CLINICAL RESEARCH – PERSONNEL QUALIFICATIONS AND TRAINING RECORDS

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that personnel involved in the conduct of clinical research are adequately qualified, trained and experienced and that appropriate records of these credentials are maintained, 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

TABLE OF CONTENTS

Purpose/Scope

The purpose of this procedure is to ensure that personnel involved in the conduct of clinical research are adequately qualified, trained and experienced and that appropriate records of these credentials are maintained, in compliance with NSW Health, SCHN, regulatory and protocol requirements.

This procedure must be followed by all personnel involved in the conduct of clinical research.

Background

As per NSW Ministry of Health PD2016_048 and SCHN Policy 2014-9107, personnel employed by NSW Health must undertake mandatory training and/or education in accordance with legislative, NSQHSS accreditation or local requirements, captured via MyHealthLearning.

In addition to this, and in accordance with the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), personnel involved in the conduct of clinical research must also undertake research and protocol-specific training and/or education.

Such training and/or education must be undertaken prior to the conduct of any tasks and duties delegated by the Investigator in accordance with the SCHN Procedure – Clinical Research – Roles and Responsibilities [DRAFT].

The maintenance of up to date training records, including licenses and credentials, will provide a means of demonstrating the adequate qualifications, training and experience of all personnel involved in the conduct of clinical research at SCHN.

Procedure

- In accordance with the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Investigator or Delegate must:

  - Be qualified by education, training, and experience to assume responsibility for the proper conduct of the clinical research in compliance with all regulatory requirements;
  - Meet all the qualification requirements specified by the Sponsor or Delegate and as per the applicable regulations (e.g. current medical license or equivalent);
  - Ensure that each individual involved in the conduct of clinical research is adequately qualified by education, training, and experience to perform his or her respective, delegated task(s);
- All personnel involved in the conduct of clinical research must:
  - Provide evidence of their qualifications through the provision of an up-to-date CV (signed and dated on a 3 yearly basis) and other relevant documentation (medical license or equivalent, if applicable);
  - Maintain an up-to-date record of any research and protocol-specific training and/or education undertaken and undertake periodic review to ensure continued adequacy of skills of relevance to the task(s) performed;
  - Undertake initial or refresher accredited GCP training meeting the requirements of the TransCelerate Site Qualification and Training Initiative Mutual Recognition Program at least every 3 years or in the event of a significant amendment to the regulations;
- The SCHN Short Form CV Template and Protocol-Specific Training Log (Individual and Group) (Appendix) is recommended for adaptation;
- If training records and/or supporting documentation (e.g. GCP certificates) (including superceded records) are stored centrally, a file note must be included in the TMF indicating the location of the records;
- Training records and/or supporting documentation must also be made available for the purposes of inspection by the Sponsor or Delegate and/or any other Inspecting Party, on request.

Appendices

Short Form Curriculum Vitae Template

Protocol-Specific Training Log (Individual)

Protocol-Specific Training Log (Group)

Abbreviations and Definitions

Accredited Training	Training that provides a participant with a recognised qualification on completion. This includes courses which meet

	the TransCelerate BioPharma Inc. Minimum Criteria for ICH Good Clinical Practice (GCP) Investigator Site Personnel Training
CV	Curriculum Vitae
ICH	International Conference on Harmonisation
GCP	Good Clinical Practice
NSQHSS	National Safety and Quality Health Services Standards
NSW	New South Wales
PD	Policy Directive
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration
TMF	Trial Master File

Related Documents

1. Australian Code for the Responsible Conduct of Research (2018) - https://www.nhmrc.gov.au/guidelines-publications/r41
2. National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 - https://www.nhmrc.gov.au/guidelines-publications/e72
3. NSW Health PD2016_048 - Mandatory Training - Criteria for Approval as a NSW Health Requirement - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2016_048.pdf
4. SCHN Policy – Clinical Research [DRAFT]
5. SCHN Policy 2014-9107 - Mandatory Training and Chief Executive (CE) Directive Training - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3399
6. SCHN Procedure – Clinical Research – Creating Certified Copies [DRAFT]
7. SCHN Procedure – Clinical Research – Personnel Roles and Responsibilities [DRAFT]
8. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
9. SCHN Procedure – Clinical Research – Trial Master File [DRAFT]
10. SCHN Procedure- Clinical Research – Use of Electronic Signatures [DRAFT]
11. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf
12. Trancelerate BioPharma Inc. GCP Mutual Recognition - http://www.transceleratebiopharmainc.com/gcp-training-attestation