PARTICIPATING SITE STUDY BINDERS – Instructions for Coordinating Lead Sites

Purpose

The purpose of this document is to provide guidance to persons involved in maintaining Essential Documents for clinical studies where MCRI / RCH is the Sponsor and/or Coordinating Lead Site and to ensure MCRI/RCH meets the regulatory requirements for clinical research in Australia.

Responsibilities

When MCRI or RCH is the coordinating lead site for a multi-centre clinical study, it is the responsibility of the Coordinating Principal Investigator to maintain a Study Binder for all sites participating in the study. This responsibility may be delegated to another member of the study team, e.g. Research Coordinator.

Definitions

Clinical Research Development Office (CRDO): A core group within the Melbourne Children's Trials Centre established to facilitate and increase capacity for clinical and public health research across the Melbourne Children's campus through education and training.

Coordinating Lead Site: Site selected by the Sponsor to coordinate all ethics submissions on behalf of all participating sites. Added responsibilities for Investigator-initiated research depend on what has been agreed with the Sponsor but may include monitoring and maintenance of the Master Study Binder.

Coordinating Principal Investigator (CPI): The individual who takes overall responsibility for the research project and usually submits the project for ethical review. The CPI is responsible for ongoing communication with the reviewing HREC and passing on information from the HREC to the sponsor and the Principal Investigator (PI) and project coordinator at each site conducting the research. The CPI is the PI at their own site and is therefore responsible for passing on information from the HREC to their own site's Research Governance Officer (RGO).

Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study the quality of the data produced

Master Study Binder: File containing all essential documents that are common to all participating sites and in addition the site-specific essential documents that pertain to the Coordinating Lead Site.

Participating Site Study Binder: File containing site-specific essential documents.

Process

The Clinical Research Development Office (CRDO) recommends a separate Study Binder be set up for each participating site.

The Participating Site Study Binder(s) only needs to contain those Essential Documents that are specific to the site. Essential Documents that are common to all sites must be filed in the Master Study Binder. The Master Study Binder also contains the Essential Documents specific to the Coordinating Lead site.

The checklist below lists the documents that need to be filed in the Participating Site Study Binder. Documents are listed by section in accordance with the CRDO guideline, *"STUDY BINDERS – Guidelines, Table of Contents and Section Detail"*, dated 8 August 2014. Note: Sections that are only relevant to common essential documents have been omitted from this checklist.

Section	Contents
1.0 Study Contact List	Include all study staff at site, i.e. PI, SC, laboratory staff (where applic), pharmacy staff (where applic).
4.0 Participant Information	Blank Site-specific PICF (current and superseded) Note: Signed PICFs to stay at site
5.0 Ethics & Governance	
5.1	• Ethics Approval Letter / certificates (current and superseded), if not on same ethics approval as lead site • Governance approval letter / certificate (current and superseded)
5.2	HREC membership list, if not on same ethics approval as lead site
5.3	Submission documentation (initial & amendments)
5.4	Annual and final study reports
5.5	Other Correspondence
9.0 Adverse Events	
9.2	Internal SAEs and SUSARs – copy of all documentation submitted to approving HREC. Note: All participant data to be de-identified.
11.0 Monitoring / Audit	Monitoring reports, correspondence related to monitoring
12.0 Site Documentation	• Local lab certification (if applicable) • Local lab reference ranges (if applicable) • Tissue log (if applicable)
13.0 Study Team Documentation	
13.1	Delegation and Signature Log
13.2	Qualifications (CV) and Training Logs, copy of Site Initiation Visit Presentation and any other study training materials used at site
14.0 Supplies/Shipping records	Documentation relating to provision of study supplies (excluding Investigational Product / devices), e.g. paper CRF
15.0 Legal Documentation	Copy of agreements as applicable, e.g. Clinical Trial Agreement, Material Transfer Agreement, Confidentiality Agreement Correspondence with hospital lawyers
16.0 Finance Documentation	Any finance documentation specific to the site (if applicable)
17.0 Correspondence	All correspondence pertinent to study conduct at site

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20.0 Regulatory Documents	Copies of all TGA correspondence – submission of CTN, CTN acknowledgement, CTN completion
22.0 Investigational Product	Copy of documentation in site Pharmacy Folder, including: • product delivery to site • product inventory including dispensing to and returns by participants, product expiry product disposal • product storage