Purpose

The purpose of this SOP is to describe the standard procedures involved in obtaining informed consent from caregivers. This SOP applies to caregivers of inpatients. In order to conform to the ICH-GCP principles for informed consent:

- The subject/guardian must be COMPETENT in the language of communication
- The research team must disclose ALL relevant information regarding participation in the study to the parent / guardian
- The parent / guardian must COMPREHEND the information and understand how their child's involvement in the study affects their child, e.g. additional samples, increased follow-up.
- The subject must AGREE to the proposed intervention/procedures in the research study
- The subject's agreement must be VOLUNTARY and free from coercion
- The subject must be informed that, even after voluntarily agreeing to take part, they may
- WITHDRAW their agreement at any time without penalty
- If the parent or guardian is unable to read the informed consent documentation, the consent process must be witnessed (by an impartial witness).
- This SOP describes the process to be followed for obtaining written informed consent from subjects/guardians taking part in the CHAIN Network study to ensure compliance with the above principles.
- The study sponsor is Oxford University.

Responsibility

This SOP applies to study clinician/nurses/field workers involved in obtaining informed consent from parents and /or guardians in this trial. Appropriate training on study content and consenting procedure shall be provided at the before assignment of this role.

The principal investigator retains the final responsibility of protecting the rights and safety of study participants in the context of taking informed consent, as stipulated in the ICH /GCP guidelines.

The Site Coordinator is responsible for answering questions you may have about the content of this SOP and any other relevant study documentation.

Abbreviation/ Definitions

ICH /GCP: International Conference on Harmonization (ICH) / Good Clinical Practice
ICF: Informed Consent Form
PI: Principal Investigator

Equipment / Materials

1. Informed consent forms with participant information sheet (English or local language translations)
2. Screening and eligibility log.
3. Pen
4. Ink pad

Methods

1.0. General considerations

The study staff will be trained by the local site PI using the training materials provided by the CHAIN coordination team and taking into account local site cultures and practices. This will include scenarios and role plays to gain experience and familiarity with the documents used.

2.0. When and where will consent be taken?

- Take informed consent from the parent / guardian of an **eligible** child – i.e. eligibility should have been confirmed by a study clinician. Find an appropriate time, and environment to explain the study to the parent / guardian and obtain full informed consent. Ensure privacy during the consenting process by talking to parent/carer in a private room/section where possible. The parent/carer should feel comfortable to ask questions about the study.
- Informed consent is an ongoing process. Every time the parent / guardian has contact with the research team, they should be asked about their understanding of the study and inform the family again what will happen to data and samples, and what future procedures and appointments can be expected. Additionally, they should be actively asked if they have any questions.
- The parent/guardian should be emotionally capable of listening and participating in the process. Only if the child's medical condition requires emergency intervention, consider verbal consent/assent and deferring full consent until later. Verbal assent should be taken

for admission / enrollment samples only. A single page verbal assent form should be signed.

3.0. Who gives and witnesses consent?

Written informed consent is acceptable from the recognised parent or carer/guardian of a child, who will advocate for the child during study procedures. This may include staff from care-homes and orphanages.

If an impartial witness is required, the witness shall be an independent person chosen by the guardian or a hospital staff member not involved with the trial.

4.0. How will it be sought?

4.1. Greet the parent/guardian and introduce yourself. Introduce the purpose of the meeting/session. i.e. his/her child has an acute illness requiring admission, and that we would like to talk about a research study that involves recovery of hospitalized children in relation to nutrition.

4.2. Inform the guardian that there is a form with information about the study and is available in English, or in their language. Ask the guardian to choose the language of preference. The guardian **MUST** understand at least one of the consent languages available for the process to continue.

4.3. Inquire from the parent/ guardian whether they can read and write.

4.4. If the parent/guardian cannot read and sign, explain that the informed consent process will require an independent person to sit in, to witness the process. The witness role will be to ensure information provided by staff to the carer/guardian is correct and accurate according to information in the patient information forms.

4.5. Witnesses are chosen by the parent/carer in the following order of preference:

- 1st preference- a relative/friend/or confidant of the parent/ guardian
- 2nd preference- a fellow parent of the parent/carer's choice of a child admitted in the ward who can read and write
- 3rd preference- a hospital staff member not directly involved with the study.

4.6. With the information sheet of participant's language of choice at hand, go through the points in the form pertaining to the study one after the other. Cover all the aspects of the study to include voluntariness of participation and any potential risks and benefits for participation. Pause periodically to answer any questions raised and to assess if all information provided has been understood properly.

4.7. At the end of the session, assess subjectively the understanding of the parent/ guardian about the study. This may be done by a different member of the research team at another time to ensure the information is retained. One way is to ask simple questions about the study to check understanding. This should be as informally as possible, i.e. should not be seen as a test.

4.8. Provide an opportunity for decision making by the parent/guardian. Allow full voluntary decision making.

4.9. If parent/ guardian agrees to enroll the child into the study, provide 2 copies of the consent form to be signed. Complete relevant sections in the consent form such as time, date, initials and staff name. Tick boxes and parent/carer names and signatures MUST be filled by the parent/carer, or by a WITNESS if one has sat in on the conversation.

4.10. Remind the parent /guardian that they are free to withdraw the child from the study at any time should they decide to, despite signing the forms.

4.11. Retain one copy of the consent form for study file and give the second copy to the parent/guardian. Thank him/her for their time with you.

4.12. If the parent/ guardian decides NOT to join the study, DO NOT sign the informed consent form. Thank the parent/guardian for the time given and allow him/her to leave at will. Ensure the parent / guardian that this will not affect their child's clinical care.

4.13. Document the outcome of the informed consent process in the screening log.

4.14. Consent should be confirmed at follow up appointments and sampling. If the child requires deterioration samples, explain that these are for clinical assessment and to inform clinical management, and that samples will be stored for research.

5.0. Verbal assent

5.1. Take verbal consent/assent if the full informed consent process is not possible at time of enrolment as stated above and use the one-page assent form to confirm this.

5.2. Staff shall follow up with full informed consent within 24 hours of enrolment, but not later than day 3 of the study.

5.3. WITHDRAW from study any participant who has not signed a full informed consent by 72h of admission. Discard the CRF and admission samples for these participants.

6.0. Ensuring the quality of the consent process

6.1. The study team shall ensure that the consent process is adhered to by ensuring the consent and verbal forms are properly signed and by obtaining feedback from the guardian regarding the consenting process.

6.2. The quality assurance mechanisms of monitoring will ensure that the procedures described in this document are adhered to by checking adherence to this SOP during the monitoring process

6.3. Check understanding of parent/guardian during subsequent contact with them while admitted in the wards to confirm that they continue to understand that their child is enrolled in a research study and that their participation is voluntary.

REFERENCES:

- CHAIN informed consent SOP
- F75 Informed Consent SOP
- ICH-GCP Guidelines

APPENDICES:

1. Informed consent log
2. Screening log
3. Enrollment log

Document History

Version 1	Author	Approved by	Dated	SOP No:
1.0	IP			