Accompanying information for:

A global network for investigating the genomic epidemiology of malaria
The Malaria Genomic Epidemiology Network
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Further information at http://www.malariagen.net

TEMPLATE FOR INFORMED CONSENT FOR GENETIC STUDIES OF MALARIA

This informed consent template, which should be used in conjunction with the supporting guidelines (Supplement F), is intended to help investigators in the preparation of information sheets for MalariaGEN projects. Procedures for obtaining valid consent will inevitably vary between settings. The aim of this template is to outline essential core information, and to set out some practical considerations about the process of informed consent.

This template is likely to evolve as the consortium grows in experience. The current version is based on discussions with members of the MalariaGEN consortium up to August 2006, including the Bamako ethics workshop in February 2006. Any suggestions or practical lessons, e.g. wording that works well, would be gratefully received.

Overview of the information sheet and the consent form

The key goal of a MalariaGEN information sheet is to communicate effectively, and investigators must guard against information overload. A concise document that draws from the local context will communicate information much more effectively than a long document that tries to cover every eventuality.

In general, the information sheet should include the following sections:

1. Study title
2. Who are the researchers
3. What is the problem that this research project is trying to solve, and how it may benefit others in the future
4. How the researchers aim to tackle this problem
5. What will happen to the participant if they take part in the study
6. What are the risks
7. What are the benefits
8. What will happen to the sample
9. What will happen to the information including a statement about anonymity
10. A statement that participation is voluntary; that it will not affect decisions about medical care; and that the participant has the right to withdraw at any time
11. Name and details of the key contact person

The consent form should include:

1. A brief summary of key items from the information sheet
2. A record of the fact that consent was given and by whom
3. A record of the name of the person who obtained consent

Information sheet

1. Study title

Try to come up with a short simple study title – avoid any words, acronyms or phrases that might be misconstrued.

2. Who are the researchers

e.g. "We are researchers from XXX and we are working with other researchers in 20 different countries on malaria"

3. What is the problem that this research project is trying to solve

e.g. "As you know, many children become ill with malaria during the rainy season. It is a big problem here in XXX and we need to find ways to stop this happening. The illness is carried from person to person by certain types of mosquito that are present in the rainy season. Some children are able to fight off the malaria illness and others are not, and we want to discover why that is. If we can discover how some children are able to fight off the malaria illness, then we may be able to use this information to make a medicine that we can give to everyone, that will stop them developing malaria."

You might consider adding a sentence to distinguish between research and treatment, especially if samples are collected in a treatment facility. A possible way to do this is by pointing at the time difference in expected results, and the fact that research is for the benefit of all, whereas treatment is for the benefit of the patient only.

e.g. "research is looking for new ways of preventing and treating illnesses in the future for the benefit of everyone"

4. How the researchers aim to tackle the problem

e.g. "What we are asking to do is to take a sample of blood from your child to study the genetic material that it contains, and we would like to explain to you what that genetic material is. The genetic material is what makes everyone different from birth - in our height, in our looks, and in many other ways, including our ability to fight off illnesses like malaria. We are studying the genetic material from some children who are very ill with malaria, and other children who are not ill with malaria, to try to discover the exact part of the genetic material that is responsible for fighting off malaria."

In the information sheet, it is important not to deviate too far from the topic of study with unrelated examples to explain difficult concepts such as genetics. But on the other hand, one should also seek to make sure that all the necessary information a person might want to evaluate to make an informed choice, is present in the informed consent form.

5. What will happen to the participant if they take part in the study

e.g. "If you agree to participate in this study, we will take [this amount of] blood from your child, and will collect some information about your child and their medical condition. We would also like to ask you some information about yourself, such as your ethnicity."

Or : *"If you agree to participate, when the doctors take blood as part of the treatment of your child, they will also take [this amount of] extra blood for this study. We will collect some information about your child and their medical condition. We would also like to ask you some information about yourself, such as your ethnicity."*

In describing [this amount of] blood, think about the most informative way of conveying this. One way is to show a tube containing a coloured fluid. Another is to refer to a well-known quantity such

as a ‘teaspoonful’. Make sure that, in doing so, you do not offend any local cultural sensitivities, e.g. if blood in a spoon is locally associated with witchcraft!

6. What are the risks

e.g. “It will hurt a little bit when we put a needle into your child’s arm to collect the blood, but the study will not damage your child in any way”

Being explicit about risks, even if these are minor, can help to prevent ill-founded rumours about the study.

7. What are the benefits

e.g. “This study will not help your child to get better, but we hope that it will benefit future generations of children in XXX by helping us to make medicines that prevent the malaria illness. However you must realise that we are trying to tackle a very difficult problem, and that it may be many years before we achieve our goals.”

If you intend to offer participants some benefit, e.g. nutritional supplements or a test for anaemia, be careful to avoid any suggestion of coercion.

8. What will happen to the sample

e.g. “We will take the blood sample back to our laboratory in XXX, where we will extract the genetic material. We will keep some of this genetic material in XXX, and we will send some of it to researchers in the UK who are working with us on this project. We will do some tests on this sample immediately, but other tests will take many years to develop, and we are asking your permission to store the sample until we have finished all the genetic tests.

This section should alert participants to the fact that at the moment we have the ability to do only a limited genetic analysis, and that for a full genetic analysis we will need to store the sample for years.

9. What will happen to the information, including a statement about anonymity

e.g. “Once we take your child’s blood sample, we will assign it a code number and we will separate your child’s name from the sample. Only the principal researcher or somebody authorized by him or her will be able to link the sample back to your child. We will be very careful about the information that we have collected about your child, and we will make absolutely sure that when we tell people about our findings on the genetic material, no-one will be able to discover that this genetic material came from your child.”

10. A statement that participation is voluntary; that it will not affect decisions about medical care; and that the participant has the right to withdraw from the study at any time

e.g. “Your participation in this study is entirely voluntary – it is up to you. If you don’t want your child’s sample to be taken, then this will in no way affect the help you or your child will get in this clinic, now or in the future. If at any time in the future you change your mind and decide that you don’t want your samples to be used, please tell us and the sample will be destroyed. This will have no consequences for you.”

11. Name and details of the key contact person

The form should state who to contact for further information about the study, or to withdraw from it, and how to contact them.

e.g. "If you have any further questions please contact xxx and s/he will be able to explain better to you what our study is about. You should also contact this person if you would like to withdraw from the study, or if you have any worries regarding your child's participation in this study."

Consent form

1. A brief summary of key items from the information sheet

e.g. "I confirm that I have been read the form explaining [study title]. I understand that the researchers are asking for a sample of my child's blood. I have been given a chance to ask questions and feel that all of my questions have been answered. I know that my participation is entirely voluntary and that this will have no consequences for the medical care my child or I will receive. I also know that I can withdraw my consent at any time in the future. I have been given a copy of the consent form to keep."

2. A record of the fact that consent was given and by whom

Make space to record a thumbprint for those who cannot give a signature, or consider asking a witness to sign the consent form.

"I, _____ (name of parent or guardian), being 18 years or older and having full capacity to consent for _____ (name of child) give my consent for a blood sample to be taken from my child for inclusion in the research study entitled xxxx (name of research study)"

Signature or thumbprint _____ Date _____

3. A record of the name of the person who obtained consent

e.g. "I have read/explained the study to the mother/father named below in a language that she/he understands well. I believe she/he has understood the information and is allowing a small amount of blood from xxx to be taken out of her/his own free will"

Signature _____ Date _____