CLINICAL RESEARCH - PERSONNEL ROLES AND RESPONSIBILITIES

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that Investigators appropriately assign duties or tasks to clinical research personnel, supervise the performance of any duties or tasks delegated and maintain appropriate records of such, in compliance with NSW Health, SCHN, regulatory and protocol 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 conduct of 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

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Background

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Principal Investigator may assign duties and tasks to duly qualified and trained personnel, operating under their supervision.

Clinical research personnel may include, but are not limited to: Sub-Investigators, Research Coordinators, Research Nurses, Research Assistants, Pharmacists and Allied Health Professionals.

In a clinical research context, there may also be personnel who are associated with, but not directly involved in, the conduct of clinical research, including, but not limited to Clinicians, Ward Nurses, Radiologists, Laboratory Technicians, Phlebotomists and Third Party Vendor Personnel.

Any delegation of protocol-specific (i.e.: non-standard of care) duties and tasks must be defined, established and allocated prior to enactment as evidenced by the Signature and Delegation Log (Appendix).

All personnel must be aware of the nature and extent of their involvement in clinical research, their responsibilities and the limits on their authority in accordance with the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).

Procedure

- It is recommended that the Principal Investigator assigns some or all duties relating to the management of clinical research within SCHN to appropriately qualified and trained personnel operating under their supervision;
- The Principal Investigator must ensure appropriate training, supervision and oversight of all clinical research personnel listed on the Signature and Delegation Log (Appendix), documented in accordance with the SCHN Procedure – Clinical Research - Record Keeping [DRAFT];
- Personnel delegated to perform significant study related duties must retain evidence of their qualifications, education and/or training in accordance with the SCHN Procedure - Clinical Research – Personnel Qualifications and Training Records [DRAFT];
- The Principal Investigator must maintain a legible and accurate list of appropriately qualified personnel to whom they have delegated 'significant' duties or tasks in accordance with the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 4.1.15, via the Signature and Delegation Log (Appendix);
- At SCHN, 'significant' duties or tasks refer to any undertakings that could impact significantly on the clinical research participants safety, protocol compliance or the quality and the integrity of data;
- Personnel who are associated with, but not directly involved in, the conduct of clinical research through the performance of non-standard of care or no-significant protocol-specific tasks will be represented on the Log through the inclusion of the relevant Department Head or Delegate;
- Clinical research personnel who are performing delegated duties or tasks must ensure consistent use of the signature and initials recorded on the Signature and Delegation Log during the conduct of the clinical research for verification purposes;
- The original of the Signature and Delegation Log must be retained in the TMF and copy returned to the Sponsor or Delegate(s), as required;
- The Signature and Delegation Log must be updated in a timely manner in the event of clinical research personnel being added/removed and/or any changes in the delegation of significant duties or tasks;
- The Principal Investigator must initial and date any changes to confirm and acknowledge the addition or deletion of delegated duties or tasks to clinical research personnel;
- In the event of a change in the Principal investigator post initiation of the clinical research, an end date for the outgoing Principal Investigator should be recorded, and a new Signature and Delegation Log completed and authorised by the incoming Principal Investigator;

- In the event that the role of clinical research personnel changes during conduct, an end date must be recorded on the Signature and Delegation Log and a new entry on the Log completed.

Appendices

Signature and Delegation Log

Abbreviations and Definitions

GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
NSW	New South Wales
PD	Policy Directive
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration
TMF	Trial Master File

Related Documents

1. SCHN Policy – Clinical Research [DRAFT]
2. SCHN Procedure - Clinical Research - Personnel Qualifications and Training Records [DRAFT]
3. SCHN Procedure - Clinical Research - Record Keeping [DRAFT]
4. SCHN Procedure – Clinical Research – Trial Master File [DRAFT]
5. SCHN Procedure- Clinical Research – Use of Electronic Signatures [DRAFT]
6. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf