PARTICIPANT INFORMATION SHEET (CHILD)

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 let your child take part in a research study. Before you decide you need to understand why the research study is being done 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 is not clear or you do not understand. You may also wish to consult your spouse, family members, friends or others before deciding to let your child take part in the study.

If you decide to allow your child to join the study, you will need to sign or put a thumbprint on a consent form saying you agree for your child to be in the study. If your child is between the ages of 12-17, we will ask for his/her assent as a signature or thumbprint.

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 toady and how many people have antibodies to trachoma showing they had trachoma in the past.

We would like to check your child’s eyes for signs of trachoma, take a photograph of your child’s eyelid, and test his/her blood to see if he/she has 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 child’s eyes cannot be examined because of an eye disease, we will refer him/her to the nearest eye health unit for appropriate care.
If the research study needs to be stopped, you will be informed and your child will have the 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 child’s finger with a sharp pin to collect the blood. This can cause some discomfort to your child 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 or your child, the information we get from this study will help us determine if the 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 your child’s/ward’s participation in the study?
You will not get paid for participation of your child in the study.

What happens if you refuse to participate in the study or change your mind later?
You are free to let your child participate or not in the study and you have the right to stop his/her participating at anytime without giving a reason. This will not affect the medical care that your child would normally receive.
In case you decide to withdraw your child’s participation during the study, we will not work on your child’s 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 child’s participation, you will be informed as soon as possible.

What compensation will be available if your child is injured during the study?
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 your child’s information be kept and who will be allowed to see it?**

All information that is collected about your child in the course of the study will be kept strictly confidential. Your child’s 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 / ASSENT FORM

Participant’s Name __________________________________________

Participant’s Identification Number: |__|__|__|__|__|__|__|__|__|__|

___________________________________________ OR ____________________________________________

(Participant’s signature/thumbprint* for assent (child aged 12-17 years)

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

Participant’s parent/guardian 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/parent/guardian. 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.