-Investigators named in the protocol, Trial Coordinator, Statistician, Database Manager, Members of the Trial Management Group.

Note: Where the Melbourne Children's campus is recruiting and enrolling participants (i.e. it is also a Site), refer also to PART 2 for personnel logs, training and evidence of qualifications and experience.

Documentation of qualifications and experience (CV)

CV's should be obtained from all key Central Trial Coordinating Team personnel. CVs must include details of qualifications, training and current and previous appointments; include copies of Medical Licenses, if applicable.

PART 2 - PARTICIPATING SITE TEAMS

Key research personnel at Participating Sites include:

1. Site Principal Investigator
2. All Sub-Investigators
3. Clinical Trial Pharmacist
4. Study Coordinators / Research Nurses
5. Clinical Trial Assistants (if applicable)
6. Data Manager/s (if applicable)
7. Laboratory Manager (if applicable)
8. Those undertaking a trial-specific procedure that is additional to standard of care.

Other personnel may include:

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

Documentation of personnel - Signature and Delegation of Duties Log

The CRDO template Signature and Delegation of Duties Log (available on the CRDO website) should be used as this template contains all required fields and facilitates governance audits by the Research Ethics Governance group on campus. The Log should include all key site staff involved with the trial. At a minimum this should include the site Principal Investigator, Sub-Investigators, Study Coordinators/Research Nurses, Clinical Trial Pharmacists, as well as any personnel collecting data from a trial participant or accessing/entering participant data in a trial database. Consideration should be given to also including any of the other roles listed above.

Documentation of qualifications and experience (CV)

CV's should be obtained from all key members of the participating site team and retained in the Trial Master File as these are considered Essential Documents. CVs must be current and include details of qualifications, training, and current and previous appointments; copies of Medical Licenses should be included, if applicable.

An abbreviated CV template is available on the CRDO website.

Documentation of training

A training record is required for any personnel listed on the Signature and Delegation of Duties Log. Templates training records are available on the CRDO website.

REFERENCES:

- Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice E6(R2) - Current Step 4 version dated 9 November 2016 https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

- Australian Commission on Safety and Quality in Health Care. Sydney: ACSQHC; National Clinical Trials Governance Framework - Guide for implementation https://www.safetyandquality.gov.au/standards/clinical-trials#the-national-clinical-trials-governance-framework
- CRDO research resources page https://www.mcri.edu.au/research/training-and-resources/clinical-research-development-office-crdo/resources-quantitative