STANDARD OPERATING PROCEDURE FOR THE USE OF INTERPRETING SERVICES FOR RESEARCH STUDIES UNDERTAKEN BY NHS FIFE

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1. PURPOSE

This document describes the procedure for utilising Interpreting Services in clinical research studies sponsored or hosted by NHS Fife.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This SOP applies to all staff involved in research sponsored or hosted by NHS Fife. Where Interpreting Services are provided by external contractors, sub-contractors, agencies, temporary workers or third parties on behalf of NHS Fife on the basis of a specification set by the Board, these parties are responsible for adhering to the Board's Dignity & Respect Policy whilst providing services.

3. POLICY

3.1 The Medicines for Human Use (Clinical Trials) Regulations 2004 which governs the conduct of CTIMPs requires that a patient must give informed consent to participate in a clinical trial. That means that the patient (or person with parental responsibility or legal representative) has been informed of the nature, significance, implications and risks of the trial. This should be communicated in a way as to be understandable to the patient or the patient's legally acceptable representative.

3.2 It is the responsibility of the Sponsor to assess their intended patient group and to decide which Interpreting Services are acceptable. This should be clearly written in the study protocol. If information is not provided in the protocol, then the Sponsor must be contacted to confirm if patients requiring Interpreting Services are eligible for the trial.

3.3 The CI and Sponsor for each study will be responsible for determining if translated written material is to be provided to patients who do not have English as their first language.

3.4 NHS Fife provides Interpreting Services for patients who:

- Do not have English as their first language
- Have a hearing impairment
- Have sight impairment

- Are registered Deafblind

These services can either be provided face to face, by telephone, or in some circumstances it may be more appropriate to use Interpreter Services such as the app (LanguageLine InSight Interpreters) available on the hospital iPads within each ward area. This allows instantaneous connection to an NHS approved interpreter and gives the option of either an audio or video call.

Information on the services available in NHS Fife can be found in the Interpreting and Translation Services section of StaffLink:
https://app.joinblink.com/#/hub/4b68ce38-c621-4127-a2e2-6c581cd71727

It is the responsibility of the study Sponsor/CI to decide which Interpreting Services are appropriate and if these are required for all study visits/communication with the patient.

3.5 It is not appropriate for family members to act as interpreters and all Interpreting Services must be provided by an official NHS Interpreting Service.

3.6 If Interpreting Services are deemed necessary and the Sponsor is not willing to meet the cost, the Assistant R&D Director will make a decision as to the appropriateness of the R&D Department covering the cost.

3.7 It is the responsibility of all staff to:

- Identify and record individual need: finding out if someone has any information or communication needs and recording them in the Patient's medical records on TrakCare if they do.
- Share and check individual need: passing on information about an individual's needs to people who are looking after them. This also means checking the patient's needs are met to the best of our capability, each time the individual comes to use the service.
- Take action to meet the patient's needs: making sure that the person's needs are met, for example sending them information in the right format or providing the communication support they need (i.e. arranging for Interpreting Services).

4. PROCEDURE

4.1 Once a study patient requiring communication support has been identified and has agreed to participate in a research study, the local Research Team must discuss and agree the most appropriate Interpreting Service with the Sponsor, prior to the patient attending for their first study visit. Details of the discussion and the Sponsor's decision must be clearly documented in the Patient's medical records on TrakCare.

4.2 Where a study Sponsor has provided a Patient Information Sheet (PIS) and Consent Form in an appropriate language for patients who do not have English as their first language, these must be used. A copy of the translated PIS and Consent form must be given to the patient and a copy of both the translated documents and the English version must be uploaded to the patient's medical record via SCI-store, with a File Note explaining the reason for the additional language PIS/Consent Form.

4.3 If required, Face to Face Interpreting Services should be arranged in advance of the patients visit by contacting the NHS Fife Equality and Human Rights Department at:

- Phone - 01592 729130 (external) or 29130 (internal)
- Email - fife.EqualityandHumanRights@nhs.scot

4.4 For face to face Interpreting Services every effort must be made by the Research Team to provide continuity of care and arrange for the same Interpreter for each study visit.

4.5 Regardless of the Interpretation Service used, the information exchanged between the patient, the interpreter and the research staff should be clearly documented in the patient's medical records via TrakCare, at each visit. This must include confirmation that the patient was advised of the nature and purpose of the study, the risks and benefits of the trial, their rights to withdraw, instructions on how to take study medication (if appropriate), any questions asked and the response given to the questions. The Interpreter's name, where and when the Interpreting Service was provided and who was present must also be recorded in TrakCare.

4.6 For all patients requiring Interpretation Services, an alert must be put on TrakCare detailing the Interpreting requirements, if one has not already been added. This will highlight to all staff that the patient is not an English-speaking patient or has hearing or sight impairment and may require Interpreting Services.

5. ASSOCIATED DOCUMENTS & REFERENCES

Medicines for Human Use (Clinical Trials) Regulations 2004.
(http://www.legislation.gov.uk/uksi/2004/1031/contents/made)
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

UK Policy Framework for Health and Social Care Research
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/.

Fife R&D SOP14 – Informed Consent

6. ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Products
PIS	Patient Information Sheet
R&D	Research and Development
SOP	Standard Operating Procedure

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Karen Gray Lead Nurse, R&D	21/11/2018	N/A – new SOP
2	Karen Gray Lead Nurse, R&D	15/04/2021	Title updated to clarify that SOP relates to Interpreting Services rather than Translating Services. Updated to include use of LanguageLine. Reference to Information on StaffLink added. Updated to reference TrakCare rather than research notes or paper medical records.

8. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	15 Apr 2021