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
1	Index participant (≥18 years) (with TB, or non-TB control)	Individual consent Questionnaire: symptoms, TB and HIV care history, healthcare utilisation, cost of accessing care, including (for TB index participants only) consent to collect sputum specimen for TB testing and blood specimens for HIV, HIV VL and CD4 tests Consent to approach other household members Consent to store sputum specimen (TB index participants only)
	Parent or guardian of index participant (aged 15-17 years) (with TB, or non-TB control)	[This form was previously amended and is attached as a separate document]
3	15-17 yr old index participant (with TB, or non-TB control)	Assent Questionnaire: symptoms, TB and HIV care history, plus for index participants, healthcare utilisation, cost of accessing care, including (for TB index participants only) consent to collect sputum specimen for TB testing and blood specimens for HIV, HIV VL and CD4 tests. Consent to store sputum specimen. (TB index participants only)
4	Adult (≥18 years) head of household	Consent for collection of household-level data Questionnaire: household demographic and socioeconomic status
5	Adult (≥18 years) household member	Individual consent Questionnaire: TB symptom screen, TB and HIV care history
6	Parent /guardian of 15-17yr old household member	Consent for 15-17yr old household member to take part Questionnaire: TB symptom screen, TB and HIV care history
7	15-17 yr old household member	Assent Questionnaire: TB symptom screen, TB and HIV care history
8	Parent/guardian of child household contact (aged 2-14)	Consent for 2-14yr old child household contact to take part including consent to collect blood specimen (IGRA and HIV). Questionnaire: child's health, TB and HIV care history of child, TB contact history of child.
9	12-14 year old child household contact	Assent Questionnaire: symptoms, TB and HIV care history, healthcare utilisation, TB contact history (to the extent appropriate for age), including assent to collect blood specimen (IGRA and HIV)
10	7-11 year old child household contact	Assent Questionnaire: symptoms, TB and HIV care history, healthcare utilisation, TB contact history (to the extent appropriate for age), including assent to collect blood specimen (IGRA and HIV)
11	Healthcare workers	Individual consent Questionnaire: provider cost survey
12	Experts in TB case finding	Individual consent Expert elicitation exercise

1: Index participant

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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
Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign or make your mark on a consent form. It is your right to withdraw 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 have I been chosen to be invited to take part in this study?
You have been chosen because [*researcher to explain why, based on the group the potential participant belongs to: either 1. you are a resident in the AHRI demographic surveillance area, so we would like you to be in our group of healthy people; or 2. you started TB treatment at a local clinic or hospital]*

If I take part in this study, what will happen?
TB index / control participant : if you take part in this study, we will ask you some questions about your health currently and in the past, including any treatment for TB, visits to health facilities, and how much this cost. This will take about 30-45 minutes.

TB index patients only: We would like you to also have a chest x-ray to assess the TB in your lungs. This investigation is not available routinely to all TB patients through the TB programme. We will arrange transport for you to and from the chest x-ray. We would also like to collect two sputum specimens from you

for TB testing at the AHRI laboratory in Durban and to take blood for HIV viral load and CD4 count if you are 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 you at a later date by phone to ask you more detailed questions about costs you have incurred including income loss and money spent on accessing healthcare. You will be reimbursed for your time.

*Household information: W*e 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 household 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 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 you as part of the Vukuzazi study (if you took part in Vukuzazi), and the information that Africa Centre / AHRI has collected about you and 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 I give for the study be stored?
With your permission we will store the sputum sample you give 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 you, these will be destroyed after the tests are completed.

What are the possible risks of taking part?
For the adults (over 15 years) taking part in this study, 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 an adult or child in the household has symptoms suggesting TB, we will help them get checked for TB at a local clinic. If a person has TB disease and starts treatment quickly, the TB is less likely to cause serious disease.

[*only applicable where the index participant has TB*: If anyone in the household 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 assessment and if active TB is excluded, then they may be prescribed this treatment. Parents will be reimbursed the cost of travel to the appropriate health facility for assessment. We will also arrange clinical

assessment for any child with symptoms and/or positive blood test for TB infection. 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]

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 you are willing to take part in the study, we will give you a refreshment and a cloth facemask as a token of appreciation for your time. If your household takes part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time spent taking part in this research. If we invite you to take part in an additional questionnaire on costs incurred by you and your household, you will be reimbursed for your time with an airtime or food voucher to a value of ZAR50.

What happens if I do not agree to take part in this study?
You do not have to take part in this study: if you do not take part, this will not affect you in any way. You can stop taking part in the study 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 your name. This means that your 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. Your 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

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

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

CONSENT TO TAKE PART IN RESEARCH

1: Index participant **Study ID**

AHRI Household Contact Study

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The researchers doing this study are:
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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

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 me and what will happen if I take part in the study.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I may withdraw from this study at any time without giving a reason, and without affecting my 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 personal details will be shared.

I agree to take part in the study.

Study participant name (printed)	Signature/ thumbprint	Date

If the participant gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:

Witness name (printed)	Signature	Date

CONSENT FOR SPECIMEN STORAGE

1. TB index participant only **Study ID**

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My questions concerning specimen storage have been answered by:

Research staff name (printed)	Signature	Date

I agree for my specimens to be stored for use in future research for the purposes described.

Study participant name (printed)	Signature/ thumbprint	Date

If the participant gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:

Witness name (printed)	Signature	Date

3: Assent from index participant aged 15-17 years

AHRI Household Contact Study

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The researchers doing this study are:
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Introduction
Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign or make your mark on a consent form. It is your right to withdraw 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 have I been chosen to be invited to take part in this study?
You have been chosen because [*researcher to explain why, based on the group the potential participant belongs to: either 1. you are a resident in the AHRI demographic surveillance area, so we would like you to be in our group of healthy people; b. your sputum showed TB, as we have previously explained or 2. you started TB treatment at a local clinic]*

If I take part in this study, what will happen?
TB index/control participant : if you take part in this study, we will ask you some questions about your health currently and in the past, including any treatment for TB, visits to health facilities, and how much this cost. This will take about 30-45 minutes. We would like you to also have a chest x-ray to assess the TB in your lungs. This investigation is not available routinely to all TB patients through the TB programme. We will arrange transport for you to and from the chest x-ray facility. *TB index participant only:* We would also like to collect two sputum specimens from you for TB testing at the AHRI laboratory in Durban and to take blood

for HIV viral load and CD4 count if you are HIV-positive. We will make sure that all results are shared with your treating clinician.

Household screening for TB: We would like to check everyone in your household 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 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 you as part of the Vukuzazi study (if you took part in Vukuzazi), and the information that Africa Centre / AHRI has collected about you and 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 I give for the study be stored?
With your permission we will store the sputum samples you give 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 you, these will be destroyed after the tests are completed.

What are the possible risks of taking part?
For the adults (over 15 years) taking part in this study, 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 an adult or child in the household has symptoms suggesting TB, we will help them get checked for TB at a local clinic. If a person has TB disease and starts treatment quickly, the TB is less likely to cause serious disease.

[*only applicable where the index participant has TB*: If any child in the household 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. Parents will be reimbursed the cost of travel to district hospital for the first review. We will also arrange clinical review at a local clinic for any child with symptoms and/or positive blood test for TB infection. 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.]

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 you are willing to take part in the study, we will give you a refreshment and a cloth facemask as a token of appreciation for your time. If your household takes part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time spent taking part in this research. If we invite you to take part in an additional questionnaire on costs incurred by you and your household, we will reimburse you for your time with an airtime or food voucher to a value of ZAR 50.

What happens if I do not agree to take part in this study?
You do not have to take part in this study: if you do not take part, this will not affect you in any way. You can stop taking part in the study 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 your name. This means that your 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. Your 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

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

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

ASSENT TO TAKE PART IN RESEARCH

3: Assent from index participant aged 15-17 years

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 me and what will happen if I take part in the study.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I may withdraw from this study at any time without giving a reason, and without affecting my 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 personal details will be shared.

I agree to take part in the study.

Study participant name (printed)	Signature/ thumbprint	Date

If the participant gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:

Witness name (printed)	Signature	Date

ASSENT FOR SPECIMEN STORAGE

3. Assent from TB index participant aged 15-17 years only

Study ID

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My questions concerning specimen storage have been answered by:

Research staff name (printed)	Signature	Date

I agree for my specimens to be stored for use in future research for the purposes described.

Parent/guardian name (printed)	Signature/ thumbprint	Date

If the participant gave verbal assent, enter the name of the independent person who witnessed the assent here and their signature:

Witness name (printed)	Signature	Date

4: Adult head of household

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Introduction
Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign or make your mark on a consent form. It is your right to withdraw 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 have I been chosen to be invited to take part in this study?
You have been chosen because you are the head of this household or have been asked to represent the head of the household.

If I take part in this study, what will happen?
Questionnaire: if you take part in this study we will ask you some questions about the number of people living in your household and the household structure, such as materials used to construct the buildings; access to water, sanitation and electricity; and the type of appliances in your household. We will also ask about whether people in the household have been treated for TB.

Linkage to other records: We would like to link information from this study to other information that AHRI has collected about your household as part of the Vukuzazi study (if you took part in Vukuzazi), and the

information that Africa Centre / AHRI has collected about your household over the years. We will be very careful to be sure that all information you give us is kept confidential.

What are the possible risks of taking part?
We will ask you questions about your household. There are no major risks from answering these questions.

What are the possible benefits of taking part?
The information you provide us with about your household will help us understand how households are affected by TB.

If you and your household take part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time you have spent taking part in this research.

What happens if I do not agree to take part in this study?
You do not have to take part in this study: if you do not take part, this will not affect you in any way. You can stop taking part in the study 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 your name. This means that your 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. Your 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

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

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

4: Adult head of household **Study ID**

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

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 me and what will happen if I take part in the study.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I may withdraw from this study at any time without giving a reason, and without affecting my 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 personal details will be shared.

I agree to take part in the study.

Study participant name (printed)	Signature/ thumbprint	Date

If the participant gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:

Witness name (printed)	Signature	Date

5: Adult household member

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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
Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign or make your mark on a consent form. It is your right to withdraw 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 have I been chosen to be invited to take part in this study?
You have been chosen because [*researcher to explain why, based on the group the potential participant belongs to: either 1. you or someone in your household is a resident in the AHRI demographic surveillance area or 2.* someone in your household took part in an earlier AHRI study. Some of the people in this earlier study had TB, and some had no signs of TB.

If I take part in this study, what will happen?
Questionnaire: if you take part in this study we will ask you some questions about your health currently and in the past, including any treatment for TB. This will take about 15 minutes.

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

What are the possible risks of taking part?
We will ask you questions about current and past health. There are no major risks from answering these questions.

What are the possible benefits of taking part?
If you have symptoms suggesting TB, we will help you get checked for TB at a local clinic. 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 you and your household take part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time you have spent taking part in this research.

What happens if I do not agree to take part in this study?
You do not have to take part in this study: if you do not take part, this will not affect you in any way. You can stop taking part in the study 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 your name. This means that your 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. Your 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?
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Who has reviewed the study?
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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
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PO Box 198, Mtubatuba 3930
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We will give you a copy of this information sheet which explains the study to take away with you.

5: Adult household member **Study ID**

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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
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 me and what will happen if I take part in the study.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I may withdraw from this study at any time without giving a reason, and without affecting my 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 personal details will be shared.

I agree to take part in the study.

Study participant name (printed)	Signature/ thumbprint	Date

If the participant gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:

Witness name (printed)	Signature	Date

6: Parent/guardian of 15-17 year old household member

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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. you or someone in your household is a resident in the AHRI demographic surveillance area or 2.* someone in your household took part in an earlier AHRI study. Some of the people in this earlier study had TB, and some had no signs of TB.

If your child takes part in this study, what will happen?
Questionnaire: 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 or HIV,. This will take about 15 minutes.

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.

What are the possible risks of taking part?
We will ask your child questions about current and past health and possible contacts with people with TB. There are no major risks from answering these questions.

What are the possible benefits of taking part?
If your child has symptoms suggesting TB, we will help them to get checked for TB at a local clinic. 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 household takes part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time you have spent taking part in this research.

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 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 the name. This means that all 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. Personal information will remain confidential, unless we are required by law to release information. Reports about the study will never include information which allows you or your child 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?
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Who has reviewed the study?
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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:

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

6: Parent/guardian of 15-17 year old household member

Study ID

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

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:

Research staff name (printed)	Signature	Date

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.

Parent/guardian's name (printed)	Signature/ thumbprint	Date

If the parent/guardian gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:

Witness name (printed)	Signature	Date

7: Assent from household member aged 15-17 years

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, Janet Seeley
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Introduction
Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign or make your mark on a consent form. It is your right to withdraw 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 have I been chosen to be invited to take part in this study?
You have been chosen because [*researcher to explain why, based on the group the potential participant belongs to: either 1. you or someone in your household is a resident in the AHRI demographic surveillance area or 2.* someone in your household took part in an earlier AHRI study. Some of the people in this earlier study had TB, and some had no signs of TB.

If I take part in this study, what will happen?
Questionnaire: if you take part in this study, we will ask you some questions about your health currently and in the past, including any treatment for TB. This will take about 15 minutes.

Linkage to other records: We would like to link information from this study to other information that AHRI has collected about you as part of the Vukuzazi study (if you took part in Vukuzazi), and the information that

Africa Centre / AHRI has collected about you and your family over the years. We will be very careful to be sure that all information you give us is kept confidential.

What are the possible risks of taking part?
We will ask you questions about current and past health and possible contacts with people with TB. There are no major risks from answering these questions.

What are the possible benefits of taking part?
If you have symptoms suggesting TB, we will help you get checked for TB at a local clinic. 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 you and your household take part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time you have spent taking part in this research.

What happens if I do not agree to take part in this study?
You do not have to take part in this study: if you do not take part, this will not affect you in any way. You can stop taking part in the study 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 your name. This means that your 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. Your 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?
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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:

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

ASSENT TO TAKE PART IN RESEARCH

7: Assent from household member aged 15-17 years

Study ID

AHRI Household Contact Study

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

The researchers doing this study are:
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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 me and what will happen if I take part in the study.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I may withdraw from this study at any time without giving a reason, and without affecting my 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 personal details will be shared.

I agree to take part in the study.

Study participant name (printed)	Signature/ thumbprint	Date

If the participant gave verbal assent, enter the name of the independent person who witnessed the assent here and their signature:

Witness name (printed)	Signature	Date

8: Parent/guardian of child household contact (aged 2-14 years old)

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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. you or someone in your household is a resident in the AHRI demographic surveillance area or 2.* someone in your household took part in an earlier AHRI study. Some of the people in this earlier study had TB, and some had no signs of TB.

If your child takes part in this study, what will happen?
Questionnaire: if your child takes part in this study, we will first ask you some questions about your child's health currently and in the past, including any treatment for TB or HIV, and visits made to health facilities. If your child is old enough to answer questions about their own health, we will ask them some questions also. This will take about 15 minutes.

Health status assessment: If your child is under the age of 7 years old, the study nurse will request to review the Road to Health Card or child's clinic book to check their vaccination status; exposure to HIV; and last recorded weight and height measurements. The study nurse will also weigh and measure the height of your child and assess their growth.

Blood sample: If you and your child agree, we will take a blood sample from one of their arms. First we will put cream on the skin to make it numb. Then we will put a tight band around their upper arm, clean the skin, then put a fine needle through the skin and into a vein. We will take 8mls (one and a half teaspoons) of blood, then take out the needle and press on the skin to stop a bruise developing. The blood sample will be sent to our laboratory in Durban and tested for signs of TB infection. This test is used in research studies but is not usually used in public clinics in South Africa. If you agree, we will also test your child for HIV. If your child is already on ART, we will not test for HIV. We will report the results by SMS if both tests are negative or in the case of a positive test either for TB or HIV, we will contact you by phone to arrange a time and give the results in person. The TB result might take a month or more to come back. If your child is aged 12-14 years, although we would encourage them to discuss HIV testing with you present, it is their right to discuss HIV testing and their result in private if they prefer.

Linkage to other records: We would like to link information from this study to other information that AHRI has collected about your child and your family over the years. We will be very careful to be sure that all information you give us is kept confidential.

What are the possible risks of taking part?
There might be some pain from having the blood sample taken. We will reduce this by using cream to numb the skin. There is also the risk of a bruise developing at the site where the blood was taken but 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 local clinic or district hospital. You will be reimbursed the cost of travel to a local clinic or district hospital for the first review. If your child is diagnosed with HIV through this study then we ensure that you and your child receive adequate post-test counselling and will facilitate referral to the nearest clinic for HIV care. The earlier that HIV is diagnosed, the earlier your child can start treatment, the better the health outcomes will be for your child.

If you 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.

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 household takes part in the study, we will give the household a supermarket voucher for ZAR 100 in appreciation of the time you have spent taking part in this research.

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. Although we encourage HIV testing because it's very important to get treatment if a person is HIV-positive, as part of this study you or your child may choose not to be tested for HIV and it will not affect your child's participation.

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 the name. This means that all 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. Personal information will remain confidential, unless we are required by law to release information. Reports about the study will never include information which allows you or your child 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 or your child, such as name or address or date of birth.

Will blood samples that are taken from my child be stored?
No, after the blood tests for TB and HIV have been done, the blood samples will be destroyed by the laboratory.

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

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

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

8: Parent/guardian of child household contact (aged 2-14 years)

Study ID

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

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:

Research staff name (printed)	Signature	Date

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.

Please select YES or NO: I agree for my child [*name of child*_____] to be tested for HIV ☐ YES ☐ NO [If the child is already taking ART, select NO]

Parent/guardian's name (printed)	Signature/ thumbprint	Date

If the parent/guardian gave verbal consent, enter the name of the independent person who witnessed the consent here and their signature:

Witness name (printed)	Signature	Date

9: Child household contact (aged 12-14 years)

AHRI Household Contact Study

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

The researchers doing this study are:

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

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

Introduction

Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign or make your mark on a consent form. It is your right to withdraw 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 better why TB is passed from one person to another. We can do this by studying the number of children who have TB infection in different households. We hope that this will help us find people with TB so they can be treated earlier.

Why have I been chosen to be invited to take part in this study?

You have been chosen because [*researcher to explain why, based on the group the potential participant belongs to: either 1. you or someone in your household is a resident in the AHRI demographic surveillance area or 2.* someone in your household took part in an earlier AHRI study. Some of the people in this earlier study had TB, and some had no signs of TB.

If I take part in this study, what will happen?

Questionnaire: We will ask you some questions about your health currently and in the past, including any treatment for TB, HIV and other illnesses, and visits to clinics or hospitals.

Blood sample: We will take a blood sample from your arm. First we will put cream on your skin to make it numb. Then we will put a tight band around your arm, clean your skin, then put a fine needle into a vein. We will take 8mls (one and a half teaspoons) of blood, then take out the needle and press on the skin to stop a bruise developing. The blood sample will be sent to our laboratory in Durban and tested for signs of TB infection *[omit the remainder of this paragraph if the parent/guardian has declined permission for HIV testing. Researcher will first establish the child's understanding of HIV, and give age- and maturity-*

appropriate counselling.] and for HIV, if you agree. If you are already taking ART, we will not test you for HIV. We will let you know the results and if you need any treatment. If you have a positive HIV test result, we would like to share this with your parent, but we would only do this with your permission.

Linkage to other records: We would like to link information from this study to other information that AHRI has collected about you and your family over the years. We will be very careful to be sure that all information you give us is kept confidential.

What are the possible risks of taking part?
There might be some pain from having the blood sample taken. We will reduce this by using cream to numb the skin. There is also the risk of a bruise developing at the site where the blood was taken but 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 you are HIV-positive, then you may benefit from having a course of treatment (TB preventive treatment) to prevent TB disease, if you have not already taken this medicine. We will help you access care for clinical review and if active TB is excluded, then you may be prescribed this treatment at a local clinic or the district hospital. Your parents will be reimbursed the cost of travel to a local clinic or the district hospital for the first review. If you are HIV-positive we will help you start treatment for HIV – the sooner you start treatment, the better it is for your health.

If you have 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. Your parents will be reimbursed the cost of travel to the local clinic and if required for the first review at the district hospital.

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 household takes part in the study, we will give the household a supermarket voucher for ZAR 100 to that you for your time.

What happens if I do not agree to take part in this study?
If you do not want to take part, it is fine to say no. Even if you agree to take part, you can change your mind later, without giving a reason. Although we encourage HIV testing because it's very important to get treatment if a person is HIV-positive, as part of this study you may choose not to be tested for HIV and it will not affect your participation

How will the information collected during this study be kept private?
All information collected during this study will be kept privately at AHRI 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 your name. This means that your information remains private.

We will present the results from the study to people who treat TB in South Africa and other countries. These results will never reveal the identities of the 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.

Will my blood samples be stored?
No, after the blood tests for TB and HIV have been done, the blood samples will be destroyed by the laboratory.

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

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

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

ASSENT TO TAKE PART IN RESEARCH

9: Child household contact (aged 12-14 years) **Study ID**

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

This study has been discussed with me. I understand what I am being asked to do.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I can stop taking part in this study at any time without giving a reason.

I understand that the information collected from me may be shared with other researchers in the future, but my personal information will be kept private.

I agree to take part in the study.

Please select YES or NO: I agree for to be tested for HIV ☐ YES ☐ NO

If YES: I would like to discuss HIV testing ☐ with my parent/guardian present ☐ without my parent/guardian present.

Participant's name (printed)	Signature/ thumbprint	Date

If the participant gave verbal assent, enter the name of the independent person who witnessed the assent here and their signature:

Witness name (printed)	Signature	Date

10: Child household contact (aged 7-11)

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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
Good day, my name is [*name of researcher*], and I am a researcher at AHRI. Research is the process to learn the answer to a question. We would like you to take part in our research study. I am going to tell you about the study. You can ask me questions about it. You can decide if you want to take part or not. It is fine to say no. Even if you say yes, you can stop being in the study any time you want.

Why are we doing this study?
TB is an illness which makes many people sick in South Africa. TB is caused by a germ which is passed from person to person through the air, for example by coughing, sneezing or singing. We can understand how much TB is passed between people by studying children. TB can be cured if a person takes the right medicine.

If I take part in this study, what will happen?
We will ask you some questions about how you feel at the moment, for example if you have a cough. We will ask about any illness you had before, any medicines you take, and how often you have been to health clinics or hospitals.

We will take some blood from your arm. First we will put cream on your skin to make it numb. We will use a small needle to take blood. We will test the blood for TB.
[Omit if parent/guardian has declined permission for HIV testing. Researcher will first establish the child's understanding of HIV, and give age- and maturity-appropriate counselling.] We will also test for HIV infection. If the test shows you need any treatment, we will let [*relevant parent/guardian]* know. If you are already on ART, we will not test for HIV.

What happens if I do not agree to take part in this study?
If you do not want to take part, it is fine to say no. Even if you say yes at first, it is fine to say no later. Although we encourage HIV testing because it's very important to get treatment if a person is HIV-positive, as part of this study you may choose not to be tested for HIV and it will not affect your participation.

Will my blood samples be stored?
No, after the blood tests for TB and HIV have been done, the blood samples will be destroyed by the laboratory.

What if I have questions about this study?
If you have any questions, please ask me. If you have questions 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

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

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

ASSENT TO TAKE PART IN RESEARCH

10: Household contact (aged 7-11 years) **Study ID**

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

This study has been discussed with me. I understand what I am being asked to do.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I can stop taking part in this study at any time I like without saying why.

I agree to take part in the study.

Please select YES or NO: I agree to be tested for HIV: ☐ YES ☐ NO

Participant's name (printed)	Signature/ thumbprint	Date

If the participant gave verbal assent, enter the name of the independent person who witnessed the assent here and their signature:

Witness name (printed)	Signature	Date

11: Provider cost survey

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign on a consent form. It is your right to withdraw from the study at any time. Your decision to take part or not will not affect your employment in any way.

Why are we doing this study?

As you know, TB is a major health problem in South Africa, and particularly in KwaZulu-Natal. We are doing a study aiming to investigate different ways that TB screening could be provided; what would be the effect of these different approaches to TB screening, and what the cost would be. We hope that this will help people in departments of health to plan TB services in South Africa and other countries where TB is common.

Why have I been chosen to be invited to take part in this study?

You are being asked to take part because you have experience of delivering care for TB or HIV or both in a health facility serving people who live in the AHRI demographic surveillance area.

If I take part in this study, what will happen?

We will ask you questions about how care for people with TB is organised in your facility; how many TB patients you treat in your facility; what drugs you use to treat TB; which staff members are involved in TB care, how much they are paid and how much time they spend on TB care; and what equipment you have which is used in TB care. The questions may take about 40 minutes to complete.

What are the possible risks of taking part?

We will ask questions about the costs of delivering TB services in your clinic. There are no major risks from this.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in the study. We hope that, overall, 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.

What happens if I do not agree to take part in this study?

You do not have to take part in this study: if you do not take part, this will not affect you in any way. You can stop taking part in the study 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 your name. This means that your 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. Your 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

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

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

11: Provider cost survey **Study ID**

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

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 me and what will happen if I take part in the study.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I may withdraw from this study at any time without giving a reason.

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. No information which identifies me will be shared.

I agree to take part in the study.

Study participant name (printed)	Signature/ thumbprint	Date

12: Expert elicitation exercise

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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
Good day, my name is [*name of researcher*], and I am a researcher at AHRI. We would like to invite you 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 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 to take part, to show that you understand the study and agree to take part, we will ask you to sign on a consent form. It is your right to withdraw from the study at any time. Your decision to take part or not will not affect your employment in any way.

Why are we doing this study?
As you know, TB is a major health problem in South Africa, and particularly in KwaZulu-Natal. We are doing a study aiming to investigate different ways that TB screening could be provided; what would be the effect of these different approaches to TB screening, and what the cost would be. We hope that this will help people in departments of health to plan TB services in South Africa and other countries where TB is common.

Why have I been chosen to be invited to take part in this study?
You are being asked to take part because you are an established expert in TB case finding approaches.

If I take part in this study, what will happen?
We will ask you to participate in an iterative multi-stage process designed to combine opinion into group consensus, known as the Delphi method. We are inviting you to participate as a Delphi panel member. As a member, you would first participate in an individual online interview with investigators about potential costs associated with TB case finding strategies. We would subsequently invite you to participate in a remote workshop conducted online, along with other participants. During the workshop, we will present a summary of member's responses to the survey and conduct a further online questionnaire to adjust the initial list of resources and costs. This process would continue until a group consensus is achieved or three Delphi rounds have been completed.

What are the possible risks of taking part?
We will ask questions about the costs of finding TB cases. There are no major risks from this.

What are the possible benefits of taking part?
There is no direct benefit to you from taking part in the study. We hope that, overall, 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.

What happens if I do not agree to take part in this study?

You do not have to take part in this study: if you do not take part, this will not affect you in any way. You can stop taking part in the study 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 your name. This means that your information remains private.

We will audio record the interview and workshops to help us remember what has been said, and assist with our analysis. The audio recordings will be deleted as soon as transcripts from the interview and workshops have been verified. There will be no video recording.

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. Your 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

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

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

12: Expert elicitation exercise **Study ID**

AHRI Household Contact Study

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

The researchers doing this study are:
Africa Health Research Institute (AHRI): Alison Grant, Emily Wong, Nigel Klein, Willem Hanekom, Thabang Manyaapelo, 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

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 me and what will happen if I take part in the study.

My questions concerning this study have been answered by:

Research staff name (printed)	Signature	Date

I understand that I may withdraw from this study at any time without giving a reason.

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. No information which identifies me will be shared.

I give permission for researchers to audio record the interview and group discussion to aid with qualitative analysis. I understand that the audio recordings will not be made publicly available, and will be deleted as soon as transcripts from the discussion have been verified.

I agree to take part in the study.

Study participant name (printed)	Signature/ thumbprint	Date