

## Informed consent and parental consent form community-based surveys

**Title: The Center for the Study of Complex Malaria in India: A cluster randomized trial to assess effectiveness of malaria camps as part of the Odisha state malaria elimination drive (Phase 1)**

Name of Principal Investigators: Jane Carlton, Praveen Sahu, Sanjib Mohanty (co-Lead)

### To the Participant:

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

This study aims to learn more about malaria, malaria prevention, and malaria elimination in Odisha.

This study will last for 4 visits including this one. Each visit includes blood tests from you or your child and questionnaires. The blood will be tested for malaria and we will study your and the malaria parasite's genetic code (DNA). The blood will be stored for a long time for study purposes. A comprehensive list of all possible risk and discomforts related to this research is included below. The most common risk is pain, bruising, or bleeding from having blood taken. Your direct benefit from participation will be testing for malaria and referral for treatment.

For in-depth details regarding this study, please refer to the full informed consent document attached.

- I have read the information sheet concerning this study and I understand what will be required of me *[of my child]* if I agree to take *[my child agrees to take]* part in it
- My questions concerning this study have been adequately answered by the research team member
- I understand that at any time I *[my child]* may withdraw from this study without giving a reason. If I withdraw from the study, only information and blood samples collected up to the point of withdrawal will be used in the study, unless I specify all samples *[of my child]* should be destroyed and all data should be removed.
- I agree *[for my child]* to take part in this study

### Storage of Specimens and Future Use:

Initial ONE choice

I agree to allow my *[my child's]* samples and information to be kept for future research on genes and characteristics of malaria parasites or diseases. The future studies can also include studying my *[my child's]* genes and characteristics that make me *[my child]* fight infections. Examples of such studies include tests for other diseases such as dengue, or analyses using new malaria tests that have not yet been developed.

I do not agree to allow my *[my child's]* samples and information to be kept or used for future research.

Print Name of Participant

Signature of Participant

Date (month/day/year)

Print Name person obtaining consent

Signature of person

Date (month/day/year)

Print Name of Witness

Signature of Witness

Date (month/day/year)

Print Name of Parent/guardian\*

Signature

Date (month/day/year)

**\*If consent form is used for a minor (1-17 years). Note: if 7-17 years, use additionally assent form**

**Finger print in lieu of signature:**



# Information sheet informed and parental consent form: Community based surveys

**Title: The Center for the Study of Complex Malaria in India: A cluster randomized trial to assess effectiveness of malaria camps as part of the Odisha state malaria elimination drive (Phase 1)**

**Name of Local Principal Investigator:** Praveen Sahu; Sanjib Mohanty (co-Lead)

**Contact Details:** E-mail: praveenkishore.sahu@gmail.com, Phone: +91 77 3511 6665

## A) Purpose of the study

You are being asked *[for your child]* to volunteer in a research study. A research study is when researchers collect information to learn more about a disease. This is a research done by the New York University (New York, USA), Community Welfare Society Hospital (Rourkela, Odisha), and the Odisha State Malaria Control Programme. We are doing this research study to learn more about people infected with malaria and how to prevent malaria infection. After we tell you about this research study, we will ask you if you would like *[your child]* to be in this research study or not. If you decide *[for your child]* to be in this research study, you will be asked to sign this paper and you will be given a copy of this document to take home with you. In this study we want to look at the different types of malaria and why some people do and do not get sick when they are bitten by mosquitoes that have malaria. We will need to take a blood sample and ask some questions. The goal of this study is to get more information on how to prevent malaria. We also want to learn whether increasing education and awareness about malaria and malaria prevention measures is helpful in further lowering incidents of infection and disease.

## B) Subject participation

We will ask a total of about 2,244 people to take part in this study of malaria at approximately 12 different villages in Odisha. Asking questions and taking blood will take about 30 minutes. In this study we will ask to see participants during enrollment (now) and at 3 additional follow up time points. Only people age from 12 months to 69 years of age can take part. Children aged 7-17 will also receive an assent and information sheet to review and sign.

## C) Description of research

We are going to houses in this community and asking them take part. You are free to take part in this study or not. We will ask persons with malaria symptoms and also persons without malaria symptoms to take part in this study. This is important because sometimes people may have malaria and not feel sick. This helps us to understand why some people can resist becoming sick, while others cannot. Blood will be taken from all individuals at all visits (e.g. the initial visit happening now and all 3 follow up visits).

If you choose *[for your child]* to take part in this study, we will take approximately 1 ml of blood (less than 20 drops) today *[from your child]*. We can take this blood from your *[your child's]* finger or we can take the blood from a vein in your *[your child's]* arm using a small sterile needle. If you are *[your child is]* found to have malaria parasites, we will need an additional sample of 5 ml of blood (about a teaspoon) that would be taken from a vein in the arm using a small sterile needle. This will be done by a health professional trained in taking blood. You will be asked questions *[for your child]*, like: what is your *[your child's]* birthday, have you *[has your child]* had any recent illnesses, and are you *[is your child]* currently taking any medications? All this information will be kept private. If you are uncomfortable answering certain questions, you may skip those. During this visit, we will take your *[your child's]* temperature, measure your *[your child's]* weight, height and arm thickness, and perform a rapid malaria test to see if you have *[your child has]* malaria now. If you are *[your child is]* found to have malaria parasites, you *[your child]* will be given malaria treatment at no cost by the local government authority within one day.

If you have malaria, we will test the malaria parasites in your *[your child's]* blood to see which malaria types you have. The tests on the blood will help us know how a person fights malaria. We will look at malaria parasite molecules (genes and proteins) that are necessary for malaria parasites to infect persons. We will also do tests to see how the body fights malaria. In the blood sample we will look at the genetic code (DNA) for body cells and the malaria parasite, to find out what makes a person strong or weak to fight malaria or other diseases. DNA contains the information that all of the cells in the body need in order to function. The tests we will do are for research purposes related to malaria to help us with understanding, preventing, and treating malaria. We will not use your *[your child's]* DNA for tests that will be useful to you *[your child]* as an individual. These test results will not be given to participants.

All samples will be coded with a unique number. Only few people (the principal investigator and the data manager) will be able to link your *[your child's]* private information and samples to the unique number. Samples and your *[your child's]* information can be kept for use in the future until they are used up. Only trained study staff can access these

stored samples and this information. These samples are only for research and we would not be returning any results to you. If you change your mind and no longer want your *[your child's]* samples to be kept for use in the future, you can request that we destroy any remaining samples by contacting the principal investigator (his contact information is at the top of this form).

#### **D) Costs**

There are no costs (expenses) when taking part in the study.

#### **E) Potential risks and discomforts**

The taking of blood by a small needle can cause a little pain. Some pressure is applied to the site after collecting the blood. Bruising at the site might occur, but should be slight and will go away in the next few days. Most people agree that taking blood with a small needle is less painful than a finger stick. We can collect the blood by a finger stick, if you would like *[for your child]*. No other side effects are expected from blood taking. There are no risks of taking part for children, women who can become pregnant, or pregnant women.

#### **Genetic testing:**

As said before, in your *[your child's]* blood sample we will look at the genetic code for your cells and the malaria parasite, to find out what makes a person strong or weak to fight malaria or other diseases. These types of tests (genetic testing) can give information about your *[your child's]* risks on diseases and this can cause problems (like an increase in being scared for your health, or a loss of health insurance). For this reason, the information will be kept in locked cupboards and in safe databases accessible only to the study team. The test results will not be given to participants, or other people or organizations. Names of participants or other personal information will not be mentioned in publications or reports.

#### **F) Potential benefits**

You *[your child]* will be tested for malaria. If you have *[your child has]* malaria, you *[your child]* will get malaria treatment at no charge by the local government authority. Additionally, when you take *[your child takes]* part you *[your child]* will help to get valuable information to help your community and the world develop ways to treat and prevent malaria and improve health.

#### **G) Alternatives to participating in the study**

Your *[your child's]* participation in this study is voluntary. If you do *[your child does]* not want to take part in this study, you *[your child]* can still be tested and treated for malaria at no charge by the local government authority (in a clinic). You can agree to only take part if you don't feel well *[your child does not feel well]* and think you have *[the child has]* malaria.

#### **H) Confidentiality**

As a participant in the research you can expect that all the information you give *[for your child]* will be treated in confidence. This means that your *[your child's]* name will not be used when we write our reports about the research. It also means that no one outside the research team will know how you as an individual answered the questions *[for your child]*. Your *[your child's]* blood samples will be stored using a unique code that will be linked to your *[your child's]* personal information, including your *[your child's]* name and contact information. Only few people (the Principal Investigator and the Primary Data Manager) can look at this information. The organization paying for the study (NIH), or people from ethical committees who keep the study under careful observation, or national regulatory agencies may look at documents and records kept by the Principal Investigator, including records for the participants in this study, to make sure the study is done in agreement with regulations.

#### **I) Compensation/treatment in the event of injury**

All forms of medical diagnosis and treatment involve some risk of injury. If you get *[your child gets]* any injury directly because of the research, please contact the local principal investigator Dr. Praveen Sahu (or co-Lead Dr. Sanjib Mohanty) at the following telephone number +91 77 3511 6665. If such problems arise, the study doctor will assist you getting medical care *[for your child]* but this study does not give money for medical or other injury-related costs.

#### **J) Voluntary participation and authorization**

Your decision to take part in this study *[for your child]* is completely voluntary (of your free will). You do not get money to take part. You do not give-up any legal rights by taking part or signing this consent form and your *[your child's]* participation does not affect your *[your child's]* routine medical care.

#### **K) Withdrawal from the study and/or withdrawal of authorization**

You are free to withdraw your consent and to stop *[your child]* taking part in this study at any time without problems for you at the institute which organizes the study. In the event that you become *[your child becomes]* diagnosed with a too low blood level, we will only take blood from a finger prick. A too low blood level is one of many symptoms that malaria can give. If you want to have your *[your child's]* blood sample not to be taken for storage for future use, the samples will be immediately destroyed after the blood tests for this study. Storage of the blood sample is optional, and can only be done if you agree with it *[for your child]*.

**M) Contact person**

If you have any questions about the research or if you have *[your child has]* a research-related injury, you can contact Dr. Praveen Sahu or Dr. Sanjib Mohanty; the contact information is on the top of this form. If you have any questions regarding your *[your child's]* rights as participant of this study, you can contact the clinician who is visiting your community. If you have any question about the ethical review of this study, please contact Dr. Mary Bara, Member Secretary and Senior Consultant, O&G, Community Welfare Society Hospital Rourkela, e-mail- iec.cwsh@gmail.com, office number- +91-8895501210.