

**The Fred Hollows Foundation, Ethiopia**  
**The Oromia Regional Health Bureau, Ethiopia**  
**London School of Hygiene and Tropical Medicine, UK**

**Stronger SAFE: Phase 1 - understanding transmission for an enhanced SAFE Strategy for trachoma elimination in Ethiopia**

**INFORMATION SHEET B: POPULATION-BASED STUDY**

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**Who is sponsoring / conducting these studies?**

These studies are being conducted through a partnership between the Ethiopian Federal Ministry of Health, the Oromia Regional Health Bureau, the Fred Hollows Foundation Ethiopia and the London School of Hygiene & Tropical Medicine. This work is funded by the Wellcome Trust (UK).

**What is the purpose of this study?**

Trachoma is an eye disease caused by infection (with a bacterium or germ called Chlamydia) which is passed from eye to eye. After people have had many infections, it can cause scars to form in the upper eyelid. This pulls the eyelashes inwards, causing damage to the surface of the eye. This is painful and causes blindness in some cases. The purpose of this study is to learn more about how the germ that causes trachoma (Chlamydia) is passed from eye to eye in your community. We are interested to learn more about the daily routines, including washing and sanitation practices, of rural Ethiopians and how this may affect health and the transmission of this eye disease. We believe that flies can also transmit trachoma. We want to learn more about how flies transmit trachoma. We hope that we will be able to use the information we learn from this study to understand how we can stop trachoma being transmitted in your community and improve trachoma control in Ethiopia.

**What will I be asked to do if I participate in these studies?**

(Field Worker to tick the box of sections relevant to each participant)

**Structured observation and interviews in households**

Should you agree to participate, two of our female field workers will arrange a time to visit your house. The researchers will spend time in your home and will take notes about your daily routines and the way you do things as a family. On the agreed day of the research the field workers will either arrive early in the morning around the time you wake up and spend the following 4 hours with you or they may arrive after lunchtime and stay for 4 hours until the evening. You will notice that the field staff are taking notes, this is just to document and learn from what you are doing. They will not judge how you behave. The observations they make will be anonymous and when the results of this study are shared your name and identify will not be mentioned. While the researchers are in your home they may accompany you for all your daily tasks including things like water collection, food preparation and eating and farming. The researcher may also ask to take video footage or photos of you. You can decide whether you are happy with us taking these photos or videos and specify how we may use them on the consent form. At any point you can change your mind or say no. Once the observation has concluded the field staff will conduct a short interview with you. They will ask you some questions about your family's household routines and your health. Altogether this process will use no more than 5 hours of your time, but during this time we expect you to continue doing your daily activities as you normally would.

**Trapping and collection of flies around the household and compound**

Should you agree to participate our field workers will arrange a time to visit your house. The researchers will spend time in your home and compound observing the behaviour of flies that are thought to be important in transmitting disease. They will make notes about the fly behaviours and will install some traps to capture the

flies to study in the laboratory. On the agreed day of the research the field workers will either arrive early in the morning around the time you wake up and spend the following 4 hours with you or they may arrive after lunchtime and stay for 4 hours until the evening. You will notice that the field workers are taking notes, this is just to document and learn from what you are doing. The observations they make will be anonymous and when the results of this study are shared your name and identify will not be mentioned. While the researchers are in your home they will accompany you for all your daily tasks including things like water collection, food preparation and eating and farming to observe the flies around the household and compound. The researcher will also ask to take video footage of you, focused on your face, to record the fly behaviour. We will catch flies as they leave your face. We will also catch flies in the compound using different types of traps to count the numbers present and assess the fly responses to different odours and lures. You can decide whether you are happy with us taking these photos or videos and specify how we may use them on the consent form. At any point you can change your mind or say no. Altogether this process will use no more than a four hours of your time but during this time we expect you to be able to continue doing things as you normally would.

**Swabbing of surfaces and cloths in the household**

Should you agree to participate, our field workers will arrange a time to visit your house. To find out whether the trachoma germ (Chlamydia) is present on surfaces that we think are important in the transmission of trachoma, we will collect swabs to test for Chlamydia from surfaces and fabrics in your household and compound. These swabs will be tested in laboratories in Ethiopia and the UK.

**Eye examination with digital photographs and conjunctival (eyelid) swabs**

Should you agree to participate, our field workers will arrange a time to visit your house. To find out whether the trachoma is present in your household, we would like to examine the eyes of all members of your household. We will take a photo of each eye that we examine using a special camera. We will also take two samples (with cotton swabs) to test for the presence of the trachoma germ (Chlamydia). These swabs will be tested in laboratories in Ethiopia and the UK. The eye examination is a little uncomfortable but will not harm eyes in any way. The examination takes only a few moments to complete. There are no risks associated with taking swab samples. This examination has been carried out in many countries including Ethiopia without problem.

**Swabs of hands and faces of household members**

Should you agree to participate, our field workers will arrange a time to visit your house. To find out whether the trachoma is present in your household, we would like to take some swabs (cotton swabs) from hands and faces of members of your family to look for the presence of the trachoma germ (Chlamydia). We will also take photos of your hands and faces. These swabs will be tested in laboratories in Ethiopia and the UK. Collecting swabs from hands and faces will not harm you or your family in any way; it is not uncomfortable and does not cause any pain. The swabs take only a few moments to collect. There are no risks associated with taking swab samples.

## **General Information**

### **Where are these studies taking place?**

This research is taking place in communities in Oromia. Around 200 households will participate in this study.

### **Your participation is VOLUNTARY**

Study staff will help you understand this form and answer your questions. You are free to choose whether you want to participate or not. If you feel uncomfortable with the researcher being in your house or watching what you do then you should inform us. You can withdraw from any part of the study at any time, for any reason. If you do agree, you are still free to withdraw participation at any time without any consequences to you or your family; should you withdraw from the study, you will continue to obtain the regular benefits of any health care services you normally get at the clinic.

**What are the possible benefits to being in these studies?**

Research is designed to benefit society by contributing new knowledge which will help shape future health programs. You may, however, receive no direct benefit from the study. As part of the assessment we will examine your eyes and if any significant problems are identified we will arrange for you to be referred for help.

**What are the possible risks or discomforts involved with being in these studies?**

This study does not pose any risks to you or your family. Our field workers are trained and sensitized to respect your emotions. Our field workers are aware that the study is aimed at understanding and documenting behaviour; not judging you or your family's behaviour. If you feel uncomfortable during any stage of the study please let our field workers or the field supervisor know. The collection of the eye swabs is associated with a few seconds of mild discomfort.

**Will people find out what I do or say?**

Your personal identity will be protected at all times and nothing the researcher observes you doing or discusses with you will be linked to you by name when they write up the study.

**What will happen to the information we collect?**

All the information collected and photographs taken will be kept confidential. It will be kept securely. Only the people organising the study will have access to it. The photographs will only be used for documenting the clinical signs and for independent verification. They will be anonymised. They will not be used for publication. Data collected in the study may be made publically accessible. However, this will not contain any identifying information.

**What if I have questions about this study?**

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, or concerns please contact: Mr Oumer Shafi, Principal Investigator, Mobile Telephone: +251912048181.

**What if I have questions about my rights as a research participant?**

All research on human volunteers is reviewed by both the National and Oromia Health Bureau Ethical Review Board and LSHTM Research Ethics Committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact:

Name: Mr Oumer Shafi (Tel: +251912048181)