



<b>Informed Consent SOP</b>		<b>SOP No: 002</b> <b>Version No: 2.0</b> <b>Supersedes: 1.0</b> <b>Effective Date:</b>	
<b>Title: Informed Consent SOP</b>			
	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>REVIEWING AUTHORITY</b>	Isaiah Njagi		
<b>QUALITY ASSURANCE AUTHORITY</b>	Aisha Bwika		
<b>APPROVING AUTHORITY</b>	Caroline Ogwang		

**1.0 PURPOSE / INTRODUCTION:**

1.1 In order to conform to the ICH-GCP principles for informed consent:

- The parent/guardian must be COMPETENT in the language of communication

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- The research team must DISCLOSE all relevant information to the parent/guardian
- The parent/guardian must COMPREHEND the information and understand how their involvement in the study differs from normal clinical care
- The parent/guardian must AGREE to the proposed intervention/procedures in the research study
- The parent/guardian's agreement must be VOLUNTARY and free from coercion
- The parent/guardian must be informed that, even after voluntarily agreeing to take part, they may WITHDRAW their agreement at any time without penalty
- In Kenya, children below the age of 18 years are not legally permitted to give consent, thus informed consent for them to take part in studies is sought from their parents or legal guardians. If the parent or guardian is unable to read the documentation, the consent process must be witnessed (by an impartial witness).

1.2 This SOP describes the process to be followed to obtain written informed consent from subjects/guardians taking part in the FLACSAM study to ensure compliance with the above principles.

## 2.0 SCOPE / RESPONSIBILITY:

2.1 This SOP applies to study clinicians/nurses/field workers involved in obtaining informed consent from parents and /or guardians in this study.

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

## 3.0 DEFINITIONS/ INITIALS:

3.1 CGH: Coast General Hospital

3.2 ICH /GCP: International Conference on Harmonization (ICH) / Good Clinical Practice

3.3 ICF: Informed Consent Form

3.4 PI: Principal Investigator

3.5 KCH: Kilifi County Hospital

3.6 SAM: Severe Acute Malnutrition

## 4.0 MATERIALS

4.1 Informed consent forms (English, Kiswahili and local language translations)

4.2 Screening and eligibility log.

4.3 Informed consent log

## 5.0 METHODOLOGY:

### 5.1 Administration of Informed Consent

#### 5.1.1 When and where will consent be taken?

- a) Assess the psychological state of parent/guardian and the medical condition of the child (according to triage) to determine whether full consent process is feasible at the point of admission

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- b) If a child is severely ill that adequate communication about the study with parent or guardian is not possible, consenting will not be initiated until the child is stable and the parent or guardian is in a sound state of communication.
- c) Ensure privacy of the informed consent process by talking to parent/guardian in a private room/section within the outpatient department or paediatric wards

#### **5.1.2 Who gives and witnesses consent?**

- a) Written informed consent is acceptable from a parent or guardian of a child eligible through screening for the study, and only after all information related to the FLACSAM study detailed in the patient information sheet has been provided.
- b) Informed consent will be asked from parents/guardians by trained study clinicians, nurses and fieldworkers.
- c) If an impartial witness is required, the witness shall be an independent person chosen by the guardian in the following order of preference;
  - 1<sup>st</sup> preference- A literate relative/friend/or confidant of the parent/ guardian
  - 2<sup>nd</sup> preference- A fellow parent of the parent/carer's choice of a child admitted in the ward who can read and write
  - 3<sup>rd</sup> preference- A hospital staff member not directly involved with the study.

#### **5.1.3 How will it be sought?**

- a) Greet the parent/guardian and introduce yourself. Introduce the purpose of the meeting/session, i.e. his/her child is sick, hospitalised requiring antibiotics and may or may not have severe malnutrition, and that we would like to talk about a research study that involves children receiving antibiotics.
- b) Inform the guardian that there is a form with information about the study and is available in English, Swahili, Giriama, Luganda, Lusigere, Lusoga, Ateso and Lumasaba. 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
- c) Inquire from the parent/ guardian whether they can read and write.
- d) 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 parent/guardian is correct and accurate according to information in the patient information forms.
- e) With the information sheet of parent's/ guardian'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.

- f) At the end of the session, assess subjectively the understanding of the parent/ guardian about the study. One way is to ask simple questions about the study to check understanding. This should be as informal as possible i.e. should not be seen as a test.
- g) Provide an opportunity for decision making by the parent/guardian. Allow full voluntary decision making.
- h) If parent/ guardian agrees for their child to enrol into the study, provide 2 copies of the consent form to be signed. Allow parent/guardian to complete first. 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.
- i) Complete the part for the investigator/designee in the consent form and include at least TWO names (as they appear in the duty delegation log), time, date and signature.
- j) 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 consent forms. 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.
- k) 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.
- l) Document the outcome of the informed consent process in the screening log.

### **5.2 Ensuring the quality of the consent process**

- a) The study team shall ensure that the consent process is adhered to by ensuring the consent forms are properly signed and by obtaining feedback from the parent/guardian regarding their understanding on participation in the study.
- b) The quality assurance mechanisms of monitoring by the KEMRI-Wellcome Trust's Clinical Trials Facility will ensure that the procedures described in this document are adhered to by checking adherence to this SOP during the monitoring process.
- c) 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 the FLACSAM study, and that their participation is voluntary.

### **5.3 Key messages**

#### **Trial participants**

1. Child requires hospital admission

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2. Child has severe acute malnutrition
3. Standard management for SAM
  - a. Investigations (E.g. malaria/FBC).
  - b. The child will receive intravenous antibiotic treatment in hospital
  - c. Child will receive therapeutic feeds that include special milk and plumpy nut.
4. Introduce KEMRI as a research institution and its collaboration with hospital
5. Introduce the problem the study wishes to address— which antibiotics that are given to treat infections in children admitted with malnutrition are most effective
6. An explanation of the study intentions for the trial
  - a. To give children one of two different types of antibiotics that are given by injection
    - i) Ceftriaxone
    - ii) Penicillin and Gentamicin
  - b. To give children either one of the following:
    - i) Metronidazole (often known as Flagyl)
    - ii) A similar liquid that does not contain an antibiotic
  - c. The decision on which child gets which drugs will be decided by a system based on chance, without any preference.
  - d. To make sure that the findings of this study are as accurate as possible it is important that no one knows which child is receiving which oral medication until the end of research.
7. We will first assess their clinical status by taking body measurements, asking you questions about their health and factors that might contribute to their illness, as well as examining them.
8. The participant will be asked to come to the hospital 14 days after admission, at day 45 and again at day 90 during which the participant's anthropometry will be done, samples will be taken and the participant will be asked some questions regarding their health,
  - a. Blood Samples will be taken –at admission alongside other clinical samples and at discharge
  - b. Rectal swabs and stool samples will be taken at admission, discharge, day 45 and day 90 of follow-up
9. Study ends at day 90 after admission

### **PK Participants**

1. Explanation of the study intentions for PK study:
  - a) We would like to check that the doses of the antibiotics are alright for malnourished children.

- b) We will take 1 blood sample at admission, before the child has received any medication. This sample will be taken alongside other clinical samples.
- c) 2 small blood samples (1/4 teaspoon) will be taken during the first 24 hours after your child has received medication.
- d) The PK study will end 24 hours after your child has received medication. The child will then continue with other aspects of the main trial.

**FC only participants**

- 1. Explanation of the study intentions for FC
  - a. To take a sample of faeces at admission (now) and again when the child is discharged from hospital using a soft cotton wool swab.
  - b. To use the information about the child's condition at admission and discharge, and which antibiotic drugs they are given in hospital.
- 2. Study ends at discharge
- 3. No results will be available at the time of discharge of the participant

**6.0 APPENDICES**

**Informed Consent Log Form for FLACSAM study**

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Version 1.0: Title: <b>Informed Consent SOP</b>	Dated: <b>13/7/ 2017</b>	SOP No.: <b>002</b>	No. Pages: <b>7</b>
Version 2.0: Title: <b>Informed Consent SOP</b>	Dated: <b>20/11/2019</b>	SSP No.: <b>002</b>	No. Pages: <b>9</b>
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:

**SOP Review and Updating Logs**

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW
25 Nov 2019	Isaiah Njagi		<ul style="list-style-type: none"> <li>• Periodic SOP review</li> <li>• Adopted the SSP template</li> </ul>
25 <sup>th</sup> Nov 2019	Isaiah Njagi		<ul style="list-style-type: none"> <li>• Removed Nancy Kagwanja as the preparer of the SSP</li> </ul>

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**SSP AWARENESS LOG**

I, the undersigned below, hereby confirm that I am aware that the accompanying SSP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SSP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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