

Neuroimaging Plus Study of Children in Malaria Fever RCT

My name is _____ and I am a nurse working for the Neuroimaging Plus study. When you were sick with malaria, you were part of a clinical trial using ibuprofen and paracetamol. Now I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian and they know that we are also asking you for your agreement. If you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at any time and I will take time to explain.

In this neuroimaging plus study we are going asking that children who were part of the Malaria Fever study come back to the hospital so we can do some evaluations to see how they are thinking and behaving and also to take a picture of the brain. We are doing this to help us understand whether the medicines used in the fever study were helpful or not. We are inviting all the children who were in the malaria fever study to come back for this additional study.

You don't have to be in this research if you don't want to be. It is up to you. If you decide not to be in the research, it is okay and nothing changes. This is still your clinic, everything stays the same as before. Even if you say "yes" now, you can change your mind later and it is still okay.

If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?

I have checked with the child and they understand that participation is voluntary _____(initial)

If you agree to participate, we will ask you some questions and ask for you to do some tasks. You might be asked to do some activities on a computer. These evaluations are to help us understand how you are thinking and behaving. Then we will take you to a large machine that is a camera that can take a picture of your brain. You will need to lie quietly for some minutes for this picture to be taken. Your parent can stay with you during this time. The camera can make some noise but it does not hurt. If lying still for this picture is very difficult for you, we can give you a tablet to help you relax and sleep while we take the pictures. We will also ask for a urine sample and do one fingerprick for blood at each of your two visits to see how your kidneys are working after the malaria infection.

Can you tell me what will happen if you agree to be in this study?

I have checked with the child and they understand the procedures _____(initial))

You may get bored or annoyed at what we ask you to do including that you will need to lie quietly for some minutes while the picture is taken but none of this will hurt you. If we find that you have a problem with thinking or behavior or there is a problem in the brain we see on the picture, we will send you to someone who can help you with the problem we find. If we find problems with your kidneys, we will make sure you are taken care of for that problem, too.

Can you tell me what might be bad about being in this study? And what might be good?

I have checked with the child and they understand the benefits _____ (initial)

If you agree to be in this study, then your parent will be provided with transportation funds and some money for the time and inconvenience.

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study. Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you

will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the researchers, the organization who paid for the research, and those who are in charge of making the research safe and appropriate.

Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?

You do not have to be in this research. No one will be mad or disappointed with you if you say no. It is your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want. You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

"I understand the research is about seeing how I am thinking and behaving and how my kidneys are working after my malaria infection and also taking a picture of my brain. I understand I will be tested by a nurse for about 1 hour and then I will have to lie still for some minutes while they take a picture of my brain. I understand there will be one fingerprick and I will be asked to give a urine sample.."

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have not signed the assent below._____ (initialled by child/minor)

Only if child assents:

Print name of child _____

Signature of child: _____

Date: _____
day/month/year

If illiterate:

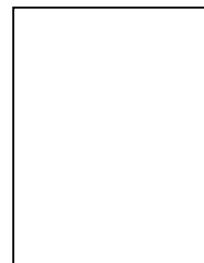
A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year



I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher _____

Signature of researcher _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

- 1. Tests of thinking and behavior**
- 2. A picture of the brain (MRI or CT) will be taken**

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent _____

Signature of Researcher /person taking the assent _____

Date _____
Day/month/year

Copy provided to the participant _____ **(initialled by researcher/assistant)**