CLINICAL RESEARCH - TRIAL MASTER FILE

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose is to outline the procedure for the maintenance of essential documents as part of the TMF for clinical research, in compliance with NSW Health, SCHN and regulatory requirements
- The procedure must be followed by all personnel involved in the conduct of clinical research.

CHANGE SUMMARY

- Not applicable – New Sydney Children's Hospitals Network Procedure.

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Personnel involved in the maintenance of essential documents as part of the TMF for clinical research.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st March 2019	**Review Period**: 3 years
Team Leader:	Clinical Trials Program Manager	**Area/Dept**: Kids Research Institute

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Purpose/Scope

The purpose is to outline the procedure for the maintenance of essential documents as part of the TMF for clinical research, in compliance with NSW Health, SCHN and regulatory requirements.

Adherence to this procedure will ensure that:

- Essential documents are filed using a standardised index aiding the efficient and compliant management of clinical research; and
- Readiness for inspection by representatives of the Sponsor, HREC and/or regulatory authorities as part of the process is maintained.

This procedure must be followed by all personnel involved in the maintenance of essential documents as part of the TMF for clinical research.

Background

Essential documents are those documents which individually and collectively permit evaluation of the conduct of clinical research and the quality of the data produced.

Essential documents serve to demonstrate the compliance of the Investigator, Sponsor and their Delegates with the regulatory requirements of clinical research in relation to its conduct, as well as the validity and integrity of the data obtained.

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), Sections 4.9.4 and 5.5.6, the Investigator and Sponsor retain responsibility for maintaining essential documents of relevance to their role.

The list of essential documents provided in the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 8 provides guidance as to the minimum requirements for essential documents, their purpose and whether filing is required in either or both the Investigator or Sponsors files.

The essential documents are grouped according to the stage of the clinical research during which they would normally be generated as either: Before the clinical research commences, during the conduct of the clinical research; and/or after completion or termination of the clinical research.

Procedure

- The TMF must be established during the start-up phase for each clinical research initiative and prior to initiation, in accordance with SCHNs role as either Investigator or Sponsor;
- The TMF can consist of a single or series of files stored in either paper and/or electronic formats, under the direct control of SCHN in their capacity as either the Investigator or Sponsor;

- The TMF should be clearly labelled or marked to enable rapid identification of the clinical research protocol to which it relates and the name of the responsible Investigator;
- Measures must be taken to ensure the security of the TMF and prevent the accidental or premature destruction of any essential documents in accordance with the SCHN Procedure – Clinical Research - Record Keeping [DRAFT];
- The TMF must be easily accessible to the Investigator or Delegate to ensure that information regarding the conduct of the clinical research is readily available and to encourage the regular filing of essential documents;
- All essential documents, regardless of SCHNs role as either Investigator or Sponsor, must be filed in a timely manner in compliance with the nomenclature and conventions detailed in the TMF Index with Annotations (Appendix);
- Additional sections or artefact(s) can be filed as part of the TMF Index with Annotations if required with consideration of the specific requirements of the clinical research in consultation with the Investigator or Delegate;
- All previously approved documents must be retained to ensure a complete audit trail and clearly marked as 'superseded' in accordance with the SHCN Procedure – Record Keeping [DRAFT];

  Note: It may be acceptable for only the first page of large, superseded documents such as the Investigators Brochure to be retained, post consultation and approval by the Sponsor or Delegate;
- Any clinical research participant-related documentation must be kept distinct within the TMF as part of 'Section 20 - Participant File';
- Where essential documents are missing or filed in an alternate location, the use of Note to File specifying the reason for their omissions or their alternate location, as applicable, must be included in the TMF;
- Any change in the location of the TMF during the conduct of the clinical research, must be communicated to the Sponsor (as applicable) in writing;
- Any or all of the essential documents included within the TMF, including those filed in alternate locations, may be subject to inspection by the Sponsor, HREC and/or regulatory authorities and must be made readily available on request;
- In accordance with the SCHN Procedure – Clinical Research – Close Out and Archiving [DRAFT], both the Investigator and Sponsor TMFs must be reviewed and deemed complete prior to final close out and archiving;

Appendices

Trial Master File Index with Annotations

Trial Master File Checklist

Abbreviations and Definitions

GCP	Good Clinical Practice
NSW	New South Wales
NTF	Note to File
PD	Policy Directive
SCHN	Sydney Children's Hospitals Network
Source Documents	Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial);
TGA	Therapeutic Goods Administration

Related Documents

1. SCHN Policy – Clinical Research [DRAFT]
2. SCHN Procedure – Clinical Research – Use of Electronic Signatures [DRAFT]
3. SCHN Procedure – Clinical Research - Personnel Qualifications and Training Records [DRAFT]
4. SCHN Procedure - Clinical Research – Personnel Roles and Responsibilities [DRAFT]
5. SCHN Procedure- Clinical Research – Record Keeping [DRAFT]
6. NSW Health PD2012_069 - Health Care Records - Documentation and Management - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2012_069.pdf
7. SCHN Policy 2014-9045 – Health Care Records Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3274/download
8. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf