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Official Title: Exploring the impact of scaling up mass testing, treatment and tracking on malaria prevalence among children in the Pakro sub district of Ghana

NCT:

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Document: Consent form

GHS-ERC CONSENT INFORMATION SHEET

Title: Exploring the impact of scaling up mass testing, treatment and tracking on malaria prevalence among children in the Pakro sub district of Ghana

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General Information about Research

This study is implementation research. We are trying to find out how something that has work for a small population can work in a normal community with a large population like your community. The research is looking at ways to reduce the level of malaria in your community. Malaria is caused by something called the malaria parasite. When the mosquito bites you it passes the parasite that causes malaria into your blood. Everybody in your community can suffer from malaria especially pregnant women and children. When the parasite that causes malaria enters the blood of some adults, sometimes they may not have malaria. These adults have something in their blood that protects them against the malaria parasite. So as an adult, you may sometimes carry the parasite but will not be ill of malaria. Children suffer more from malaria, because they do not have that thing that fights malaria in their blood, so anytime they have the malaria parasite they will have malaria. When you treat malaria in the children and pregnant women and even those people who are ill, you remove the malaria parasite from their blood. But the parasite is still found in the blood of the people in your community who carry the parasite but are not ill. So, if you do not have that thing which will protect you from malaria and the mosquito bites a person around you who has malaria, it will carry the parasite. If the mosquito comes and bites you, it will transfer the parasite to you. This will make you to become ill again. We will like you to participate in this study so that we can remove the parasite from the blood of many of the people living in your community. How are you going to do this? You and every member of your household will be tested. If you are carrying the malaria parasite, you will be treated and we will follow up to see whether you have side effects such as vomiting, dizziness, weakness etc. If you do this, then you will remove the malaria parasites from the blood of those people who are not ill. If every both takes part, then you can reduce the effect of malaria in your community and the money you are using to treat malaria every year can be used to do other things in the house.

You will be participating in this mass testing, treatment and follow up of everybody with the malaria parasite once every four month over a period of two years. However, when you have malaria in the community, you will go to the community volunteer and the person will test you with a fast test and treat you if you are carrying the parasite that causes malaria. When the research team comes to your house, you will allow them to collect 200ul of blood (two drops of blood) and test to find out whether you have malaria. But if you have signs and symptoms of malaria and you do not have malaria the volunteer will send you to the Health Centre for check up by the Medical personnel. You will also be asked questions on the things you do at home to prevent malaria such as use of mosquito net etc.

Possible Risks and Discomforts

When your finger is pricked, you will have some pain. But this is only for a short time. Also when you take the malaria medicine you may vomit so the drug will be repeated. You may also feel weak, dizziness, have stomach upset, body weakness, etc in the course of treatment.

Possible Benefits

The level of malaria in your community could possibly drop and so many children will not be absent from school because of malaria. Your families will be able to use the money that you spend on malaria on other items needed by the family. Results from this work will help the National Malaria programme to be able to expand this programme to the whole of Ghana.

Confidentiality

To the best of our ability we will protect information about you and store it in a safe location at NMIMR for a period of five years and after that will be discarded. You will not be named in any reports and your name will not be released to any third party. Some staff of Epidemiology Department of NMIMR may sometimes look at your records for research purposes only. For this to happen, the person must have written permission from the Head of Department, co-signed by the data management unit head for a specified purpose under a project that has been cleared by the Noguchi IRB.

Compensation

Except for the free treatment given to those who test positive, there is not compensation of any kind. However, we will be providing some biscuits for children when they are tested.

Voluntary Participation and Right to Leave the Research

Participation in this project is voluntary and you can leave the study at any time.

Termination of Participation by the Researcher

If you migrate from the research area your participation will be terminated.

Notification of Significant New Findings

Any new finding or challenges related to the research will be communicated in due course to the District, Regional Health Service and the National Malaria Control Programme.

Contacts for Additional Information

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Your rights as a Participant

This research has been reviewed and approved by the Ethical Review Committee of the Ghana Health Service (GHS-ERC). If you have any questions about your rights as a research participant you can contact the ERC Office between the hours of 8am-5pm through the landline 0302682709 or email addresses info@ghsmail.org.

VOLUNTEER CONSENT FORM

The above document describing the benefits, risks and procedures for the research title ***(Exploring the impact of scaling up mass testing, treatment and tracking on malaria prevalence among children under fifteen years of age in the Pakro sub district of Ghana)*** has been read and explained to me. I have been given an opportunity to have any questions about the research answered to my satisfaction. I agree to participate as a volunteer.

_____ _____

Date Name and signature or thumbprint of volunteer

If volunteers cannot read the form themselves, a witness must sign here:

I was present while the benefits, risks and procedures were **translated** to the volunteer **in a language that she/he understands.** All questions were answered **to her/his satisfaction** and the volunteer has agreed to take part in the research.

_____ _____

Date Name and signature of witness

I certify that the **research information, that is the** nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above **volunteer in a language that the volunteer understands**.

_____ _____

Date Name Signature of Person Who Obtained Consent