CLINICAL RESEARCH - USE OF INTERPRETERS

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to enable equitable access to, and effective communication with, people who require the use of interpreter services in order to consider and/or participate in clinical research.
- 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

- Read Acknowledge Only – All 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 January 2019	**Review Period**: 3 years
Team Leader:	Clinical Trials Program Manager	**Area/Dept**: Kids Research

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Purpose/Scope

The purpose of this procedure is to enable equitable access to, and effective communication with, people who require the use of interpreter services in order to consider and/or participate in clinical research.

Adherence to this procedure will ensure that:

- An inclusive and equitable approach to the opportunity for involvement in clinical research is taken;
- Effective communication and/or support is provided to individuals prior to, and during, participation in clinical research; and
- Appropriate records of the use of interpreter services are maintained in compliance with the SCHN Procedure - Record Keeping [DRAFT]

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

Background

As per the National Statement Section 5.2.17, any information for clinical research should be presented in a way that ensures support of an individual's needs, with consideration of:

- The need for accurate and reliable translation (written and/or oral) into a participant's first language or dialect;
- Culture and its effects on how language (English or other) is understood; and
- Visual, hearing or communication impairment.

In accordance with NSW Health Policy Directive PD2017_044 professional health care interpreters are used to facilitate communication between people who are not fluent in English, including people who are deaf, and personnel of SCHN in all situations where communication is essential.

Procedure

- Interpreter services for clinical research must be provided by a current NSW Health accredited provider of interpreter services supporting SCHN;
- It is unacceptable, in any circumstance, for bilingual health care staff, family members or friends to provide interpreter services;
- It is the responsibility of the Investigator or Delegate to apply their professional judgement and knowledge of the participant (as applicable), to determine whether interpreter services are required;
- Clinical research participants also retain the right to request that an Interpreter is provided;
- Interpreter services are to be used in all situations where communication is essential, in the clinical research context, this will include, but is not limited to, facilitating informed consent/re-consent, obtaining medical history, explaining study procedures and assessments, and the administration/review of mandatory patient reported outcome measures;
- The Investigator or Delegate must document any use of interpreter services during the informed consent process and/or during a participant's involvement in clinical research, in accordance with the SCHN Procedure – Clinical Research - Record Keeping [DRAFT];
- In circumstances where a witness to the informed consent process is mandated, the Interpreter may not act as a witness;
- Additional annotations to source documentation may be required if interpreter services are used during the informed consent process but are not deemed necessary by the Investigator or Delegate for selected or all subsequent interactions.

Abbreviations and Definitions

NSW	New South Wales
PD	Policy Directive
SCHN	Sydney Children's Hospitals Network

Related Documents

1. Anti-Discrimination Act 1977
2. Community Relations Commission and Principles of Multiculturalism Act 2000
3. Mental Health Act 1990
4. National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 - https://www.nhmrc.gov.au/guidelines-publications/e72
5. NSW Health PD2017_044 - Interpreters – Standard Procedures for Working with Health Care Interpreters - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_044.pdf

6. SCHN Policy – Clinical Research [DRAFT]
7. SCHN Policy 2014-9057 – Interpreter Services - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3303
8. SCHN Procedure – Clinical Research - Personnel Qualifications and Training Records [DRAFT]
9. SCHN Procedure - Clinical Research – Personnel Roles and Responsibilities [DRAFT]
10. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
11. SCHN Procedure 2016-9002 - Consent to Participate in Human Research – Participant Information and Consent - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3666