# Standard Operating Procedure	SOP No: HALI-CON **-001** Version: **1** Effective Date: 18-01-10

Title: INFORMED CONSENT PROCESS PUPILS' PARETNS IN CLASSES 1 AND 5.

Principles for informed consent

- The subject/guardian must be COMPETENT in the language of communication
- The research team must DISCLOSE all relevant information to the subject
- The subject must COMPREHEND the information and understand how their involvement in the study differs from normal clinical care.
- 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

In Kenya, children below the age of 18 years are not allowed to give consent, and 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 informed consent documentation, the consent process must be witnessed.

1.0 PURPOSE / INTRODUCTION: This SOP describes the process to be followed for obtaining written informed consent from subjects/guardians taking part in the Health and Literacy Intervention project to ensure compliance with the above principles.

Study Title: Impact of malaria prevention on health and education in Kenyan school children
SSC No.: 1543
Study PI: Dr Simon Brooker, KEMRI-Wellcome Trust Research Programme

2.0 SCOPE / RESPONSIBILITY: This SOP applies to study staff involved in obtaining informed consent from participants in this study.

3.0 EQUIPMENT CHECKLIST:

3.1 1 consent timetable
3.2 1 verification timetable
3.3 1 education assessment timetable
3.4 1 Frequently Asked Questions sheet
3.5 1 information sheet
3.6 The list of names and ID numbers for the pupils in classes 1 and 5
3.7 The original school enrolment list as per school register
3.8 All consent forms labeled with names and IDs for the students in the school
3.9 Information sheets for as many consent forms as are present
3.10 1 clipboard
3.11 1 pen

4.0 METHODOLOGY:

4.1 **Where and when where will consent be taken?** Consent will be sought during pre-arranged parent meetings. The head-teacher will be contacted by the field office to arrange the meeting and asked to inform the parents of all pupils in the selection stream in Class 1

and in Class 5. Parents should be asked to come to the school at 8.30 am. Stress the importance that they attend, even if they have given their consent as there are some changes to the study that need to be explained.

4.2 **Who gives and witnesses consent?** Consent will be sought from parents or guardians of selected children. A witness is required who is independent of the study.

4.3 **How will it be sought?**

4.3.1 The language used while conducting the informed process should be one which the subject can comprehend and understand while speaking. The informed consent team member should be proficient in both written and spoken mode of the language used.

4.3.2 Start the meeting with a prayer and thank all the parents for coming again for the meeting. Ask the head teacher or school chairman will provide a brief introduction.

4.3.3 The literacy level of the subject will be assessed by asking the subject to read out a sentence or a paragraph in the written consent form. If a potential subject/guardian is considered illiterate, the consent documents and any other written study related materials must be read to them in a language best understood to them in the presence of an impartial literate witness.

4.3.4 Explain the changes to the study design since last year due to the withdrawal of amodiaquine. The main changes are as follows:

- because of the screening aspect of the intervention, there will no longer be a placebo group;
- treating only those children found to be infected with malaria parasites using rapid diagnostic tests (RDTs), not all children;
- the use of a different drug: Coartem instead of Fansidar and amodiaquine;
- malaria parasitaemia will no longer be assessed at baseline, but only at follow-up. This is because it was felt that it would be confusing to screen for malaria parasitaemia in the control group without providing treatment.

Also see **Frequently Asked Questions**.

4.3.5 After the information sheet has been read to/by the participant, the person seeking consent should ask one or two open questions to check understanding (note that it's not a useful check to ask "have you understood?"). The field worker should be available to answer all research questions asked by the potential subjects. See **Frequently Asked Questions**.

4.3.6 Once an individual has had all/his questions answered, after and their comprehension has been confirmed using one or two open questions, and has agreed to voluntarily participate in the study, the subject should sign and date the consent form.

4.3.7 The participant will be informed that even after voluntarily accepting to take part in the study; he/she may withdraw from the study at any time without penalty. If they have refused this should be immediately accepted, and nothing further (such as

signing anything) requested.

4.4 Signing the consent form.

If the consent giver can read there is no need for a witness

1. The fieldworker to ask the subject/guardian to print their name, sign and date the informed consent form
2. The fieldworker to sign and date the informed consent form
3. A copy of the informed consent form is given to the subject/guardian by the fieldworker
4. The giving of informed consent form is recorded in the source document by the fieldworker.
5. The signed informed consent form will be filed in a designated file which will be kept in the study office.
6. The outcome of all informed consent meetings is filled in the screening and recruitment log.
7. If consent is declined, the patient's data will not be included in the study.

If the consent giver cannot read then a witness is needed:

1. The witness is required to print the name of the subject/guardian on the informed consent form; and sign and date the consent form confirming that the information has been provided and that they have understood fully.
2. The subject/guardian should make their mark i.e. thumb print on the consent form

4.5 Completed consent forms. These should be returned to the field office where they will be crossed checked against the screening and recruitment log.

4.6 Preparing for the next day. Ensure lists and labeled consent forms are prepared.