

# AHRI Household Contact Study

Defining drivers of TB transmission in the era of universal ART, and implications for finding the walking well

This document includes the following participant information sheets and informed consent / assent forms:

No.	Participant	Main procedures for which consent / assent requested
2	Parent or guardian of index participant (aged 15-17 years) (with TB, or non-TB control)	Consent for 15-17yr old index participant to take part in study Questionnaire: symptoms, TB and HIV care history, healthcare utilisation, cost of accessing care, TB index participants only: consent to collect sputum specimen for TB testing and blood specimens for HIV, HIV VL and CD4 tests and consent to approach other household members TB index participants only: Consent to store sputum specimen

## 2: Parent/guardian of 15-17 year old index participant

### AHRI Household Contact Study

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#### The researchers doing this study are:

*Africa Health Research Institute (AHRI):* Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyapelo, Janet Seeley

*London School of Hygiene & Tropical Medicine, UK:* Alison Grant, Palwasha Khan, Katherine Fielding, Nicky McCreesh, Rein Houben, Richard White, Anna Vassall, Janet Seeley, Sedona Sweeney

#### Introduction [for parent/guardian]

Good day, my name is [name of researcher], and I am a researcher at AHRI. We would like to invite your child to take part in a research study. Research is the process to learn the answer to a question. This information sheet explains our study. You are free to decide whether you wish your child to take part. Before you decide, it is important that you understand why the research is being done and what it will involve. Please ask me if there is anything which is not clear. If you decide your child can take part, to show that you understand the study and agree that your child can take part, we will ask you to sign or make your mark on a consent form. It is your right to withdraw your child from the study at any time. Your decision to take part or not will not affect your health care in any way.

#### Why are we doing this study?

TB is a major health problem in South Africa, and particularly in KwaZulu-Natal. TB is caused by a germ which is passed from person to person through the air, for example by coughing, sneezing or singing. In South Africa, many people breathe in TB germs at some time in their life. For most people, their body controls the TB germs, and the TB germs do not cause harm. This is called TB infection. People with TB infection are well, and doctors can only find out if a person has TB infection by doing a skin test or blood test. In a few people, the TB germs do cause illness, usually in the chest. This illness can start months or years after breathing in the TB germs. If a person with TB takes the right TB treatment, they stop being infectious very quickly. TB can be completely cured by taking a combination of medicines, usually for six months.

To stop TB being passed from person to person, we need to understand why some people with TB are more infectious than others. We can do this by studying the number of children who have TB infection in different households. If we can understand why some people with TB are more infectious than others, we may be able to work out how to find people with TB earlier and start them on treatment earlier, which would help reduce the number of people who get TB infection and who get sick with TB.

#### Why has my child been chosen to be invited to take part in this study?

Your child has been chosen because [researcher to explain why, based on the group the potential participant belongs to: either 1. they are a resident in the AHRI demographic surveillance area or 2. because s/he has been found to have TB.

#### If your child takes part in this study, what will happen?

*TB index/control participants:* if your child takes part in this study, we will ask your child some questions about their health currently and in the past, including any treatment for TB, visits made to health facilities, and how much this cost. This will take about 30-45 minutes.

*TB index participants only:* We would like your child to also have a chest x-ray to assess the TB in their lungs. This investigation is not available routinely to all TB patients through the TB programme. We will arrange an appointment for your child to have a chest x-ray and we will also arrange transport to take you and your child

to and from the chest x-ray facility. We would also like to collect two sputum specimens from your child for TB testing at the AHRI laboratory in Durban and to take blood for HIV viral load and CD4 count if your child is HIV-positive. We will make sure that all results are shared with your treating clinician.

*All participants (TB index and control):* With your consent, we may also contact your child at a later date by phone to ask your child more detailed questions about costs your child has incurred including money spent on accessing healthcare. Your child will be reimbursed for their time.

*Household information:* We may need to ask the head of household some questions about the household, such as type of house, source of water, and things that are owned by people in the household. If AHRI recently collected this information, we will use information already collected.

*Household screening for TB:* We would like to check everyone in your child's homestead for TB by asking them some questions about their health. For very young children, we would ask these questions to their parent or main caregiver. If anyone in the household has signs of possible TB, we can help them access care at a local clinic. Testing and treatment for TB is free of charge at all Department of Health clinics.

*TB infection in children:* We would like to take a blood sample from all children in your child's household aged between 2 and 14 years, and test the blood sample for TB infection and HIV. We will also ask some questions, either to the child or (for young children) their caregiver, about the child's health, any illness they have had, visits to clinics or hospitals and contact with other people with TB.

*Linkage to other records:* We would like to link information from this study to other information that AHRI has collected about your child as part of the Vukuzazi study (if your child took part in Vukuzazi), and the information that Africa Centre / AHRI has collected about your family over the years. We will be very careful to be sure that all information you give us is kept confidential.

#### **TB index participants only: Will sputum specimens that your child gives for the study be stored?**

With your permission we will store the sputum sample your child gives us, as well as any TB germs grown from it and the genetic material of the TB germs. We will store these samples in our laboratories in Durban for up to 20 years. It is possible that these samples and the information we collect from this study could help with a future research study to understand TB better. In that case, we would ask approval from the Ethics Committee to use the specimens. The Ethics committee's job is to make sure that people taking part in our studies are protected from any harm. If you decide later on that you want us to stop storing your samples, please tell us, and then we will destroy the samples. We will not be storing any of the blood specimens we collect from your child, these will be destroyed after the tests are completed.

#### **What are the possible risks of taking part?**

For people with TB taking part in this study, including your child, we will ask questions about current and past health and possible contacts with people with TB. There are no major risks from answering these questions. For the children who give a blood sample, there might be some pain from having blood taken from the arm. We will reduce this by putting some cream on the child's arm that helps to numb the skin. There is also the risk of a bruise developing at the site where the blood was taken. This will be reduced by pressing firmly on the skin after the needle is taken out.

#### **What are the possible benefits of taking part?**

If your child is aged 5 years or below, or is HIV-positive, then they may benefit from having a course of treatment (TB preventive treatment) to prevent TB disease, if they have not already taken this medicine. We will help them access care for clinical review and if active TB is excluded, then they may be prescribed this treatment at the district hospital. You will be reimbursed the cost of travel to district hospital for the first review.

If your child is over 5 years of age and has either symptoms or a positive test for TB infection, we will arrange clinical review at a local clinic by our study clinician. If the study clinician feels that further clinical review is

required then we will arrange review at the district hospital. Parents will be reimbursed the cost of travel to the local clinic and if required for the first review at the district hospital.

If a person has TB disease and starts treatment quickly, the TB is less likely to cause serious disease. We hope that this research will help us to find ways to identify and treat TB earlier, which may in the future help reduce the spread of TB among people in South Africa and elsewhere.

If your child is willing to take part in the study, we will give them a refreshment and a cloth facemask as a token of appreciation for their time. If your child's household takes part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time they have spent taking part in this research. If we invite your child to take part in an additional questionnaire on costs incurred by your household at a later date, we will reimburse your child for their time with an airtime or food voucher to a value of ZAR 50.

### **What happens if I do not agree for my child to take part in this study?**

You do not have to agree for your child to take part in this study: if you do not agree, this will not affect you or your child in any way. You can change your mind at any time, without giving a reason.

### **How will the information collected during this study be kept confidential?**

All information collected during the course of this study will be kept securely and confidentially at AHRI. We will store information on a secure computer system. The information we collect will be identified on forms and computer files only by a study number or barcode, not you or your child's name. This means that you and your child's information remains private.

Study information may be looked at by the Ethics Committee, and authorised independent monitors, to check that the study procedures were done correctly, and the information is accurate. You and your child's information will remain confidential, unless we are required by law to release information. Reports about the study will never include information which allows you to be identified.

Results from the study will be presented to people working in the TB programme, the Department of Health, and other researchers as presentations and publications in medical journals. In all these presentations and reports, it will not be possible to identify people who took part.

We will share the information that we collect in this study with other researchers. When we share information, we will not share any information that identifies you, such as name or address or date of birth.

### **Who is funding the research?**

This research study is funded by the National Institutes of Health in the United States of America.

### **Who has reviewed the study?**

All research at AHRI is reviewed by an independent group of people, called a Research Ethics Committee, to make sure that the research is important for science, and to protect the interests of people taking part. This study has been approved by the Biomedical Research Ethics Committee at the University of KwaZulu-Natal and the Research Ethics Committee of the London School of Hygiene & Tropical Medicine. The study has also been approved by the AHRI Community Advisory Board and by the Department of Health.

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

If you have any questions, please ask me now. If you have questions about the study later you may contact the lead researcher:

*Professor Alison Grant*

*Professor of International Health*

*c/o AHRI*

*PO Box 198, Mtubatuba 3930*

*Tel: 035-500-7500; fax: 035-550-7565; email: [alison.grant@ahri.org](mailto:alison.grant@ahri.org)*

If you have concerns about the study, you can contact the UKZN Biomedical Research Ethics Committee:

*Biomedical Research Ethics Administration*

*Research Office, Westville Campus*

*Govan Mbeki Building*

*Private Bag X 54001, Durban 4000*

*Tel: 031-260-4769; Fax: 031-260-4609; Email: [BREC@ukzn.ac.za](mailto:BREC@ukzn.ac.za)*

We will give you a copy of this information sheet which explains the study to take away with you.

2: Parent/guardian of 15-17 year old index participant

Study ID

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I have read the information sheet about this study (or the information sheet about this study has been read to me). I understand what will be required of my child and what will happen to my child if s/he takes part in the study.

My questions concerning this study have been answered by:

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Research staff name (printed)	Signature	Date
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I understand that I may withdraw my child from this study at any time without giving a reason, and without affecting my child's normal care and management.

I understand that the information collected from me may be shared with other researchers, to do projects which have been approved by an appropriate ethics committee. None of my child's personal details will be shared.

I agree for my child [*name of child* \_\_\_\_\_] to take part in the study.

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Parent/guardian's name (printed)	Signature/ thumbprint	Date
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*If the parent/guardian gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:*

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Witness name (printed)	Signature	Date
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