

Title: Assent to continue participating in CHILD trial for adolescents 10-17 years old.

NCT number: NCT05567016

Date: 04/28/2025

ASSENT TO CONTINUE PARTICIPATING IN THE CHILD TRIAL

For adolescents 10-17 years old

STUDY TITLE: Child Health and Infection with Low Density (CHILD) Malaria, a randomized controlled trial to assess the long-term health and socioeconomic impact of interventions targeting low-density malaria infection (LMI) among children in Tanzania.

PRINCIPAL INVESTIGATORS:

- Michelle Hsiang MD MSc (University of California, San Francisco, USA)
- Ally Olotu MD PhD (Ifakara Health Institute, Tanzania)

What is this study about and why are we asking you to continue participating?

Dr. Michelle Hsiang from UCSF, USA, and Dr. Ally Olotu from Ifakara Health Institute are conducting a study to determine whether treating low-level malaria has any benefits for the health of children. We have been seeing you and collecting samples for the last two years to help answer this question. However, the information we have collected so far is insufficient to conclude whether treating low-level malaria is beneficial for children. Therefore, we kindly ask you to continue participating in the study till November 28, 2025 because we believe that with more data collection, we will have enough information to answer this important question.

What will happen if you decide you might want to continue in the study?

First, your parents will be asked if they give their permission for you to continue to participate in this study. If your parents don't agree, you cannot be in the study.

If your parents do agree, and you agree too, here's what will happen next:

- You will be in the study until November 28, 2025.
- During this time, we will continue seeing you every month either at home or at the clinic as we have been doing since you joined the study.
- When we see you at the clinic or at home, we will collect samples like we have been doing while you were in the study.
- Except for urine and nasal swabs, which we will not collect during this time.

Will any parts of this study hurt or have other risks?

If you agree to be in the study, we will continue collecting the same samples we have been collecting since you joined the study. Your hand or finger may hurt a little when the needle is put into and taken out of your arm to collect blood.

What if you have questions?

If you have any questions about this study or your participation, you may call Dr. Nicolaus Gutapaka (Tel: 0719512306) who is the lead study clinician, Dr. Deborah Sumari (Tel: +255 713 413331) who is the Research Manager or any people who work at the clinic.

OR

The Secretary of the IHI-IRB Dr. Mwifadhi Mrisho Phone: +255 22 2774756 or the National Health Research ethics committee (NatHREC) (Tel: +255 22 2121400), who gave permission for this study, for questions regarding participant rights and the impact of the study on the study.

You may ask your questions now or later, any time you like. You can also ask your parents to ask questions for you.

What are your choices?

If your parents agree, you can continue to be in this study if you want to. But you don't have to be in it if you don't want to. Nothing will happen to you if you don't want to continue being in the study.

If you decide to be in the study now and you change your mind later, that's okay, too. You just have to tell the study doctor or the study staff as soon as you change your mind, and you will be taken out of the study.

If you don't want to be in this study, just say so, and don't sign this form.

If you want to be in this study, please sign your name below.

If you sign here, it means you agree to continue participating in this study.

The doctor will give you a copy of this form to keep.

Adolescent's Signature

Date

Age

Adolescent's Name (*print*)

Signature of Person Conducting Assent Discussion

Date

Name of Person Conducting Assent Discussion (*print*)