PARTICIPANT INFORMATION SHEET (ADULT)

Version 1.0 Date 05/12/2014

Study Title: Age-specific seroprevalence of anti-*Chlamydia trachomatis* antibodies and the historical prevalence of trachoma

SCC: 1408 Protocol: 

Sponsor: Wellcome Trust

What is informed consent?
You are invited to take part in a research study. Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve one’s health. The purpose of a research study is to gather information. It is your choice to take part and you can stop any time.

Before you decide you need to understand all information about this study and what it will involve. Please take time to read the following information or get the information explained to you in your language. Listen carefully and feel free to ask if there is anything that you do not understand. Ask for it to be explained until you are satisfied. You may also wish to consult your spouse, family members or others before deciding to take part in the study.

If you decide to join the study, you will need to sign or thumbprint a consent form saying you agree to be in the study.

Why is this study being done?
One reason many people go blind in The Gambia is because of trachoma. Trachoma is an eye disease that is easily passed from person to person. If you get the infection many times it can lead to scarring in your eyelid, which can cause the eyelashes to rub on the eyeball. This is painful and can eventually lead to blindness. When a person is infected with trachoma, they will produce antibodies to help fight this infection. These antibodies can stay in a person’s blood for a very long time.

The National Eye Health Programme has shown that the amount of trachoma in many communities in Gambia has gone down over time. There is much less trachoma in Gambia today than there was twenty and thirty years ago. We think this is because access to latrines and water has become better, as well as more community screening for eye health, and antibiotics for trachoma infection. Because the amount of trachoma has gone down, the younger people in your community should have less antibodies to trachoma than the older people.

We would like to conduct a study to see how many people in your community have trachoma today and how many people have antibodies to trachoma showing they had trachoma in the past.

We would like to check your eyes for signs of trachoma, take a photograph of your eyelid, and test your blood to see if you have antibodies against trachoma.

The results of the study will be made available to your community.
What does this study involve?
We will ask the people, of all ages, living in some households in your community to have their eyes examined. We will examine the eye by gently turning over the eyelid and then taking a photograph. We will also take a small sample of blood. This will be done using a new, clean lancet to prick the fingertip. We will collect a few drops of blood onto a piece of paper.
If we discover your eyes cannot be examined because of an eye disease, we will refer you to the nearest eye health unit for appropriate care.
If the research study needs to be stopped, you will be informed and you will have your normal medical care.

What will happen to the samples taken in this study?
The samples will be taken back to the MRC laboratory in Fajara for testing to see if there are antibodies against trachoma. We will also send some of the samples to a lab in England to verify the results. Samples will be stored for future research. Any future research will be approved by the Ethics Committee.

What harm or discomfort can you expect in the study?
We will prick your finger with a sharp pin to collect the blood. This can cause some discomfort but the discomfort is not expected to last more than a day.

What benefits can you expect in the study?
While there are no direct benefits to you, the information we get from this study will help us determine if trachoma has been successfully eliminated from your community. This will help researchers make decisions that will help other communities around the world in their efforts to eliminate trachoma.

Will you be compensated for participating in the study?
You will not get paid for participation.

What happens if you refuse to participate in the study or change your mind later?
You are free to participate or not in the study and you have the right to stop participating at anytime without giving a reason. This will not affect the medical care that you would normally receive.
In case you decide to withdraw your participation during the study, we will not work on your samples without your permission, but any information already generated from the samples will be kept.
Should any new information become available during the study that may affect your participation, you will be informed as soon as possible.

If you are injured in the study what compensation will be available?
We will be responsible to provide for treatment caused by procedures of the research study.
If medical treatment is required as an emergency, please refer to your health centre or clinic and contact the field worker who gave his/her telephone number to you or contact Stephanie Migchelsen on [Phone number] or Mr Sarjo Kanyi on 9901716, 3011349, 6651344 or 7510996.
How will personal records remain confidential and who will have access to it?
All information that is collected about you in the course of the study will be kept strictly confidential. Your personal information will only be available to the study team members and might be seen by some rightful persons from the Ethics Committee, Government authorities and sponsor.

Who should you contact if you have questions?
If you have any queries or concerns you can contact Stephanie Migchelsen on [Phone number] or Mr Sarjo Kanyi on 9901716, 3011349, 6651344 or 7510996 and you can always call the personal numbers of the study staff given to you.
Please feel free to ask any question you might have about the research study.

Who has reviewed this study?
This study has been reviewed and approved by a panel of scientists at the Medical Research Council and the Gambia Government/MRC Joint Ethics Committee, which consists of scientists and lay persons to protect your rights and wellbeing.
CONSENT FORM

Participant Identification Number: |__|__|__|__|__|__|__|__|__|__|__|__|

______________________________
(Printed name of participant)

☐ I have read the written information OR
☐ I have had the information explained to me by study personnel in a language that I understand,

and I
• confirm that my choice to participate is entirely voluntarily,
• confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided,
• understand that I grant access to data about me to authorised persons described in the information sheet,
• have received time to consider to take part in this study,
• agree to take part in this study.

Participant’s signature/thumbprint*

Date (dd/mmm/yyyy)             Time (24hr)

Printed name of witness*

Printed name of person obtaining consent

I attest that I have explained the study information accurately in ______________________________ to, and was understood to the best of my knowledge by, the participant. He/she has freely given consent to participate *in the presence of the above named witness (where applicable).

Signature of person obtaining consent

Date (dd/mmm/yyyy)             Time (24hr)

* Only required if the participant is unable to read or write.