

KEMRI Wellcome Trust Research Programme: Patient Information Sheet and Consent Form

STUDY & LAY TITLE

Institution	Investigators
Lead Institution	<i>(List names of investigators in a row for each institution to minimize space taken)</i>
Other Institutions	

Introduction for ill participants: You/your child's illness/symptoms

[Where relevant, start with general information about illness and tests/treatment that are part of standard care to provide reassurance on management and differentiate between standard care and study procedures]

Who is carrying out this study and what is this study about?

- *Make clear which is/are the lead institution(s) in this study, and explain their role(s) e.g. This study is being carried out by [the Ministry of Health] in collaboration with KEMRI/ by KEMRI in collaboration with [the Ministry of Education]/ by KEMRI. KEMRI is a government organisation that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit.*
- *[where indicated: Sometimes research involves only asking questions of patients, their parents, community members or health providers about what they know, feel or do].*
- *All research at KEMRI has to be approved before it begins by several national [where indicated: and international] committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.*
- *In this research, we want to learn more about [explain research question] by [outline method e.g. listening to your ideas and opinions on XXX]. We would like to hold discussions with [total numbers/types of participants/place of study e.g. a total of at least XXX patients/parents/providers who have been admitted/work/live in YYY]. We would like to talk to people individually/in groups in [state where and if applicable at what stage of admission/discharge].*

Why do you want to talk to me and what does it involve? [Use LIST/BULLETS to make easier to explain]

- *Explain selection*

e.g. for participants selected randomly through DSS: The area for this research includes 15 locations around KDH. KEMRI field workers visit all the homes in this area every 4 months to make a list of the people who live in the area. The children/adults in this research have been chosen randomly from this list of names in a way that every child/adult has the same chance of participating, without preference.

e.g. for purposive selection: We feel that your experience as [person working/living in XXX, or with XXX illness] can contribute much to our understanding and knowledge of [XXX].

- *[For focus group discussions]: We would like you to take part in a discussion with [7-8] other persons with similar experiences. The discussion will be guided by a trained facilitator. We will ask questions about [summarise issues covered in discussions]. You do not need to discuss any information you are not comfortable in sharing. The discussion will take place in [specify location/setting]. Only the people involved in the discussion, the person asking the questions, and a note-taker will be present.*
- *[For individual interviews/survey questionnaire]: I/my colleague would like to ask you a number of questions about [summarise issues covered in interviews]. If you do not want to answer any of the*

questions you may say so and the interviewer will move on to the next question. The discussion will take place in [*describe location/setting*]. No-one else but the interviewer will be present unless you would like someone else there

- [*Where recordings made*]: The discussion will be recorded to assist later in fully writing up the information. No-one will be identified by name in the recording.

Are there any risks or disadvantages to me / my child of taking part?

- The discussions should take approximately [*estimate realistically: XXX minutes*]. You will be provided with [*sodas/fare: specify amount if possible*] for your time and travel expenses.
- [*Where appropriate*] Answers about XXX and XXX can be confidential or sensitive to some individuals

Are there any advantages to me/my child of taking part?

[*Explain direct and, separately, potential societal benefits*] There are no individual benefits to taking part. In talking to us, you will contribute to knowledge of [*topic*] that may help other people in Kenya and elsewhere in the future, for example through developing new health policies [*where applicable*].

Who will have access to the information I give?

- [*For group discussions*]: We ask everybody in the discussion to keep what is said in the group confidential, but it is important to recognize that we cannot stop participants sharing what they have heard.
- All of our documents/ recordings are stored securely in locked cabinets and on password protected computers. *Where required: Indicate when recordings will be destroyed*
- The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, with [*where relevant, specify e.g. through publications/ with policy makers*].
- In future, information collected or generated during this study may be used to support new research by other researchers¹ in [*specify where indicated e.g. Kenya and other countries*] on [*specify where indicated e.g. malaria and other health problems*]. In this case, we will only share information in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.

What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences.

What if I have any questions?

You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

[*PI name and contacts*] Dr. _____, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: [Insert mobile] or 0722 203417, 0733 522063, 041 7522063

¹ i) Where data sharing is planned within a research collaboration described in this protocol, this should be made clear by including other institutions in the opening section of the information sheet; ii) Where data sharing will be undertaken through external repositories, explain this including what governance processes will be in place, or if access will be open/public. If open/public access, explain exactly what data will be made available in this way.

If you want to ask someone independent anything about this research please contact:

Community Liaison Manager, KEMRI – Wellcome Trust, P.O.Box 230, Kilifi. Telephone: 0723 342 780/0738 472 281 or 041 7522 063

And

The Secretary - KEMRI/Ethics Review Committee, P. O. BOX 54840-00200, Nairobi, Tel number: 020 272 2541
Mobile: 0722 205 901 or 0733 400 003

KEMRI-Wellcome Trust Research Programme consent form for [Study Title]

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

Yes please tick I agree to take part/for my child to take part in this research

Yes please tick I agree for the interview/discussion to be recorded

I understand that I can change my mind at any stage and it will not affect me/my child in any way.

Signature: _____ **Date:** _____

Participant/guardian Name: _____ **Time:** _____
(please print name)

Where parent/guardian cannot read, a witness* may observe consent process and sign below if needed:

I attest that the information concerning this research was accurately explained to and apparently understood by the subject/parent/guardian and that informed consent was freely given by the subject/parent/guardian.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____

**A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

Thumbprint of the parent as named above if they cannot write:

[Following section is recommended, and where verbal consent is obtained, must be signed by person undertaking informed consent.]

I have followed the study SOP to obtain consent from the [participant/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name : _____ **Time** _____
(Please print name)

THE PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

Notes [Do not include in your ICF]:

- Verbal consent can be used for interview where there are particular concerns about protecting participants' confidentiality or where you feel that signing a form is likely to importantly influence the information given. If verbal consent is sought, this must be justified in the ethical considerations section of the main protocol. For verbal consent, the template includes an optional section for the investigator/designee to sign to confirm verbal consent was obtained.*
- For FGDs, one person can sign on behalf of group with permission from the group.*